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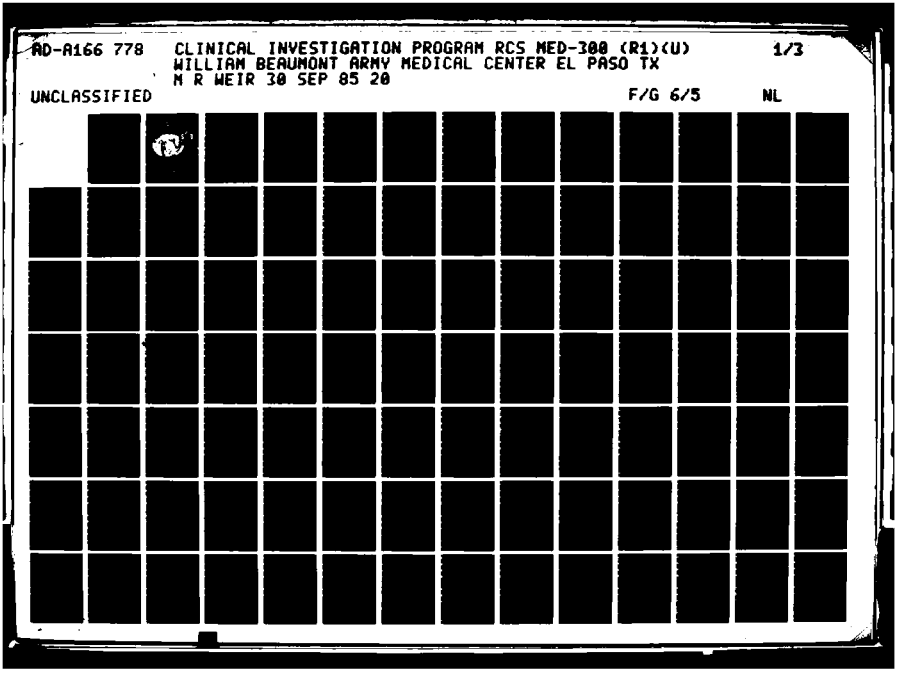

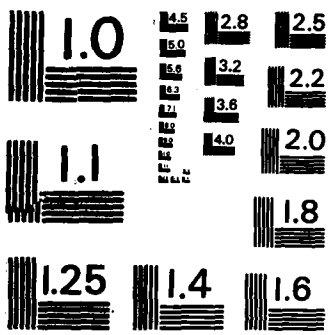

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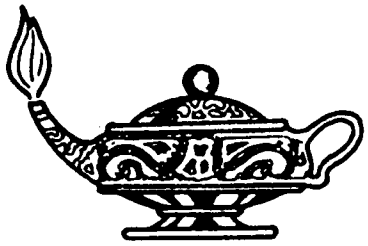

WILLIAM BEAUMONT ARMY MEDICAL CENTER

DEPT. OF CLINICAL INVESTIGATION

ANNUAL PROGRESS REPORT
FISCAL YEAR 1985

HEADQUARTERS
WILLIAM BEAUMONT ARMY MEDICAL CENTER
EL PASO, TEXAS 79920

CLINICAL INVESTIGATION PROGRAM
RCS MED-300 (R1)

FY 85 ANNUAL PROGRESS REPORT

This reports was prepared under the direction of COL M.R. Weir, Chief, Department of Clinical Investigation, William Beaumont Army Medical Center, El Paso, TX 79920

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20. ABSTRACT *(Continue on reverse side if necessary and identify by block number)*

This report serves to detail the progress, status, and funding of approved projects conducted under protocol by staff members, interns, and residents at William Beaumont Army Medical Center. The varying projects as reported are classified according to the service or department to which the principal investigator belongs. Research conducted at WBAMC is categorized as either basic experimental medicine procedures using the indigenous population for which the medical facility provides support.

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FOREWORD

Two hundred years ago a man was born who later would describe his detailed observations on a patient and set the standard for meticulous observation while advancing the knowledge of digestive function. A frontier Army physician, he would later have a frontier medical center named for him. His patient with the digestive problem would have the medical center's dining facility bear his name. There is particularly irony that the bicentennial anniversary of his birth marks the decline of case reports and descriptive studies, since his studies and consequent notoriety result from the detailed descriptiona of a single patient.

This year marks the 20th anniversary of our Clinical Investigation Program, beginning with the arrival of Walter J. Decker, Ph.D., followed promptly by Martin L. Nusynowitz, M.D., from Walter Reed Army Medical Center. The years have seen changes in sophistication, technology, regulatory constraints, and, in fact, a change in the rate of change, an acceleration in regulation by a plethora of agencies.

The whims of high level governmental officials and the excesses and dishonesties of a few have been magnified by the regulatory lenses and prisms, totally changing the nature and scope of research on humans and animals within the Army Medical Centers.

At the same time new forces on the horizon argue that all successful entities must attend to their customers (Search for Excellence, Pursuits of Excellence, MG Floyd Baker). Given that animals subjected to the stress of divergent authority would develop medical consequences, clinical investigation finds itself in the stress-provoking situation of an array of "customers" with seemingly divergent direction. The researchers want instantaneous and total support in many cases. They are under the clinical pressure of large patient loads and the pursuit of research in fortification for the assault on their accreditation. Clinical investigation faces rapidly changing constraints in human and animal research to assure protection of the research subject. Clinical investigation further faces an oversight function to protect the naive and build evidence against the frankly dishonest. This occurs at a time when all are staffed at a level usually 20% below the other areas in the medical centers. If only two divergent sources of direction lead to stress, these desparate forces should lead to schizophrenia.

There is further irony in the clear indication that the Herculean efforts that satisfy these demands result in less of the meager resources; the resources going to those who fail to meet demands. If there is a positive message in this morass of apparent complaint and contradiction, it is the hope that listening closely for the message of each and every "customer" - the clinician/researcher, the headquarters, the commander, the regulator - will guide clinical investigation and the Institutional Review Board to the solution that will satisfy all the customers simultaneously; failure to satisfy any single customer will most surely lead to difficulty, and, with current scrutiny, it will not take long.

This volume is dedicated to recently departed personnel; Major M.L. Smith, PhD, Captain C.S. Serio, PhD, and David O. Rauls, PhD, who spent a combined 13 yars in clinical studies at this institution. Their contribution of character will continue. The valuable input of Mr. Philip Barren during his brief two-year tour will be missed. The researchers and staff at William Beaumont Army Medical Center provided more papers and presentations during this fiscal year than any previous fiscal year. BG John Major provided an environment compatible with high research, productivity. The Clinical Investigation staff members who remained carried a huge load; Bruce Veit, PhD, MAJ George McNamee, DVM, John Enriquez, Maxine Lund, Brigetta Manna, Susan McIntyre, Sp Ann Brady, Sp Dominic Fama, Peggy Casteel, Susan Lamonde, Leroy Turner, James Revels and Cynthia Ramirez. Each did more than was expected or required.

MICHAEL R. WEIR
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PUBLICATIONS - FY 85

DCI

Lund M, Rauls DO, Ting S: Measurement of plasma histamine: a modification of the simple-isotope enzymatic method. J Allergy Clin Immunol 75:124, 1985 (Abstract)*

Manna B, Penney LL, Smith ML: Evaluation of a simple method for determining free testosterone in serum. Proc Soc Armed Forces Med Lab Sci 14:9, 1985 (Abstract)*

Mansfield LE, Ting S, Haverly RW, Rauls DO, Vaughan TR: Plasma histamine evaluation during blind food challenges which provoke migraine. J Allergy Clin Immunol 75:205, 1985 (Abstract)*

Mansfield LE, Vaughan TR, Waller SF, Haverly RW, Ting S: Food allergy and adult migraine: double-blind and mediator confirmation of an allergic etiology. Ann Allergy 55:126-129, 1985*

Mansfield LE, Yarbrough J, Ting S: The effects of acute gastric distension on the pulmonary functions of asthmatic subjects: a preliminary study. J Asthma 22:1-4, 1985*

Rauls DO, Moreno AJ, Penney LL, Parker G, Brown TJ: Indium-111 oxine platelet survival in dogs: effects of doxorubicin and dacron grafts. J Nucl Med, in press*

Rauls DO, Ting S: Effects of propranolol on terbutaline suppression of antigen induced histamine release in vivo. J Allergy Clin Immunol 75:123, 1985*

Rauls DO, Ting S, Lund M: Inhibition of histamine N-methyltransferase by opiod and related drugs. Submitted to Agents Actions*

Rauls DO, Ting S, Lund M: Analysis of plasma histamine: a modification of the enzymatic isotopic assay. J Allergy Clin Immunol, in press*

Smith ML, Fariss BL, Jennings PB: Serum zinc levels in sheep with experimental pancreatic abnormalities. Pancreas, in press

Smith ML, Jacob WH, Plymate SR, Gregory GG: Individual levels and variation in the biochemical components of human semen. Submitted*

Veit BC: Quantitation of residual T cells following T cell depletion in human bone marrow transplantation. Proc Soc Armed Forces Med Lab Sci 14:9, 1985 (Workshop Abstract)

Weir MR: Urolithiasis, in Rudolph AM (ed): Pediatrics. New York, Appleton-Century-Crofts, 18th Edition, in press

*Indicates results of protocol.

PUBLICATIONS - FY 85

Weir MR: Intramuscular penicillin. Submitted to Pediatrics, September, 1985

Weir MR, Segapeli JH, Tremper LJ: Sedation for pediatric procedures. Milit Med, in press

Weir MR, Ting S, Mansfield LE: Orthostatic proteinuria and milk sensitivity. J Adoles Health Care 6:401-403, 1985

Weisman IM, Moreno AJ, McAbee W: Computed tomography in noncerebral disseminated coccidiodomycosis, in Einstein HE, Catanzaro A (Eds): Proc 4th International Cong Symposium on Coccidioidomycosis. The National Foundation for Infectious Diseases, Washington, DC, Chapter 8, pp 390-408, 1985

Weisman IM, Moreno AJ, Parker AL, Sippo WC, Liles WJ: Gastrointestinal dissemination of coccidioidomycosis. Submitted.

Weisman IM, Zeballos RJ, Johnson B, Moreno AJ: The cardiopulmonary effects of stressful exercise at 4,000 ft (1,270 m) of individuals with sickle cell trait. Am Rev Respir Dis 131:A307, 1985 (Abstract)*

Zeballos RJ, Weisman IM, Johnson B, Moreno AJ: $P(A-a)O_2$ during exercise in healthy young blacks with sickle cell trait and controls. Fed Proc 44:1368, 1985 (Abstract)*

Weisman IM, Zeballos RJ, Johnson B, Moreno AJ: The percent hemoglobin S (HbS) and percent sickling (%S) as correlates for exercise performance at 4,000 ft in individuals with sickle cell trait. Fed Proc 44:1012, 1985 (Abstract)*

Weisman IM, Zeballos RJ, Johnson B, Moreno AJ: Pulmonary blood flow distribution determined from perfusion lung scintigraphy during rest and exercise. Fed Proc 44:625, 1985 (Abstract)*

DENTISTRY

Richards HE, Strider JW, Short SG, Theisen FC, Larson WJ: Large peripheral osteoma arising from the genial tubercle area. Oral Surg, in press

Richards HE, Strider JW, Theisen FC, Short SG, Larson WJ: An aggressive cemento-ossifying fibroma involving the maxilla and the mandible. Submitted to Oral Surg, September, 1985

Strider JW, Richards HE, Short SG: An anomaly of the mandibular inferior alveolar canal. Oral Surg, in press

PUBLICATIONS - FY 85

Strider JW, Richards HE, Thiesen FC, Short SG: Low risk transfusion therapy for oral surgery. Submitted to J Oral Maxillofacial Surg, July, 1985

MEDICINE

Brown JM, Moreno AJ, Weisman I, Baker FJ, Lundy MN, Brown TJ: Positive Ga-67 scintigraphy associated with pulmonary embolism. Yearbook of Nuclear Medicine, 1985

Cuetter AC, Stuart RB: Sudden death associated with intravenous phenytoin. Submitted to Milit Med

Cutler RE, Forland SC, Misson RT, Davis GM: Drugs and the kidney, in Gonick HC (ed.): Current Nephrology. New York: John Wiley & Sons, 1985, vol. 8, pp. 395-439

Friedman SJ, Fox BJ, Albert HL: Solid facial edema as a complication of acne vulgaris: treatment with isotretinoin. J Derm, in press

Friedman SJ, Schroeter AL, Homburger HA: IgE antibodies to Staphylococcus aureus. Prevalence in patients with atopic dermatitis. Arch Dermatol 121:869-872, 1985

Greenberg DI, O'Brien AW, Tobin HE, Miles PA, Pfeiffer CJ: Cimetidine's effect on the healing rate of gastric ulcers in rats. Gastroenterology 88:1404, 1985 (Abstract)*

Jordan WE, Shildt RA: Adenocarcinoma of unknown primary site. Cancer 55:857-860, 1985

Karl RD, Yedinak MA, Hartshorne MF, Cawthon MA, Bauman JM, Howard WH, Bunker SR: Scintigraphic appearance of the piriformis muscle syndrome. Clin Nucl Med 10:361, 1985

Kemp J, Bodman S, Prenner B, Selner J, Ting S, Townley R, Vanas A: Controlled multicenter clinical trial of nedocromil sodium in bronchial asthma. Ann Allergy 55:257, 1985 (Abstract)*

Moreno AJ: Fetal absorbed radiation dose in sheep from maternal administration of Tc-99m radiopharmaceuticals. Submitted to Radiation Research, September, 1985*

Moreno AJ: Multiple anaerobic hepatic abscesses demonstrated on hepatobiliary scintigraphy. Clin Nucl Med, in press

Moreno AJ, Brazier JM, Baker FJ, Fox BJ, Pittman DL: Gallium-67 citrate localization in disseminated sporotrichosis. Clin Nucl Med 10:424-426, 1985

PUBLICATIONS - FY 85

Moreno AJ, Brown JM, Jackson JH, Turnbull GL, Brown TJ: The widened renal fossa sign on liver-spleen scintigraphy and adrenal disease. Arch Intern Med 144:2355-2356, 1984

Moreno AJ, Brown JM, Spicer MJ, Yedinak MA, Brown TJ: Thyroid localization of Ga-67 citrate. Semin Nucl Med 15:224-225, 1985

Moreno AJ, Byrd BF, Berger DE, Turnbull GL: Abdominal varices mimicking an acute gastrointestinal hemorrhage during Tc-99m red blood cell scintigraphy. Clin Nucl Med, in press

Moreno AJ, Byrd BF, Spicer MJ, Lundy RO, Turnbull GL: Splenic rotation as demonstrated by Tc-99m SCOL. Eur J Nucl Med 10:259-261, 1985

Moreno AJ, Hartshorne MF Yedinak MA, Crooks LA, Fox BJ: Unusual occurrence of tinea corporis overlying the thyroid gland after I-131 radioiodine treatment of Graves' disease. Cutis, in press

Moreno AJ, Orr CD, Morales E, Weisman IM: Bacillus cereus food poisoning from drying apples at home. Ann Intern Med 102:868-869, 1985

Moreno AJ, Parker AL, Rodriquez AA, Sorensen LA, Turnbull GL: Combined common bile duct and gastric outlet obstruction demonstrated during hepatobiliary scintigraphy. Eur J Nucl Med 10:563-565, 1985

Moreno AJ, Spicer MJ, Torrington KG, Yedinak MA, Morrison RE: Nonbacterial thrombotic endocarditis in fatal varicella infection. Submitted to Arch Pathol Lab Med, September, 1985

Moreno AJ, Swaney J, Spicer MJ, Henry CD, Turnbull GL: The Ga-67 citrate bone scan. Clin Nucl Med 8:594-595, 1985

Moreno AJ, Weisman IM, Yedinak MA, Spicer MJ, Brown T: Gallium-67 citrate scintigraphy in pulmonary embolism. Chest 8:319, 1984 (Abstract)

Moreno AJ, Weisman IM, Yedinak MA, Spicer MJ, Turnbull GL: Gallium-67 citrate scintigraphy in pulmonary embolism. Clin Nucl Med, in press

Moreno AJ, Yedinak MA, Berndt MD, Turnbull GL: Delayed renal visualization during hepatobiliary scintigraphy. J Nucl Med 26:551-552, 1985

Moreno AJ, Yedinak MA, Rahnema A, Fredericks P: Bone scintigraphy in latent congenital syphilis. Clin Nucl Med, in press

Moreno AJ, Yedinak MA, Spicer MJ, Turnbull GL Byrd BF, Brown TJ: Myositis ossificans with Ga-67 citrate positivity. Clin Nucl Med 10:40-41, 1985

Moreno AJ, Yedinak MA, Turnbull GL, Spicer MJ, Brown TJ: Cholelithiasis demonstrated on hepatobiliary scintigraphy as a photopenic defect within the inferior portion of the liver. Clin Nucl Med 9:655-656, 1984

PUBLICATIONS - FY 85

Old CW, Herrera GA, Reimann BEF, Latham RD: Acute post-streptococcal glomerulonephritis progressing to rapidly progressive glomerulonephritis. South Med J 77:1470-1472, 1984

Pearl W: Balloon pulmonary valvuloplasty. Submitted to Chest, March 1985

Pearl W: The post-tachycardia syndrome. Clin Pediatr, in press

Pearl W: Discrete subaortic stenosis, ventricular septal defect and interruption of the aortic arch. Submitted to Chest, April, 1985

Sanders LR, Moreno, AJ, Pittman DL, Jones JD, Spicer MJ, Tracy KP: Painless giant-cell thyroiditis diagnosed by fine-needle aspiration and associated with intense thyroidal uptake of gallium. Am J Med, in press

Shelton AL, Ting S, Lund M, Reimann BEF: Naloxone does not inhibit codeine induced histamine release in vivo. Ann Allergy 55:305, 1985 (Abstract)*

Ting S: Exercise-induced anaphylaxis: H2 blocker urged. Congress News 1:2, 1985

Ting S, Mansfield LE: Ethanol induced urticaria. Submitted, September, 1985

Ting S, Mansfield LE, Rauls DO: Use of cimetidine in the treatment of exercise-induced anaphylaxis. Ann Allergy 55:335, 1985 (Abstract)*

Ting S, Mansfield LE, Rauls DO: Failure of verapamil in inhibiting allergen-induced histamine release in vivo. Allergy 40:519-522, 1985*

Ting S, Rauls DO: Increased in vivo skin histamine releasability in atopic dermatitis. J Allergy Clin Immunol 75:196, 1985*

Ting S, Rauls DO, Reimann BEF: Inhibitory effect of hydroxyzine on antigen-induced histamine release in vivo. J Allergy Clin Immunol 75:63-66, 1985*

Ting S, Reimann BEF, Zweiman B: Effects of cromolyn on codeine-induced histamine release in vivo. Allergy 39:493-497, 1985*

Yarbrough J, Mansfield LE, Ting S: Metered dose inhaler induced bronchospasm in asthmatic patients. Ann Allergy 55:25-27, 1985*

NURSING

Carroll KJ: Pediatric home hyperalimentation: a realistic option. Submitted to Topics in Clinical Nursing, September, 1985

PUBLICATIONS - FY 85

Jackson BJ, Schodt D, Flahive J: Hospital information systems: a nursing perspective. Submitted

Odom JD: Letters to Gwynn: a brief history of military nursing. Am J Nursing, in press

Odom JD: Environmental variables and acute asthmatic attacks in children. Submitted to J Pediatr Nursing, August, 1985

Parry BA: Non-abusing parents are key to halting child abuse. The Monitor, May 2, 1985, p 16

Parry BA: High technology and caring. Amer J Maternal/Child Nursing, 11, July/August, 1985

Waddell KP, Rinke WJ: Effectiveness of a computer-assisted instruction program for teaching sanitation. J Am Dietetic Assn 85:62-67, 1985

NUTRITION CARE

Hobson KP, Dutoit E: Multivariate data analysis applied to skinfold measurements and the percentage of body fat for black and white male soldiers. Proc 13th Conf Design of Exp Army Res Dev and Testing, ARO Report 85-2, pp 155-164, 1985

OB-GYN

Amr S, Rosa C: CPT fragments of B subunit are urinary products of the metabolism of desialylated HcG in humans. J Clin Invest, in press

Brettell JR, Miles PA, Herrera G, Greenberg M: Dysgerminoma with syncytiotrophoplastic giant cells presenting as a hydatidiform mole. Gyn Oncol 18:393-401, 1984

Fu YS, Reagan JW, Richart RM, Stock RJ: Definition of cervical cancer precursors, in Grundman E (ed): Cancer of The Uterine Cervix, Cancer Campaign, New York, Gustav Fischer Verlag, New York, Vol 8, pp 67-74, 1985

Gallup SG, Harper RM, Stock RJ: Poor prognosis in patients with adenosquamous cell carcinoma of the cervix. Obstet Gynecol 65:416, 1985

Gallup SG, Stock RJ, Sammons JJ, Paulk WE: Primary small bowel adenocarcinoma presenting as a malignant ovarian neoplasm. Milit Med 150:105-106, 1985

Kiley KC: Giant fibrosarcoma (Case Report). Gynecol Path, in press

Kiley KC, Perkins C, Penney LL: Umbilical cord stricture, association with fetal demise in two cases. J Reprod Med, in press

PUBLICATIONS - FY 85

LaForce WR, Butler A, Penney LL: Prevalence of polycystic ovarian syndrome in adolescent females. Submitted*

O'Brien AW, Penney LL. The effects of verapamil on gestational length in rabbits. Submitted*

Patterson GR, Hill PS, Miles PA, Penney LL, O'Brien AW: Effects of medroxyprogesterone acetate as an adjuvant in tubal microsurgery. Submitted*

Penney LL, O'Brien AW, Reimann BEF, Rauls DO: Acute cardio-vascular effects of delta-9-tetrahydrocannabinol in conscious pregnant sheep. Neurobehav Toxicol Teratology 7:209, 1985 (Abstract)*

Penney LL, Smith ML, Grosso D: Clinical correlation and regression analysis of cord blood prolactin, estrone, estradiol, estriol, and thyroid hormone. Submitted*

Rosa C, Amr S Birkin S, Wehmann R, Nisula B: Effect of desialylation of human chorionic gonadotropin on its metabolic clearance rate in humans. J Clin Endocrinol Metab 59:1215-1219, 1985

Rudd EG: Premature rupture of membranes: a review. J Reprod Med, in press

Salazar H, Stock RJ: Extragenital pathology in obstetrics and gynecology, in Gompel C, Silverberg SG (eds): Pathology in Gynecology and Obstetrics, Philadelphia, J.B. Lippincott, 3rd Edition, pp 574-598, 1985

Stock RJ, Labudovich M, Ducatman B: Asymptomatic first-trimester liver cell adenoma: diagnosis by fine-needle aspiration cytology with cytochemical and ultrastructural study. Obstet Gynecol 66:287-290, 1985

Stock RJ, Skelton H: Fatal pulmonary embolism occurring two hours after exteriorization of the uterus for repair following cesarean section. Milit Med 150:549-551, 1985

Vaughn DL, Cotterill RW, Penney LL, O'Brien AW: Absence of acute maternal or fetal effects of verapamil in anesthetized sheep. Submitted*

ORTHOPAEDICS

Monsivais JL, Nitz PA, Scully TJ: The role of carpal instability in scaphoid nonunion: casual or causal? J Hand Surg [Br], in press

Monsivais J, Seaber A, Urbaniak JR: Debridement and replantation of the spleen with microsurgical restoration of blood flow. Microsurgery 6:97-102, 1985

PUBLICATIONS - FY 85

Schoenecker PL, Meade WC, Pierron RL, Sheridan JJ, Cepelli AM: Blount's disease: a retrospective review and recommendations for treatment. J Pediatr Orthop 5:181-186, 1985

PATHOLOGY

Herrera GA, Reimann BEF: Electron microscopy in determining origin of metastatic adenocarcinomas. South Med J 77:1557-1566, 1984

Keniston RC: Hyperpolyaminemia and vitamin B-6 in Leklem JE, McCoy EE, Reynolds RD (ed): Vitamin B-6 nutrition and metabolism--its role in health and disease. New York, Alan R. Liss, Inc., in press

Keniston RC: Interactions between aminoglycoside antibiotics, pyridoxal 5'phosphate, and mortality in Leklem JE, McCoy EE, Reynolds RD (ed): Vitamin B-6 nutrition and metabolism--its role in health and disease. New York, Alan R. Liss, Inc., in press

Keniston RC: Correlation between serum albumin, plasma pyridoxal 5'phosphate, and mortality in Leklem JE, McCoy EE, Reynolds RD (ed): Vitamin B-6 nutrition and metabolism--its role in health and disease. New York, Alan R. Liss, Inc., in press

Keniston RC: Pyridoxal 5'phosphate as an antidote for cyanide, aminoglycoside, and dopamine toxicity in Leklem JE, McCoy EE, Reynolds RD (ed): Vitamin B-6 nutrition and metabolism--its role in health and disease. New York, Alan R. Liss, Inc., in press

Keniston RC, Weir MR: Rapid decrease in plasma pyridoxal-5'-phosphate caused by aminophylline and gentamicin. Submitted to Am J Clin Nutr, September, 1985*

Mena H: Diagnosis of peripheral nerve specimens. Proc Soc Armed Forces Med Lab Sci 14:9, 1985 (Workshop Abstract)

Mena H, Reimann BEF, Maccario M, Ashbaugh P: The diagnosis of peripheral neuropathies. Proc Soc Armed Forces Med Lab Sc 14:9, 1985 (Workshop Abstract)

Miles PA, Herrera GA, Mena H, Trujillo I: Cytological findings in primary malignant carcinoid tumor of the cervix, including immunohistochemistry and electron microscopy performed on cervical smears. Acta Cytol, in press

Miles PA, Herrera GA, Greenberg H, Eckberg DJ: Condylomas of the uterine cervix initially interpreted as squamous carcinoma. Gynecol Oncol, in press

PUBLICATIONS - FY 85

Miles PA, Kiley KC, Mena H: Giant fibrosarcoma of the ovary. Int J Gynecol Pathol 4:83-87, 1985

Pittman DL: Immunologic markers. Proc Soc Armed Forces Med Lab Sci 14:9, 1985 (Workshop Abstract)

Pittman DL: Immunologic marker studies - review of basic methodology, diagnostic utility, and major pitfalls. Proc Soc Armed Forces Med Lab Sci 14:9, 1985 (Workshop Abstract)

Pittman DL: Nonspecific staining of mast cells by avidin-biotin-peroxidase technique. Submitted to Acta Path, January 1985

Pittman DL: Evaluation of the efficacy of immunoperoxidase staining: a study of 302 reactions in 116 cases. Submitted to Am J Clin Path, March 1985

Pittman DL, Jones JD, Liles WJ, Sanders LR: Fine needle aspiration cytology of the thyroid, an analysis of approximately 350 cases. Proc Soc Armed Forces Med Lab Sci 14:14, 1985 (Abstract)

Pittman DL, Zuckerman MJ, Bowman D, Farley PC: Multiple lymphomatous polyposis of the gastrointestinal tract: case report with immunologic marker studies. Proc Soc Armed Forces Med Lab Sci 14:9, 1985 (Workshop Abstract)

Reimann BEF: Substance abuse and drug interactions. Neurobehav Toxicol and Teratology 7:206, 1985 (Abstract)

Reimann BEF, Ashbaugh PH: The applicability of the electron microscope for clinical investigations other than routine histopathology. Proc Soc Armed Forces Med Lab Sci 14:15, 1985 (Abstract)

Tobin HE, Miles PA: Radiation induced osteosarcoma of the clavicle: a case report and literature review. Proc Soc Armed Forces Med Lab Sci 14:13, 1985 (Abstract)

Tobin HE, Miles PA: Radiation induced osteosarcoma of the clavicle: a case report and literature review. Submitted to Milit Med, July, 1985

York WB: Laboratory microcomputing. Proc 1984 Symp Computer Appl in Med Care 213-214, 1984 (Abstract)

PEDIATRICS

Demmler GJ, Schydlower M, Lampe RM: Texas, teenagers, and CMV. J Infect Dis, in press

Kelly PC, Banks R, Weir MR: The cusum graph: concept and use. Submitted to Am J Dis Child, September, 1985

PUBLICATIONS - FY 85

Kelly PC, Pearl W, Weir MR: Infantile polyarteritis nodosa/mucocutaneous lymph node syndrome (IPN/MCLNS) treated with long-term corticosteroids. Submitted to South Med J, November, 1985

Kelly PC, Weir MR, Atkinson AW: Unsupervised children in motor vehicles. Am J Public Health 75:690, 1985 (Letter)

Kelly PC, Weir MR, Fearnow RG: A survey of parental opinions on corporal punishment in schools. J Dev Behav Pediatr 6:143-145, 1985

Kossoy AF, Weir MR: Therapeutic indications in carbamazepine overdose. South Med J 78:999-1000, 1985

Kossoy AF, Weir MR: Potentially toxic theophylline ingestions: are heroic measures indicated? South Med J 78:1000-1002, 1985

Kossoy AF, Weir MR: Renal tubular acidosis in infancy: a clinical approach to diagnosis and treatment. South Med J, in press

Lampe RM, Weir MR: Erythromycin versus sulfisoxazole prophylaxis for recurrent otitis media. Submitted to Clin Pediatr, April, 1985

Lampe RM, Weir MR, Scott MR, Weeks JL: Revaccination antirougeoleuse chez l'enfant vaccine avant l'age d'un an. Journal de Pediatrie 4:131-135, 1985

Lampe RM, Weir MR, Scott MR, Weeks JL: Measles reimmunization in children immunized before 1 year of age. Am J Dis Child 139:33-35, 1985

Lampe RM, Weir MR, Spier J, Rhodes MF: Acoustic reflectometry in the detection of middle ear effusion. Pediatrics 76:75-78, 1985

Shoemaker M, Lampe RM, Weir MR: Peritonsillitis: abscess or cellulitis? Pediatr Infect Dis, in press

Stafford EM: Flying, peanuts, and crying babies. Pediatrics, in press

Stafford EM: Airline snacks pose choking hazard to young passengers. National Safety Council Air Transport Newsletter 2:6, 1985

Ting B, Knott MD, Mansfield LE, Ting S: Effects of oral cromolyn on food-induced headaches and behavioral changes. Ann Allergy 55:399, 1985 (Abstract)*

Weir MR, Archambault JM: A tympanocentesis learning aid. Am J Dis Child 139:553-554, 1985

Weir MR, Gwinn JV, Fearnow RG: A program for pediatric intern orientation. Milit Med 150:109-111, 1985

PUBLICATIONS - FY 85

Weir MR, Lampe RM: Assessing middle ear disease: beyond visual otoscopy. Am Fam Physician 30:201-210, 1984*

Weir MR, Lampe RM: Reflections from the middle ear: acoustic reflectometry. Contemporary Pediatrics, in press*

Weir MR, Salinas JA, Rawlings PC: Intrauterine twin demise and oligomeganephronia. Nephron 40:482-484, 1985

Wynder SG, Lampe RM, Shoemaker M: Uvulitis and Haemophilus influenzae b bacteremia. Pediatr Emer Care, in press

PHARMACY

Massey R: Dilution and stability data of commonly used intravenous piggyback medications. Submitted, May, 1985

PRIMARY CARE AND COMMUNITY MEDICINE

Coleridge ST: Diagnostic peritoneal lavage. Chapter in Clinical Procedures in Emergency Medicine. Roberts JR, Hedges JR (eds.), W. B. Saunders Co., pp. 557-568, 1985

Coleridge ST: Low back exercises. Chapter in Clinical Procedures in Emergency Medicine. Roberts JR, Hedges JR (eds.), W. B. Saunders Co., pp. 557-568, 1985

Coleridge ST: IUD removal. Chapter in Clinical Procedures in Emergency Medicine. Roberts JR, Hedges JR (eds.), W. B. Saunders Co., pp. 557-568, 1985

Stuart RB: The problem of alcohol abuse. Army Magazine, pp. 16 & 20, February, 1985

PSYCHIATRY

DeMeersman RE, Schaefer DC, Miller WW: Personality and self-motivation during biochemical fatigue. J Human Stress 10:3, 1984

De Meersman RE, Schaefer DC: Adaptation to maximal effort: genetics versus environment. Acta Genet Med Gemellol, in press

De Meersman RE, Schaefer DC, Miller WW: Maximal work capacity in prepubescent obese and non-obese females. Clin Pediatr, in press

DeMeersman RE, Schaefer DC: Effects of diet on rate perceived exertion. Physiol Behav, in press

Hawkins MR, Kruzich DJ, Smith JD, Silsby HD: Prevalence of polydrug use among alcoholic soldiers. Amer J Drug & Alcohol Abuse 11:27-35, 1985

PUBLICATIONS - FY 85

Hawkins MR, Silsby HD, Kruzich DJ, Sittig DR: Hematological concomitants of alcoholism: development and validation of a clinical screening technique. J Substance Abuse Treatment 1:271-276, 1984

Hawkins MR, Vichick DA, Silsby HD, Kruzich DJ, Butler R: Sleep and nutritional deprivation and performance of house officers. J Med Educ 60:530-535, 1985*

Jeffrey TB, Jeffrey LK: The utility of the modified WAIS in a clinical setting. J Clin Psychol 40:1067-1069, 1984

Jeffrey TB, Jeffrey LK, Yetter JG: The Slosson Intelligence Test and young learning disabled children: a comparative study. J Clin Psychol 40:1255-1256, 1984

Jeffrey TB, Jeffrey LK: Replication of a modified procedure for scoring the WAIS. Psychol Reports 54:37-38, 1984

Jeffrey LK, Jeffrey TB, Barnett JC, Schaefer DC: Psychology interns: by what names shall we know them? Prof Psychol: Res & Practice, in press

Kruzich DJ, Donough TM, Hawkins M Silsby HD: Alcoholism treatment outcomes among career soldiers. Int J Addict, Vol 21

Schaefer DC, DeMeersman RE, Kallman WM, Miller WW, Althaus JS, Miller ED: Perceived exertion and catecholamine reactivity in the type A and type B patterns: a clinical analysis. J Psycholphysiol 20, 1984

Silsby HD, Jones FD: The etiologies of Vietnam post-traumatic stress syndrome. Milit Med 150:6-7, 1985

Walters GD, Green RL, Jeffrey TB: Discriminating between alcoholics on the MMPI. J Pers Assess 48:486-488, 1984

RADIOLOGY

Rainey RK, Pfautsch ML: Traumatic volar dislocation of the distal radioulnar joint. Orthopedics 8:898-900, 1985

SOCIAL WORK SERVICE

Aldridge RG: Sexuality and the practicing physician: a continuing medical education program. Sexuality in Clinical Practice, Corrective and Social Psychiatry and J Behavior Technology Methods and Therapy, 31:17-26, 1985

Aldridge GJ, Aldridge RG: Sexuality and the practicing physician: a review of the literature. Sexuality in Clinical Practice, Corrective and Social Psychiatry and J Behavior Technology Methods and Therapy 30:107-108, 1984

PUBLICATIONS - FY 85

Aldridge RG: An ecological approach to family therapy. Corrective and Social Psychiatry and J Behavior Technology Methods and Therapy 30:74-75, 1984

SURGERY

Cabellon S, Brown JM, Cavanaugh DG: Accuracy of the hepatobiliary scan in acute cholecystitis. Am J Surg 148:607-608, 1984

Cabellon S, Gaines TG, Monsivais JJ, Apgar RG, Cavanaugh DG: Brachial artery mycotic aneurysms: complication of cardiac catheterization. Milit Med, in press

Cavanaugh DG, Smith DR, Cabellon S: Experience with celestin tube at William Beaumont Army Medical Center: a ten-year review. Milit Med 150:321, 1985

Cleland B, Cavanaugh DG, Smith DR, Cabellon S: Penetrating tracheal injuries. Milit Med 150:330-331, 1985

Fallon WF: Bladder rupture associated with fractured pelvis in blunt trauma to the abdomen. Submitted to Milit Med, March, 1985

Fallon WF, Cordts PR: Management of stab wounds to the abdomen. Submitted, June, 1985

Hansberry K, Thompson I, Diaz-Ball FL, OBrien G, Lamb R: Prophylaxis of implantation of transitional cell carcinoma with intraperitoneal chemotherapy. Invest Urol, in press*

Webb TJH: Glucagon: A review of the mechanism of action, cardiohemodynamic effects and possible clinical usefulness. Submitted to Anesthesiology, March, 1985

PRESENTATIONS - FY 85

DCI

Lund M, Rauls DO, Ting S: The analysis of plasma histamine-A modification of the enzymatic isotopic assay. Presented at the American Association of Clinical Immunology and Allergy meeting, New Orleans, LA, November, 1984

Lund M, Rauls DO, Ting S: Measurement of plasma histamine: a modification of the single-isotope enzymatic method. Presented at the 41st Annual Meeting of the American Academy of Allergy and Immunology, New York, NY, March, 1985

Manna B, Penney LL, Smith ML: Evaluation of a simple method for determining free testosterone in serum. Presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Mansfield LE, Ting S, Haverly RW, Rauls DO, Vaughan TR: Plasma histamine elevation during blind food challenges which provoke migraine. Presented at the 41st Annual Meeting of the American Academy of Allergy and Immunology, New York, NY, March, 1985

McIntyre S, Serio CS, Ting S: In vivo effects of cromolyn on antibody production. Presented at the American Association of Clinical Immunology and Allergy meeting, New Orleans, LA, November, 1984

Rauls DO, Ting S: Effects of propanolol on terbutaline suppression of antigen induced histamine release in vivo. Presented at the 41st Annual Meeting of the American Academy of Allergy and Immunology, New York, NY, March, 1985

Rauls DO, Ting S: Use of bonded silica cartridges for quantification of histamine in biological fluids. Presented at the American Association of Clinical Immunology and Allergy meeting, New Orleans, LA, November, 1984

Rauls DO, Ting S: Inhibition of histamine H-methyltransferase enzyme by opiod and related drug. Presented at the Fitzsimons Allergy-Immunology Symposium, Annual Scientific Session of the Association of Military Allergists, Aurora, CO, January, 1985

Rauls DO, Ting S: Inhibition of histamine H-methyltransferase enzyme by opiod and related drug. Presented at the 41st Annual Congress of the American College of Allergists, Bal Harbour, FL, February, 1985

Smith ML, Mansfield LE, Ting S: Comparison of methods for using metered dose beclomethason inhalers. Presented at the 41st Annual Congress of the American College of Allergists, Bal Harbour, FL, February, 1985

Veit BC: Quantitation of residual T cells following T cell depletion in human bone marrow transplantation. Workshop presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Weir MR: Medical emergency relief efforts. Presented to the Research Discussion Group of Texas Tech University Health Sciences Center, El Paso, TX, November, 1985

PRESENTATIONS - FY 85

Weisman IM: PEEP update: mechanical ventilation. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Weisman IM, Zeballos RJ, Johnson B, Moreno A: Percent hemoglobin S and percent sickling as correlates for exercise performance at 4000 ft in individuals with sickle cell trait. Presented at the FASEB meeting, April, 1985

Weisman IM, Zeballos RJ, Johnson B, Moreno A: The cardiopulmonary effects of stressful exercise at 4000 ft of individuals with sickle cell trait. Presented at the American Thoracic Society meeting, 1985

Zeballos RJ, Weisman IM, Johnson B, Moreno A: P(A-a)02 during exercise in healthy young blacks with sickle cell trait and controls. Presented at the FASEB meeting, April, 1985

MEDICINE

Atchley SH, Wilkin JH: Clinicians evaluation of exercise thallium imaging. Presented at the 14th Annual Session of the Army Association of Cardiology, El Paso, TX, May, 1985

Greenberg DI: Cimetidine survey II - patterns among military doctors in prescribing cimetidine for outpatients. Presented at the meeting of the American Gastroenterological Association, American Association for the Study of Liver Diseases, Gastroenterology Research Group, New York, NY, May, 1985

Greenberg DI: Epidemiology of peptic ulcer disease among U.S. military patients compared to international trends. Presented at the meeting of the American Gastroenterological Association, American Association for the Study of Liver Diseases, Gastroenterology Research Group, New York, NY, May, 1985

Greenberg DI, O'Brien AW, Tobin HE, Miles PA, Pfeiffer CJ: Cimetidine's effect on the healing rate of gastric ulcers in rats. Presented at the meeting of the American Gastroenterological Association, American Association for the Study of Liver Diseases, Gastroenterology Research Group, New York, NY, May, 1985

Haverly RW, Ting S: A comparative study between prick skin test and IgE fast test. Presented at the Fitzsimons Allergy-Immunology Symposium, Annual Scientific Session of the Association of Military Allergists, Aurora, CO, January, 1985

Haverly RW, Ting S: A comparative study between prick skin test and IgE fast test. Presented at the 41st Annual Congress of the American College of Allergists, Bal Harbour, FL, February, 1985

Larsen L, Ting S: Effects of susphrine on cutaneous allergic skin reaction. Presented at the Fitzsimons Allergy-Immunology Symposium, Annual Scientific Session of the Association of Military Allergists, Aurora, CO, January, 1985

Larsen L, Ting S: Effects of susphrine on cutaneous allergic skin reaction. Presented at the 41st Annual Congress of the American College of Allergists, Bal Harbour, FL, February, 1985

PRESENTATIONS - FY 85

Mansfield LE, Ting S, Haverly RW, Rauls DO, Vaughan TR: Plasma histamine elevation during blind food challenges which provoke migraine. Presented at the 41st Annual Meeting of the American Academy of Allergy and Immunology, New York, NY, March, 1985

Miller C, Bowman MA, Wilkin JH: Intravenous steptokinase experience at William Beaumont Army Medical Center. Presented at the 14th Annual Session of the Army Association of Cardiology, El Paso, TX, May, 1985

Moreno AJ: Gallium-67 citrate scintigraphy in pulmonary embolism. Presented at the American College Chest Physician Meeting, Dallas, TX, October, 1984

Moreno AJ, Weisman IM, Zeballos RJ, Johnson B, Turnbull G: Pulmonary blood flow distribution determined from perfusion lung scintigraphy during rest and exercise. Presented at the FASEB meeting, April, 1985

Moreno AJ, Yedinak G, Turnbull G, O'Brien AW, Berger D, Pittser L, Revels J, Sedivy P: Fetal adsorbed radiation dose in sheep from maternal administration of TC-99m radiopharmaceuticals. Presented at the International Congress of Radiology, Hawaii, July, 1985

Pearl WR, Wilkin JH: Balloon Pulmonary Valvuloplasty. Presented at the 14th Annual Session of the Army Association of Cardiology, El Paso, TX, May, 1985

Shelton AL, Ting S: Delayed hypersensitivity reaction to silicone breast implants. Presented at the 41st Annual Congress of the American College of Allergists, Bal Harbour, FL, February, 1985

Shelton AL, Ting S, Lund M, Reiman BEF: Naloxone does not inhibit codeine induced histamine release in vivo. Presented at the Fitzsimons Allergy-Immunology Symposium, Annual Scientific Session of the Association of Military Allergists, Aurora, CO, January, 1985

Ting S: Cardiogreen(C) induced in vivo histamine release. Presented at the American Association for Clinical Immunology and Allergy meeting, New Orleans, LA, November, 1984

Ting S, Rauls DO: Increased in vivo skin histamine releasability in atopic dermatitis. Presented at the 2nd Texas Allergy Symposium, University of Texas Medical Branch, Galveston, TX, November, 1984

Ting S, Rauls DO: Increased in vivo skin histamine releasability in atoptic dermatitis. Presented at the Fitzsimons Allergy-Immunology Symposium, Annual Scientific Session of the Association of Military Allergists, Aurora, CO, January, 1985

Ting S, Rauls DO: Increased in vivo skin histamine releasability in atoptic dermatitis. Presented at the 41st Annual Meeting of the American Academy of Allergy and Immunology, New York, NY, March, 1985

PRESENTATIONS - FY 85

Ting S, Rauls DO: Effects of propanolol on terbutaline suppression of antigen induced histamine release in vivo. Presented at the 41st Annual Meeting of the American Academy of Allergy and Immunology, New York, NY, March, 1985

NURSING

Ebert D: Initial management of blunt and penetrating chest trauma. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Gautreaux DD: The body's response to physiologic stress. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Housing T: Nursing actions to prevent sepsis. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Parry BA: Mothers' expectations and perceptions of their failure-to-thrive babies. Presented at the Armed Forces District of the Nurses Association, American College of Obstetricians and Gynecologists, Atlanta, GA, October, 1984

Parry BA: Maternal child patient education strategies. Strategies for Patient Education, El Paso, TX, November, 1984

Parry BA: Mothers' expectations and perceptions of their failure-to-thrive babies. Presented at the Sigma Theta Tau's Research Papers Day, Lexington, KY, November, 1984

Parry BA: Unusual occurrence reports. Presented to the Department of Nursing, WBAMC, El Paso, TX, February, 1985

Parry BA: Audit tool. Presented to the Department of Nursing, WBAMC, El Paso, TX, February, 1985

Parry BA: The educator's role in child abuse. Presented to the Delta Kappa Gamma Society, Zeta Iota Chapter, El Paso, TX, March, 1985

Parry BA: Child abuse: school intervention. Presented to the Counselors Workshop, El Paso, TX, March, 1985

Parry BA: High risk families. Presented to the University of Texas at El Paso, El Paso, TX, March, 1985

Parry BA: Child sexual abuse: the victim. Presented to the Academy of Criminal Justice Sciences, Las Vegas, NV, March, 1985

Parry BA: Child abuse: effects on the victim. Presented to the American Association of University Women, El Paso, TX, April, 1985

PRESENTATIONS - FY 85

Parry BA: Physical and emotional manifestations of abuse. Presented at the Investigation and Prosecution of Sex Offenses, Fort Bliss, TX, May, 1985

Parry BA: Extended nursing roles. Presented at the Auburn University School of Nursing, Montgomery, AL, May, 1985

Schario ME: Disaster management: evacuation, prehospital care, inpatient care; simulation of disaster exercises; triage. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Taylor RW: Respiratory management of patients with chest and/or abdominal trauma. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Yarbrough J, Haverly RW, Mansfield LE, Ting S: Comparison of methods for using metered dose becomethasone inhalers. Presented at the Fitzsimons Allergy-Immunology Symposium, Annual Scientific Session of the Association of Military Allergists, Aurora, CO, January, 1985

OB-GYN

Kiley K: Doxycycline versus cefazolin in vaginal hysterectomy. Presented at the Armed Forces District Meeting, American College of Obstetricians and Gynecologists, atlanta, GA, October, 1984

Kiley K, Penney LL, Stanley J: A comparison of oral doxycycline and intramuscular cefazolin prophylaxis for vaginal hysterectomy. Presented at the Armed Forces District, American College of Obstetricians and Gynecologists, Atlanta, GA, October, 1984

Penney LL, O'Brien AW, Reimann BEF, Rauls DO: Acute cardiovascular effects of delta-9-tetrahydrocannabinol in conscious pregnant sheep. Presented at the Annual Substance Abuse Conference, Texas Tech University Health Science Center, School of Medicine, El Paso, TX, October, 1984

Rudd EG: Premature rupture of membranes. Presented at the Armed Forces District Meeting, American College of Obstetricians and Gynecologists, Atlanta, GA, October, 1984

PATHOLOGY

Keniston RC: Hyperpolyaminemia and vitamin B-6. Presented at Banffi, Alberta, October, 1984

Keniston RC: Interactions between aminoglycoside antibiotics, pyridoxal 5'phosphate, and the polyamines in vitro in bacteria and in patients. Presented at Banffi, Alberta, October, 1984

Keniston RC: Correlation between serum albumin, plasma pyridoxal 5'phosphate, and mortality. Presented at Banffi, Alberta, October, 1984

PRESENTATIONS - FY 85

Keniston RC: Pyridoxal 5'phosphate as an antidote for cyanide, aminoglycoside, and dopamine toxicity. Presented at the Gary P. Watten Surgical Symposium, San Antonio, TX, April, 1985

Keniston RC, Cabellon S, Yarbrough KP: Pyridoxal-5'-phosphate as an antidote for cyanide and amine toxicity: an in vivo rat study. Presented at the 1985 GPW meeting, San Antonio, TX, April, 1985

Mena H: Diagnosis of peripheral nerve specimens. Workshop presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Mena H, Reimann BEF, Maccario M, Ashbaugh PH: The diagnosis of peripheral neuropathies. Presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Pittman DL: Immunologic markers. Workshop presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Pittman DL: Immunologic marker studies - review of basic methodology, diagnostic utility, and major pitfalls. Presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Pittman DL, Jones JD, Liles WJ, Sanders LR: Fine needle aspiration cytology of the thyroid, an analysis of approximately 350 cases. Presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Pittman DL, Zuckerman MJ, Bowman D, Farley PC: Multiple lymphomatous polyposis of the gastrointestinal tract: case report with immunologic marker studies. Poster presentation at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Reimann BEF: The Problem of Pot - Some Insights into the Drug Scene. Presented at the Annual Substance Abuse Conference, Texas Tech University Health Science Center, School of Medicine, El Paso, TX, October, 1984

Reimann BEF, Ashbaugh PH: The applicability of the electron microscope for clinical investigations other than routine histopathology. Presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

Tobin HE, Miles PA: Radiation induced osteosarcoma of the clavicle: a case report and literature review. Presented at the Society of Armed Forces Medical Laboratory Scientists meeting, Reno, NV, March, 1985

York WB: Laboratory microcomputing. Presented at the 8th Annual Symposium on Computer Allications in Medical Care, Washington, DC, November, 1984

PRESENTATIONS - FY 85

PEDIATRICS

Cohen ML, Kelly PC, Atkinson AW: Attention deficit disorder: the effects of ritalin on self-esteem. A comparison of ACTeRS teacher scale, Conners' parent scale, and Gordon diagnostic system in diagnosis and management. Presented at the American Academy of Pediatrics Seminar, Atlanta, GA, April, 1985

Kelly PC, Pearl WR, Weir MR: Mucocutaneous lymph node syndrome/infantile polyarteritis nodosa, the long-term use of corticosteroids. Presented at the 14th Annual Session of the Army Association of Cardiology, El Paso, TX, May, 1985

Ting B, Knott MA, Mansfield LE, Ting S: Effects of oral cromolyn on food-induced headaches and behavioral changes. Presented at the Fitzsimons Allergy-Immunology Symposium, Annual Scientific Session of the Association of Military Allergists, Aurora, CO, January, 1985

Ting B, Knott MC, Mansfield LE, Ting S: Effects of oral cromolyn on food-induced headaches and behavioral changes. Presented at the American Association of Clinical Immunology and Allergy meeting, New Orleans, LA, November, 1984

SOCIAL WORK SERVICE

Aldridge RG: Assessment of juvenile and adult sex offenders: a medico-legal approach. A full day workshop sponsored by the Larimer County Sexual Assault Task Force, Fort Collins, CO, 1984

Aldridge RG: Sexual dysfunction and substance abuse. Presented at the Chemical, Psychological and Sexual Aspects of Substance Abuse Workshop, 11th Annual Institute on Alcohol and Drug Abuse Studies, West Texas Council of Governments/University of Texas at El Paso, El Paso, TX, 1984

Aldridge RG: Sexuality in clinical practice. A two-day workshop sponsored by the El Paso Chapter of the National Association of Social Workers, El Paso TX, 1984

Aldridge RG: How to deal with my own sexuality. Presented as part of a workshop for Army spouses during Army Family Week, Fort Bliss, TX, 1984

Aldridge RG: Child sexual abuse and rape: assessment of offenders. A full day workshop sponsored by the Department of Sociology and Social Work, Texas Women's University, Denton, TX, 1984

Aldridge RG: Rapists and rape. Workshop presented as a part of the 1st Annual Institute on Family Violence entitled Ending Family Violence: Challenge for the Last Frontier, presented by the Center for Alcohol and Addiction Studies, University of Alaska at Anchorage, Anchorage, AK, 1984

PRESENTATIONS - FY 85

Aldridge RG: Child sexual abuse and the offender. Workshop presented as a part of the 1st Annual Institute on Family Violence entitled Ending Family Violence: Challenge for the Last Frontier, presented by the Center for Alcohol and Addiction Studies, University of Alaska at Anchorage, Anchorage, AK, 1984

Aldridge RG: Psychology of the sex offender. A workshop presented to the Rape Crisis Unit, El Paso Center for Mental Health and Mental Retardation Services, El Paso, TX, 1984

Aldridge RG: Treatment of sexual dysfunction. A workshop presented to the OB-GYN staff and residents at William Beaumont Army Medical Center, El Paso, TX, 1985

Aldridge RG: The child sexual abuser. Presented at the Joint National Conferences of the American Association of Mental Health Professionals in Corrections and the Academy of Criminal Justice Sciences, Las Vegas, NV, 1985

PSYCHIATRY

Schaefer DC, Stanczak DE: Behavioral management of chronic seizure disorders: a case study in the efficacy of stress management training. Presented at the 1985 AMEDD Clinical Psychology Short Course, San Francisco, CA, March, 1985

SURGERY

Apgar RG: Intra-abdominal sepsis and wound infection rate of patient's undergoing exploratory laparotomy for trauma at WBAMC. Presented at the 1985 GPW meeting, San Antonio, TX, April, 1985

Cabellon S: Incidence of a positive OPG in patients with atherosclerotic disease with no bruit and no symptoms. Presented at the Annual Vascular Seminar, USUHS, Bethesda, MD, December, 1984

Cordts P: Management of stab wounds to the torso at WBAMC. Presented at the 1985 GPW meeting, San Antonio, TX, April, 1985

Fallon WF: Expectant Management of abdominal stab wounds. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Goldberg CA, Hetzler N: Case study: assessment of chest and abdominal trauma, a team approach. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Maldonado F: GU trauma. Presented at the 4th Annual William Beaumont Trauma Symposium, El Paso, TX, November, 1984

Oliphant JR: Abdominal wall reconstructioning muscle flaps. Presented at the Association of Military Plastic Surgeons, Denver, CO, October, 1984 (Glen Burt Award)

PRESENTATIONS - FY 85

Otero C: Abdominal wall disruption, unusual case of traumatic abdominal wall hernia. Presented at the 1985 GPW meeting, San Antonio, TX, April, 1985

Smith G: Use of Limberg flaps for closure of back wounds. Presented at the 1985 GPW meeting, San Antonio, TX, April, 1985

UNIT SUMMARY

OBJECTIVES

If the goal of DCI is to further enhance the ability of fellows and residents to evaluate medical advancement and the literature as its report, the objectives appear to be more papers, more protocols, and more research; in this case, with less money and no additional personnel. Realistically, the objective must be continued support of residencies and fellowships, resulting in higher quality research and publications. Since one cannot match or exceed previous productivity year after year, a unit objective of protocol and paper production that is 70-80% of the running average of three previous years is reasonable and measurable. We met this objective.

TECHNICAL APPROACH

The Department of Clinical Investigation provides support for staff and housestaff research projects under the guidelines of the Declaration of Helsinki, Clinical Investigation Program (AR 40-38), HSC Reg 40-23, and the Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances (AR 40-7). Research is conducted under protocols approved by the Research Committee (WBAMC HR 15-1), the Human Use Committee (WBAMC HR 15-1) and the Radioisotope Committee (WBAMC HR 15-1) where applicable. In those research protocols utilizing laboratory animals, the Animal Use Committee (WBAMC HR 15-1), ensures that the investigators follow guidelines set forth in "Guide for Laboratory Animal Facilities and Care," published by the National Academy of Sciences-National Research Council, and the criteria established by the American Association for Accreditation of Laboratory Animal Care.

PERSONNEL

FY85 again saw the departure of key personnel. MAJ Michael Smith and CPT Charles Serio were reassigned to Europe. David Rauls, PhD went to a more lucrative, but not necessarily better position, in industry. Philip Barren went to a more lucrative position as well. Successors have been recruited for all doctoral level positions, but the combined personnel gap totals 30 man months.

FUNDING

Funding for FY85 was consistent with previous funding. In addition WBAMC spent $23,083 for travel to report findings at professional meetings. A new policy at WBAMC will tie paper presentation to a protocol and limit funding for the meeting to three days. However, with department chief's permission, presentors may attend the full meeting and costs for the additional days are transferred from the departmental budget to the presentation funds on a quarterly basis.

PROGRESS:

FY85 saw 76 published articles, 35 articles accepted for publication, and 28 submitted by personnel currently at WBAMC or for work done while at WBAMC. In addition, there were 99 presentations in scientific arenas.

MANPOWER

Title	Recognized Requirement (SSI/MOS)	Auth	Assigned	Name
OFFICE OF CHIEF				
Chief	90P	0-6	0-6	Weir, M.R.
Allied Sci		0-3	-	- *
Editorial Asst	01087	GS-5	GS-5	LaMonde, S
Protocol Coord	0303	GS-7	GS-7	Casteel, P.J.
Clerk, Supply	02005	GS-4	GS-4	Turner, L.
Internist	61F00	-	-	-
CHEMISTRY SERVICE				
Supv Res Chem	01320	GS-12	-	- *
Biochemist	68C	-	-	
Chemist	01320	GS-9	GS-9	Enriquez, J.
Bio Sci Asst	01H20	E-5	E-5	Brady, Ann
Med Lab Tech	00645	GS-7	GS-7	Manna, B.S.
Med Lab Tech	00645	GS-7	GS-7	Lund, M.
Med Lab Tech	00645	-	-	-
Med Lab Aide	00645	-	-	-
MICROBIOLOGY SERVICE				
Supv Microbiol	00403	GS-12	GS-12	Veit, B.
Immunologist		0-3	-	- *
Bio Sci Asst	01H20	E-5	E-4	Fama, Dominic
Microbiologist	00403	GS-9	-	-
Med Lab Tech	00645	GS-7	GS-7	MacIntyre,S.
Med Lab Tech	00645	-	-	-
Med Lab Tech	00645	-	-	-
Electron Micr Tech	00699	-	-	-
BIOLOGICAL RESEARCH SERVICE				
C, BioRes Svc	64C9B	0-3	0-4	McNamee, G.A.
Vet Anm Sp	91T20	E-5	-	-
Animal Care Sp	91T20	E-5	E-4	Ramirez, C.
Vet Anm Sp	91T10	E-4	E-4	-
Vet Anm Sp	91T10	E-4	E-4	Sedivy,P.
Vet Anm Sp	91T10	E-3	E-2	Yarborough,K.
Vet Anm Sp	91T10	E-3	-	-
Hlth Tech	00699	GS-7	GS-7	Revels, J.E.
Anm Caretaker	05048	WG-4	WG-4	Sigholtz, J.
Anm Caretaker	05048	WG-1	WG-1	Burton, A.D.
Lab Animal Tech	00704	-	-	-

*Positions vacant as of 31 Sept 85, replacements named or selected.

EXPENDITURES	FY82	FY83	FY84	FY85
Personnel (Civilian)	191,190	207,914	241,950	167,242
Consumable Supplies	122,189	120,660	108,370	104,666
MEDCASE Equipment	77,965	248,000	161,166	132,342
Capital Equipment	34,144	9,643	7,263	12,935
TDY	4,743	2,767	3,772	4,289
Contracts, Services, Printing & Reproduction	2,982	6,242	8,874	9,287
TOTAL	433,213	595,226	531,395	430,761
Military Pay	259,726	245,853	257,631	272,695
	692,939	841,079	789,026	703,456

	Protocols Ongoing 1 Oct	New Protocols Submitted During FY	Total Protocols	Protocols Completed During FY	Protocols Terminated During FY	Publications and Presentations	OMA Supply Budget
FY78	45	30	75	3	9	28	$35,923
FY79	63	43	106	9	14	46	$34,392
FY80	83	41	124	25	25	63	$60,134
FY81	74	59	133	16	17	80	$86,351
FY82	100	58	158	42	45	88	$122,189
FY83	71	51	122	24	19	161	$120,660
FY84	76	76	152	30	43	178	$108,370
FY85	79	54	133	30	28	175	$104,666
FY86	75						

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 81/36 Status: Terminated

Title:
Phase II Studies on Ketoconazole (Keto) - Comparison of Two Different Doses of Keto in Treating Coccidiomycosis

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ Idelle Weismann, MC

Dept/Sec: Dept Clinical Investigation Assoc Investigators

Key Words:
Coccidiomycosis; Ketoconazole MAJ S. Smith, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine the most efficacious dose of Keto for humans with coccidioidomycosis. To evaluate the toxicity of Keto in humans with doses up to 1600 mg per day. To evaluate the CSF penetration of very high doses of Keto.

Technical Approach:

The details are lengthy and specified in the original protocol, which is on file in the Dept Clinical Investigation, WBAMC, and is available upon request.

Progress:

Annual review of this protocol was conducted in September 1985. No patients have been entered into this study during the past year. Itraconazole has proven more efficacious, and therefore is the drug of choice at the present time. The study has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/62 Status: Terminated

Title:
Analyses of Copper Complexes in Plasma

Start Date: Est Comp Date:

Principal Investigator: Facility:

David Rauls, PhD, DAC

Dept/Sec: Dept Clinical Investigation Assoc Investigators

Key Words:

Copper salicylates

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To develop methodology for the analysis of copper salicylate complexes in plasma and measure blood levels attained upon administration of these complexes to rats.

Technical Approach:

Copper diisopropyl salicylate will be prepared by literature methods. Optimum conditions for analysis of the complex by high performance liquid chromatography will be worked out on the pure substance followed by isolation of the complex from spiked plasma to determine recovery and interferences. Attempts will be made to utilize atomic absorption spectroscopy for quantification of the complex in order to obtain adequate sensitivity. Once the accuracy, precision, and sensitivity of the assay have been established, the copper diisopropyl salicylate will be injected into rats intraperitoneally at doses (100 mg/kg) found to inhibit maximal electroshock seizures in rats. Blood samples will be analyzed at 0.5, 2, and 4 hours post-injection. The existence of the intact copper complex in plasma will be considered proven if a copper containing peak is recovered from injected rat plasma having a HPLC retention time equivalent to that of the pure copper diisopropyl salicylate and such a peak is found to be absent from a plasma sample from a rat injected with vehicle only.

Progress:

Principal investigator resigned in June, no work was accomplished due to lack of personnel. Terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/14 Status: Completed

Title:

Immunomodulating Effects of Terbutaline in Humans

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT C.S. Serio, MSC

Dept/Sec:Dept Clinical Investigation Assoc Investigators

Key Words:

Terbutaline

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To provide experimental evidence that the beta-adrenergic agonist terbutaline may have an effect on cells involved in various immunological processes such as cell mediated and humoral immunity.

Technical Approach:

Forty healthy nonpregnant volunteers will be selected at random from staff and technicians from the various departments of the hospital. The physicians in charge will thoroughly explain the implications of this study and the use/contraindications of terbutaline injections. The volunteers will be divided into four groups of 10 each. All volunteers will have three 10cc tubes of blood drawn on Day 0 for control samples. Group A controls will receive 0.5cc subcutaneous injections of saline (i.e. saline controls). Groups B,C, and D will receive total doses of 250, 500 and 750ug terbutaline sulfate subcutaneously. At days 4,7,9 and 14 post-terbutaline or saline injection blood samples will be taken and examined.

Progress:

This project has been completed and a manuscript is being prepared.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/21 Status: Terminated

Title:
Development of a Simple, Rapid and Reproducible Chemotaxis Assay for Clinical Use

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT C.S. Serio

Dept/Sec: Dept Clin Investigation Assoc Investigators

Key Words:

Chemotaxis assay

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To provide the clinical laboratory with a chemotaxis assay to measure defects in neutrophil and macrophage function in disease states such as recurrent bacterial infections and tumor insult.

TECHNICAL APPROACH:

Our plan is to develop the methodology and hardware for a chemotaxis assay which will allow for the following:

1. A simple assay that will allow a technician to perform the test with little or no training.
2. A reproducible slide technique in which the quantitation of cell movement can either be made by a scanning spectrophotometer or densitomiter (instruments that are inexpensive and common in most laboratories). In addition, the slides are inexpensive and may be stored as a permanent record or discarded.

3. A slide prepared with the positive and negative chemotactic agents that can be stored in a freezer and utilized immediately upon thawing.

Experimental Design

We will utilize a lab-tek culture dish as an incubation chamber for both the chemotaxin and the cells to be tested. This chamber consists of eight separate plastic wells (volume .5 ml per well) separated by a nontoxic rubber gasket mounted on a microscope slide. The chemotaxic agent(s) will be combined with agarose (0.4% in Hanks balanced salt solution) and placed in each of the four top test chambers at approximately 39^{o}C and allowed to solidify.

The positive chemotaxins to be utilized in this study will be N-formylmethionyl-leucyl-phenylalanine-methylester and human serum derived complement component C5a (These factors once embedded in the agarose will be frozen at -20^{o} for their freezer life and tested). Negative controls will be normal saline in agarose.

Initial studies will be performed with freshly prepared chemotaxins. After the agarose has solidified approximately 2X10^{5} test cells will be placed in opposite wells from the chemotactic factors and the slide placed at a 45^{o} angle for 30 minutes at 37^{o}C to allow for the attachment of neutrophils on the side of the chamber closest to agarose. By doing this, we virtually are lining up the cells on an imaginary starting line. After the initial 30 min incubation, the top plastic wells will be removed off leaving the base rubber gasket in place to act as a border between cells and agarose. The rubber gasket between each set of test wells will then be cut with a scalpel and 100 ul of media (Hanks balanced salt solution) added to the cellular side to allow contact with the agarose embedded chemotactic factor. This contact between media and agarose will result in a gradient formation and the subsequent dispersal of chemotaxins out of the agarose toward the cells. A plastic cover will be placed over the rubber gasket at this time and the slide reincubated in a 5% CO_2 incubator at 37^{o}C with 95% humidity. After an incubation period of 2-3 hours, the rubber gasket will be removed, the slides washed in saline, fixed in methanol and stained. The slide will then be mounted on a scanning stage of a Gilford Spectrophotometer and scanned for optical density for the number of cells that have actually migrated toward the chemotactic factor. Preliminary standards for various cell numbers on each slide will be established at different spectrophotometer settings and various slit widths in order to establish maximum sensitiviy. Background readings will be taken with standard microscope slides.

Progress:

Principal investigator was transferred in June, reporting no progress in FY85. Project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/37 Status: Ongoing

Title:
Cardiopulmonary Effects of Stressful Exercise at 4,000 feet on SCT Individuals

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ I. Weisman, MC

Dept/Sec: Dept Medicine/Pulmonary Cl Assoc Investigators

Key Words:

Sickle cell trait; stress

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

a. To establish baseline pulmonary function data (spirometry, helium dilution lung volumes, Maximum voluntary ventilation L/min (MVV), Arterial blood gas analysis (ABG), single breath diffusing capacity D_LCO_{SB} (ml/min/mmHg) and steady state diffusing capacity D_LCO_{SS} (ml/min/mmHg) (Filley technique) as well as values for the partial pressure of oxygen at 50 saturation (mmHg) (P_{50}) in Hgb AS individuals and controls and to determine percent Hgb S and percent Hgb F in individuals heterozygous for sickle cell trait (Hbg AS) at 4000 ft.

b. To carefully document cardiopulmonary response of individuals identified as having Hemoglobin AS during both strenuous incremental and submaximal steady-state exercise at altitude with age, race, sex, smoking, matched non-Hgb AS controls.

c. To correlate observed abnormalities (if any) in parameters of cardiopulmonary performance with levels of Hgb S in individuals with sickle cell trait (i.e. are patients with ≥40 percent of Hgb S more likely than controls to experience abnormalities during vigorous exercise. Also, to determine whether Hgb F levels may be protective as they are in patients with sickle cell disease.

d. To determine whether conditioning (repeat studies after six weeks) is operative in modulating cardiopulmonary performance in both SCT individuals and controls.

e. Conclusive data is not anticipated from this protocol, but a preliminary statement or suggestion may be offered on the important question of occupational restriction of subjects with Hgb AS. This is in keeping with the National Academy of Science - National Research Council's Report of 1973 [1].

Technical Approach:

Phase I (Initial Screening): Approximately 30-35 heterozygous sickle hemoglobin individuals (AS) and a similar number of age, race, smoking, physically conditioned matched normal volunteers (AA) to be used as controls will be studied. Hopefully, the numbers of participants will be screened from incoming recruits at Ft Bliss (four Hgb AS subjects - four normal controls/month). An initial positive screening blood test (modified Sickledex) will be followed up by hemoglobin electrophoresis and Hgb S and Hbg F quantification in order to exclude the possibility of actual SS disease itself and sickling variants other than hemoglobin AS (i.e., Hgb SC, sickle thallasemia, etc). Previous studies have failed to fully characterize the nature and quantity of Hgb S present in patient populations.

Once identified, the Hgb AS individuals as well as subjects to be used as normal controls will be asked to participate in the study acknowledging by signed informed consent.

Phase II. Prior to the initiation of exercise the following will be performed on the Hgb AS and control subjects. a) History and physical exam with chest x-ray. b) Blood work - baseline CBC, peripheral smear (best method to be determined in order to quantify and compare with samples taken during exercise), G-6-PD screens, SMA-20 including CPK and aldolase, and serum osmolality. c) Urine-baseline, urinalysis and urine osmolality, checking specifically for concentrating defects, RBCs in urine, etc. d) Baseline pulmonary function tests to include (1) spirometry (2) MVV (3) helium dilution lung volumes (4) D_LCO_{SB} (1-4 to be performed on pre-existing Collins-DS-520) (5) a resting ABG, 100 O_2 ABG study (to determine percent Rô L shunt) (6) P_{50} value (7) 2,3 DPG level. (8) baseline 12-lead EKG - individuals with abnormal baseline EKG (to be determined by staff cardiologist) and Hgb AS individuals with abnormal EKGs will not be included in this study. They will be referred to Cardiology for appropriate evaluation which may include being exercised in the cardiac cath lab (questionable data to be included in this study).

Individuals with EKGs interpreted as either sinus bradycardia and/or "early repolarization" phenomenon will be exercise-studied according to this protocol.

Individuals with abnormal baseline PFTS and normal EKGs will be exercise-studied.

Phase III. Exercise protocol - preliminary.

a. Preliminary. 1) Informed consent will be obtained from all participants. Both the M.D. and the exercise technician will be blinded as to whether the eight patients being studied monthly (4/4)

are AA or AS respectively).2) Individuals will have an indwelling arterial (either radial or brachial) cannula placed with a three-way stopcock and slow or intermittent heparin infusion at a concentration of 1000 u/100 ml diluent. An arterial line will allow for measurement of PaO_2, $PaCO_2$, SaO_2, pH, HCO_3 as well as allowing for additional blood sampling (i.e. lactate levels) during exercise. 3) A two-lead EKG signal integrated into the exercise system will be used with continuous oscilloscope display screen as well as trip recorders in the event an abnormality is noted on the screen during exercise (A physio-control lifepak with a Hewlett-Packard recorder). 4) An ear oximeter will be placed on the ear lobe and held in place with head straps allowing for the monitoring of SaO_2 and trending phenomena in SaO_2 appreciated during exercise. 5) Several preliminary exercise studies have been performed on patients with hemoglobin AS who were referred because of exercise induced problems in the last five-six months. These patients were studied using the pre-existing automated exercise system in the pulmonary laboratory. This automated system is the SRL Model 7000 Aerobic Measurement System with Model 7500 Treadmill System. This system incorporates a mixing chamber for expired gas analyses. As a result the readout from the nonprogrammable computer records only the last 20-30 seconds of data from each minute. It is important to note that the workout characteristics of mixing chambers may give erroneous results if mixed expired gas concentrations are rapidly changing (i.e. especially with rapidly incremental work rates which will be used in this protocol). An exercise system which allows for breath by breath analysis allows one to follow the changes of rapidly incremental exercise more accurately than a mixing chamber and would be preferable for our purposes. The Medical Graphics Corporation (MGC) System 2000B Cardiopulmonary exercise module would satisfy the requirements of this protocol design. A D_LCO_{SS} (MGC) apparatus can be interfaced with the breath by breath exercise system without difficulty. With our present system it is not possible to retrieve data not initially requested because there is no memory bank in the present computer. The computer is nonprogrammable and the data profile is that which accompanies the system and not necessarily what the investigator needs.

A treadmill for the purpose of pulmonary exercise, especially with healthy, otherwise normal individuals, appears to be suboptimal compared to a bicycle ergometer where the position of the head is more stationary allowing for better control of the ear oximeter and the mouthpiece. 6) The patient will be allowed to familiarize himself with the equipment - treadmill or cycle ergometer and especially breathing through a low resistance, low dead space mouthpiece (Keogh or Lloyd). Exercise will be performed with a technician trained in CPR as well as an M.D. present.

Exercise protocol:

The exercise protocol is a one-minute incremental exercise test to exhaustion over a 6' - 10' interval [16]. When stable baseline measurements of minute ventilation, heart rate, mixed expired PO_2 and PCO_2 are established, exercise begins. The individual exercises at workloads increasing by 150 kpm (equivalent 25 watts) at one minute intervals. Minute by minute readout of the following parameters will be evaluated: Mixed expired PO_2 and PCO_2, tidal volume (T.V.), respiratory rate (RR), minute ventilation (V_E), VO_2 (oxygen consumption), V_{CO_2} (CO_2 consumption) RQ = respiratory quotient (VCO_2/VO_2), heart rate.

(H.R)., V_D/V_T, (dead-space ventilation). At or near anaerobic threshold, ABGs and a lactate level are drawn from the arterial line. When the patient signals exhaustion another sample will be obtained and the test will be discontinued. Factor VIII levels will also be drawn. The highest Minute ventilation(V_E) (Respiratory rate X tidal volume) oxygen consumption V_{O_2}(L/min) and heart rate (H.R.) recorded will be considered the maximal V_E, max VO_2 and max H.R. With rapid incremental exercise the individual will recover quickly and can be restudied in 30-45 minutes.

Recovery ABGs as well as above parameters will be obtained at that time.

b. After approximately 30-45' from completion of the rapidly incremental exercise test, the individual will perform a resting D_LCO_{SS} maneuver (Filley modification of steady state technique) to be used as baseline. Subsequently the individual will work at a steady state submaximal level (ä 50 of Vo2-max established by incremental study) capacity for another 6' during which an exercise D_LCO_{SS} will be performed. A repeat ABG in order to obtain PaCO2 and enable V_D/V_T determination will be obtained. Minute by minute printout of the PeCO2, PeCO, PACO will be obtained with particular attention to the data generated during the last 1/2 to 1 minute of the steady state exercise. From the above measurements minute by minute D_LCO_{SS} will be computed [18].

c. Repeat incremental exercise test and D_LCO_{SS} at rest and with submaximal exercise after 6 weeks of basic training This aspect of the study is important in terms of establishing whether conditioning may be operative in attenuating the differences if any in the exercise performance of the two groups. In addition, considerable data will be generated in the control population which will enable objective determination of conditioning responses which may be of assistance to the Department of the Army.

Phase IV. Evaluation of data:

a. Consent forms and all other data generated from WBAMC will be maintained along with exercise study reports in the Pulmonary Service of WBAMC. Copies of this data will be available to appropriate individuals through command channels.

b. Evaluation of data: 1) Results of baseline spirometry, MVV, Helium dilution lung volumes and single breath diffusing capacity will be expressed as a percent of published predicted values. Standard descriptive statistical analysis, involving paired Student t-test and analysis of variance will be performed within and between group differences. The data, especially that generated in the control population, may help serve to establish new predicted values for D_LCO_{SB} and spirometry in black individuals. This is badly needed since those presently available are suboptimal [19]. Dr. Ben Burrows has agreed to serve as consultant for this aspect of the project. 2) Exercise - Criteria established by Jones et al. [16], and Wasserman et al [17] will provide predicted values for indices of exercise performance measured during the study. Gas exchange data during rest and exercise (PaCO2, PaO2, (A-a) PO2, D_LCO_{SS} ml/min/mmHg, V_E l/min, VD/VT, V_{CO_2} (L/min), V_{O2} (l/min) and RQ.) in both the Hgb AS subjects and controls will be analyzed using both Student paired t-test and analysis of variance in order to establish differences between rest and exercise and between the two groups.

Next the Hgb AS group will be categorized according to absolute levels of Hgb S. Correlation of individual parameters with levels of Hgb S will be performed by standard regression analysis in order to determine if the levels can be predictive of abnormal cardiopulmonary response. The exercise physiology laboratory, UCLA, Harborview Medical Center, will serve in a consultant capacity for exercise related questions during the study.

Progress:

Four abstracts which resulted from this protocol were published and presented recently: 1) The Cardiopulmonary Effects of Stressful Exercise at 4,000 ft (1,270 m) of Individuals with Sickle Cell Trait was presented at the American Thoracic Society Meeting (Am Rev Respir Dis 1985;131:A307); 2) $P(A-a)O_2$ During Exercise in Healthy Young Blacks with Sickle Cell Trait and Controls (Fed Proc 1985;44:1368); 3) The Percent Hemoglobin S (HbS) and Percent Sickling (%S) as Correlates for Exercise Performance at 4,000 ft in Individuals with Sickle Cell Trait (Fed Proc 1985;44:1012); 4) Pulmonary Blood Flow Distribution Determined from Perfusion Lung Scintigraphy During Rest and Exercise (Fed Proc 1985;44:625). We are presently preparing four full-length manuscripts for peer review publication based on the data contained in these four studies (abstracts on following pages).

1259

PULMONARY BLOOD FLOW DISTRIBUTION DETERMINED FROM PERFUSION LUNG SCINTIGRAPHY DURING REST AND EXERCISE. A.J. Moreno, I.M. Weisman, R.J. Zeballos, B. Johnson, G. Turnbull. Wm Beaumont Army Med Cent, Nucl Med Svc and Dep Clin Invest, El Paso, TX.

Two methods for measuring changes in the pulmonary blood flow distribution at rest (RES) and during exercise (EX) were investigated in 19 normal male volunteers. Each method consisted of two separate quantitative perfusion lung scans (4 mCi of Tc-99m macroaggregated albumin (MAA) and 80,000 macroaggregates) performed at RES and at or immediately following peak EX using a Bruce protocol stress test. The methods differed by either the MAA being given while the individual was supine (n=9) at RES and immediately after EX or the person being upright (n=10) at RES and at peak EX. Computer images of RES and EX anterior and posterior views of both lungs (Lt and Rt) were obtained for 800,000 counts collected on a 128 X 128 matrix. Equal square boxes were placed over the upper (U), middle (M), lower (L) regions of both lungs anteriorly and posteriorly. Comparisons (%) of the following regions for each lung were made: U/L, U/M, M/L, U(Lt)/U(Rt), M(Lt)/M(Rt), L(Lt)/L(Rt). Differences in these comparisons between EX and RES were calculated in each person. Upward redistribution of lung perfusion with EX between the U to M or L regions is seen using either technique. Also, Rt to Lt redistribution with EX is noted within the U and M regions of both lungs. There is a statistically greater sensitivity using the upright technique in detecting the redistribution patterns than the supine method.

5601

P(A-a)O_2 DURING EXERCISE IN HEALTHY YOUNG BLACKS WITH SICKLE CELL TRAIT (SCT) AND CONTROLS. R.J. Zeballos, I.M. Weisman, B. Johnson, A. Moreno. Wm Beaumont Army Med Ctr, El Paso,Tx 79920

Although arterial hypoxemia and desaturation at high work levels have been reported in athletes, the clinical significance of similar findings in normals is uncertain. Since a similar cardiopulmonary response, which included ABGs and P(A-a)O_2, to incremental exercise (IET) and to steady state exercise (SSET) was found between young, healthy, black, male, volunteers with SCT (n=25) and non-SCT (n=16) controls, tested at 4000 ft, the data was pooled (n=41) and the results are presented as $\bar{x}$±SEM.

	PaO_2	$PaCO_2$	P(A-a)O_2	SaO_2
Baseline	84±1	35±.5	2±.3	95±.2
6' SSET ($\dot{V}O_2$=2.2 L/min)	80±1	34±1	14±1	93±.3
Peak IET ($\dot{V}O_2$=3.1 L/min)	82±1	32±1	20±1	93±.4

The reduction in PaO_2 at peak IET and SSET was not statistically significant when compared to baseline values. The changes in SaO_2 were of a lesser magnitude. The widening of P(A-a)O_2 was progressive with the increase in work, especially beyond the anaerobic threshold. Significant correlation was demonstrated between PaO_2 reduction and magnitude of P(A-a)O_2 ($r=-.9$, $p<.01$). Individual analysis of the data showed that 16 subjects dropped PaO_2 more than 4mmHg at peak IET,17 subjects had no change from baseline (±4mmHg) and in 8 individuals PaO_2 increased more than 4mmHg. This study shows that in clinical exercise studies a drop in PaO_2 can be found in healthy, subjects at maximal exercise and that the decrease in P(A-a)O_2 at moderate exercise is not always present.

DIOPULMONARY EFFECTS OF STRESSFUL EXERCISE AT 4000 FT VIDUALS WITH SICKLE CELL TRAIT (SCT). I.M. Weisman, ballos, B.D. Johnson, A.J. Moreno. William Beaumont dical Center, Dept Clinical Investigation, El Paso, TX.

ificant controversy persists concerning the risk indi- with SCT may experience with strenuous exercise and/or e. It has been speculated that these conditions may intravascular sickling and a spectrum of multi-system lities and even death (Jones et al.: Sudden death in EJM 1970; 282:323-325). The cardiopulmonary response e strenuous exercise at 4000 ft. was evaluated in , male nonacclimatized volunteers with SCT (n=25) and (n=16) controls; age ($\bar{X}$+SEM=20+4) and race were compar- both groups. All volunteers were screened for the e of HbS with a modified sickledex. All SCT partici- ossessed an AS Hb electrophoretic pattern. All subjects d a physical exam, CXR, SMA-20, CBC and U/A. PFTs, which d spirometry, body box lung volumes, RAW, and D_LCO_{SB} t statistically different between the SCT and nonSCT

A 25 watt/min incremental exercise test (IET) to ex- n utilizing a cycle ergometer, was performed. The fol- parameters were measured during exercise; HR, BP, $\dot{V}_E$, O_2, R, V_D/V_T, SO_2 and ABGs (radial arterial catheter). y state exercise test (SSET) was performed one hour post- ion of the IET. The results of peak values during IET . 6 of the SSET are shown ($\bar{X}$+SEM).

	Control			SCT		
ers	IET	%Pred	SSET	IET	%Pred	SSET
)	250+10	98	125+6	240+7	97	120+4
in)	3.26+.14	95	2.26+.08	3.07+.09	92	2.14+.1
	189+3	96	165+5	188+2	95	158+3
%)	*8+.6		*8+.8	*10+.8		*12+.8
2	21+2		14+1	19+1		14+1
	93+4		94+.4	93+.5		93+.5

hieved a peak exercise performance close to maximum pre- values. The only parameter which was statistically diff- p<0.05)* between the SCT and control groups was the V_D/ both IET and SSET, the clinical significance of this ob- on is uncertain and is being evaluated. Our study shows T subjects had a cardiopulmonary response to acute ul exercise at altitude similar to the controls.

3519

PERCENT HEMOGLOBIN S (%HbS) AND PERCENT SICKLING (%S) AS CORRELATES FOR EXERCISE PERFORMANCE AT 4000 FT IN INDIVIDUALS WITH SICKLE CELL TRAIT (SCT). I.M. Weisman, J. Zeballos, B. Johnson, A. Moreno. Wm Beaumont Army Med Ctr, El Paso, TX 7992

Controversy persists regarding the relationship of %HbS and %S to exercise performance in individuals with SCT. We evaluated young, healthy, male, non-acclimatized volunteers with SCT (n=25) and non-SCT controls (n=16) of similar race. All were screened for the presence of HbS. All SCT subjects had ASHb. Venous blood was collected before (brachial, BV) and 1 to 3 min post exercise (femoral, FV) under anaerobic conditions for blood gases, %S (fixed in 1% glutaraldehyde buffer) and additional hematological studies. An incremental exercise test to exhaustion was performed with measurement of the following parameters: HR, BP, $\dot{V}_E$, $\dot{V}O_2$, $\dot{V}CO_2$, AT, R, V_D/V_T, SO_2, $P(A\text{-}a)O_2$ and ABGs. SCT individuals demonstrated a cardiopulmonary response to acute, stressful exercise at altitude and levels of 2,3 DPG and P_{50} similar to controls. The blood analysis in the SCT group are reported as $\bar{x} \pm$ SEM.

	%HbS	%S	2,3 DPG	P50	PVO_2	$PVCO_2$	pH
BV (n=25)	38±.6	1.1±.2	2.6±.06	26±.2	35±3	51±1	7.31±.01
FV (n=13)		1.4±.5			50±3	56±3	7.07±.02

%HbS and %S did not correlate with any of the cardiopulmonary parameters measured during exercise. %HbS correlated significantly ($p<.05$)* to %SBV ($r=.59$)* and not to %SFV. %SBV correlated to PVO_2 at rest ($r=.59$)* and to %SFV ($r=.88$)*. Our study suggests that neither %HbS nor %S in individuals with SCT correlates with acute exercise performance.

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Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/50 Status: Terminated

Title:
Effects of Terbutaline on Lymphocyte Receptors

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ M.J. Smith, MSC

Dept/Sec: Dept Clin Investigation Assoc Investigators

Key Words:

B-adrenergic receptors; lymphocytes

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

OBJECTIVE: To determine the effect of a single dose of terbutaline on beta-adrenergic and concanavalin A (con A) receptors in mouse and human lymphocytes.

Technical Approach:

The project will be approached by (a) developing the needed assays, (b) conducting animal trials, and (c) conducting human trials.

a. Assays

(1) A beta receptor assay developed by Dr. Burman at WRAMC will be established in our laboratory. In brief, the assay is a Scatchard analysis of lymphocyte beta receptors using ^{125}Iodocyanopindolol. It requires lymphocytes from 16 ml of blood for humans or the spleenocytes from one mouse. The receptors will be measured on the day of sample collection.

(2) Cyclic AMP-RIA kit (New England Nuclear) analysis of lymphocyte cytoplasm will be used.

(3) Cyclic GMP-RIA kit (New England Nuclear) analysis of lymphocyte cytoplasm will also be used. The cyclic AMP (cAMP) and GMP (cGMP) measurements will be important since changes in their concentrations indicate the level of receptor activity prior to collection of the lymphocytes. Samples for analysis will be stored at -20C and run in batch for both cAMP and cGMP.

(4) A concanavalin A(conA) receptor assay will be developed using a fluorescent activated cell sorter. In brief, Carbazol dye [6] will be bound to the lymphocytes and the receptor number determined by laser analysis of each sample. Binding affinities of the receptors will be determined by quantitation of bound and free conA using Scatchard analysis. The receptors will be measured on the same day as sample collection.

b. Mouse Study.

Two groups of inbred male mice, 60 mice per group, will be injected ip. Group I, control group, will receive saline. Group II, experimental group, will receive 250 ug/kg of terbutaline sulfate in saline. Twelve mice per group will be anesthetized in the morning at days zero, two, four, seven and fourteen after injection, using Ketamine/xlazine and their spleens removed. They will then be killed by cervical dislocation, and their spleenocytes harvested by established techniques [7]. Spleenocytes from six of the twelve mice will be processed and beta receptor density and binding constants determined [5]. Cyclic AMP and cyclic GMP will be measured in the supernatant of the processed lymphocytes [8].

ConA receptor concentrations and binding constants will be determined for spleenocytes from the other six mice killed on the day of interest using techniques developed in Part A (4).

Lymphocyte transformation using conA [9] will be determined on a portion of the lymphocytes from the twelve mice killed on the day of interest.

c. Human Study.

Two groups of adult male humans, ages 20-49 years, twenty control and twenty experimental, will be studied. They will receive a single subcutaneous injection of 0.2 cc of saline or 250 ug of terbutaline sulfate in 0.2 cc of saline, respectively. In the morning of days zero, two, four, seven, and fourteen, after injection, thirty cc of peripheral blood will be taken and the lymphocytes separated as previously described [9]. These lymphocytes will be divided for beta receptor, cAMP, cGMP, conA receptor, and lymphocyte transformation assays.

d. Statistics

GROUPS

Group I - saline control
Group II - terbutaline treated

VARIABLES OR PARAMETERS

Beta receptor density (number/lymphocyte)
Beta receptor binding strength
Con A receptor density (number/lymphocyte)
Con A receptor binding strength
Lymphocyte transformation (counts/min of incorporated ^{3}H-thymidine)
cAMP/cGMP concentration ratio.

TIME

Variables measured at 0, 2, 4, 7, 14 days post-injection.

QUESTIONS

Q. 1. Is the control group different from the experimental group for any mean variable value on a given day?
Q.2. Is the control group different from the experimental group for all variable or subsets of the variable?
Q. 3. Which variables are associated?
Q. 4. Is the response of each variable with time different for the control and experimental group?

METHODS

Question one will be answered using a Student's t-test with paired values. Question two will be answered using a multivariate analysis of variance and covariance. Question three will be answered by regression analysis. Question four will be answered using a multivariate analysis with time.

Progress:

Receptor assays have not been developed due to personnel shortages. No further progress was made on this study in FY85 due to the transfer of the principal investigator. Project is terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/07 Status: Completed
Title:

Effect of Levamisole and Vitamin A as Immunopotentiators Against Lewis Lung Carcinoma.

Start Date: Est Comp Date:
Principal Investigator: Facility:

CPT Charles S. Serio, PhD

Dept/Sec: Dept Clinical Investigation-Assoc Investigators
LTC Lyndon E. Mansfield, M.D.

Key Words:
Levamisole
Lewis Lung Carcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To monitor the therapeutic effects of a levamisole and vitamin A in the growth patterns of Lewis lung carcinoma cells in C57 black mice.

Technical Approach:

Animals: C57 BL/6 female mice 6-8 weeks old (15-20g) will be utilized in these experiments. The animals will be obtained from Jackson Laboratory, Bar Harbor, Maine.

Tumor: Lewis lung carcinoma currently maintained in both syngeneic mice and in vitro in our laboratory will be utilized as the tumor model. This tumor was selected because it is widely used by NCI in screening for potential antineoplastic agents.

Drugs: Levamisole and vitamin A will be aliquoted from single samples. Dose levels and administration of levamisole will be based on the reports of Renoux and Renoux [4]. These doses will be expanded to cover a 100-fold dose range below toxic levels. Doses and administration of vitamin A will be in accordance with previously published methods [6]. Drug solutions will be prepared immediately prior to administration when a single injection treatment schedule is employed. For multiple-treatment and combination treatment, drug solutions will be prepared at the beginning of treatment and stored at 4°C in amber bottles.

Methods

Tumor growth determination: The growth of subcutaneously inoculated Lewis lung carcinoma (10^5) will be determined directly by excising and weighing the primary tumor or indirectly by taking caliper measurements of perpendicular diameters and estimating the tumor mass by the formula [7].

$$\text{mass(in mg)} = \frac{\text{major diameter (in mm)} \times \text{minor diameter}^2\text{(in mm)}}{2}$$

The number of macroscopic lung metastases will be determined by the india ink insufflation technique of Wexler [8].

Injection schedule and data to be collected will be performed according to the outlines in Table 1 and 2.

Progress:

Study has been completed and a manuscript is in the process of being written.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/21 Status: Completed

Title:

Assessment of Immunological Potential of Ivermectin, A Potent New Antiparasitic Agent.

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT Charles S. Serio, PhD

Dept/Sec: Assoc Investigators
MAJ S. Ting, MC

Key Words:
Antiparasitic agent

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To assess the role of Ivermectin as a possible new immunomodulator.

Technical Approach:

a. Animals: C57BL mice will be utilized as the animal model.

b. Dosage and Injecting Schedule: Dose levels and administration of ivermectin will be based on a previously published findings [1]. In preliminary experiments, we will examine a wide range of doses (all below toxic levels) and measure various immune functions at various times after injection to establish these time and dose kinetics for either stimulation or inhibition by lymphocyte stimulation and quantitative antibody production assays.

c. Immunological measurements.

1. Lymphocyte stimulation. These assays will be utilized as an in vitro correlate of cell mediated immunity, mouse splenic, lymph node and thymic lymphocytes will be collected, separated and purified at various days after ivermectin injection (IP). T-cell responses will be analyzed by specific T-cell mitogens such as phytohemagglutinin and concanavalin A. B-cell responses will be analyzed by poke weed stimulation.

2. Antibody production. The effects of injected ivermectin on antibody production will be analyzed by using a modified plaque assay in which sheep red blood cells (SRBC) and ivermectin will be administered interperitoneally at various times before harvesting splenic lymphocytes. Control animals will receive only SRBC.

STATISTICAL ANALYSIS OF THE DATA: Statistical analysis will be performed by comparing controls (non-ivermectin injected) with experimental groups using the Student's t-test.

Progress:

This study has been completed and a manuscript is in preparation.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/50 Status: Completed
Title:

Investigation of Methylscopolamine and Methylatropine Nitrates and Bromides Stabilities

Start Date: Est Comp Date:
Principal Investigator: Facility:

David O. Rauls, PhD

Dept/Sec: Dept Clinical Investigation Assoc Investigators
Key Words:

Methylscopolamine; Methylatropine

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results
Study Objective:

To determine optimum, practical storage and use conditions of methylscopolamine and methylatropine nitrates and bromides.

Technical Approach:

Phosphate buffered saline solutions at pH 7.4 of methylscopolamine and methylatropine nitrates and bromides will be kept both at cold and room temperatures. Sampling of solutions will be carried out for a time span of several months. The drug potentcy will be evaluated every two weeks by HPLC. Each set of samples will be compared to a known set of freshly prepared standards.

Decomposition products will be identified. Assessment of these products' toxicity and effect on potency of drug will be investigated and statistical conclusions made on the basis of 90% standard deviation confidence limits.

Progress:

The protocol has been completed. Stability of both drugs was ascertained by HPLC. The data is under evaluation at this time.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/37 Status: Ongoing
Title:

Pyridoxine Effect in Theophylline Toxicity in Dogs

Start Date: Est Comp Date:
Principal Investigator: Facility:

COL M.R. Weir, MC

Dept/Sec: DCI Assoc Investigators
Key Words:

Theophylline toxicity, Vit B6, Aminophyllin toxicity

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To assess the effect of pyridoxine in aminophylline intoxication.

Technical Approach:

Pyridoxine deficient animals will be given aminophylline intravenously. Blood theophylline and pyridoxine levels and symptoms of toxicity will be monitored. With the appearance of jitterness, hyperalertness, hyperactivity, seizures, etc., the aminophylline will be stopped and pyridoxine will be administered. Blood levels of theophylline and pyridoxal-5-phosphate and symptoms will be monitored. EEG monitoring will be attempted.

Dogs will be used because the animal model must be large enough to sustain repeated venipuncture and subtleties of level of activity must be readily assessible. For this reason, lower vertebrates that can be made pyridoxine deficient, such as chickens and rats, are not suitable.

Should the animals develop refractory toxicity, euthanasia will be performed with T-61. Following the development of and therapy for toxicity, the animals will be placed on a regular diet and given aminophylline in the same dosage regimen as previously. The medication will, however, be continued to achieve a higher blood level than resulted in toxicity previously. Again, symptoms of toxicity, blood levels of theophylline and pyridoxal-5-phosphate will be monitored. It is anticipated that pyridoxal-5-phosphate will reverse toxicity and that signs of toxicity will not occur on a pyridoxine adequate or sufficient diet, even at higher blood levels than resulted in toxicity on a pyridoxine deficient diet.

Progress:

Dogs were placed on a B6 deficient diet in groups of four. Two in each group received B6 supplementation. Serum PLP levels were followed until stable at about 10-20% of normal. When stable, animals were given aminophylline in doses of 3,6 and 9 mg/kg at 20 minute intervals. Blood for serum theophylline and PLP levels was drawn. Some studies included halothane anesthesia for EEG/EKG monitoring. Six dogs have received aminophylline a total of 18 times. No animals have had toxic effects of the theophylline to date. PLP assays are being run and data analyzed. The study is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/52 Status: Ongoing

Title:
Pyridoxine Effect in Aminophylline Toxicity in Rabbits

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL M.R. Weir, MC

Dept/Sec: Dept Clinical Investigation Assoc Investigators

Key Words:

Pyridoxine, Vit B6, Aminophylline toxicity

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the dose response curve in normal rabbits and B6 supplemented rabbits to chronic aminophylline administration.

Technical Approach:

Six New Zealand rabbits were given single daily intraperitoneal injections of aminophylline in a dose of 17 mg/kg/day. Serum PLP levels were done bi-weekly.

Progress:

One animal was lost because of an unrelated accident that resulted in euthanasia. The unsupplemented animals showed an asymptomatic fall in PLP initially. The supplemented animals initially maintained high serum PLP levels. The latter assays are in progress. Data will be analyzed. The study is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/ 53 Status: Terminated

Title:
Pyroxidine Effect in Aminophylline Toxicity in Rats

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL M.R. Weir, DCI

Dept/Sec: Assoc Investigators

Key Words:

Pyroxidine,Vit B6, Aminophylline toxicity

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine if B6 deficient rats have a greater sensitivity to aminophylline than normal rats.

Technical Approach:

Nine Sprague-Dawley rats were used. Three were controls on regular chow. Six were on a B6 deficient chow. All were given daily IP injections of aminophylline in a dose of 22mg.

Progress:

One control and three study animals succumbed. The remaining animals were placed on a regular diet and injections were stopped. Results were inconclusive and the study was terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/19 Status: Terminated

Title:
Evaluation of the Mandibular Staple Bone Plate and the Ramus Frame Implant in the Rehabilitation of the Atrophic Edentulous Mandible.

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL F.C. Theisen, DC

Dept/Sec: Assoc Investigators

Key Words:

Mandibular staple

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To evaluate the efficacy of two alloplastic implants in the rehabilitation of the edentulous atrophic mandible. Future application will be evaluated for the reconstruction of avulsive traumatic injuries to the mandible and ablative surgical procedures in treatment of pathology in the mandible. Factors to be evaluated include a) the surgical procedure for insertion, b) stability and retention afforded the denture, c) patient function and comfort, d) complications, e) long term followup stability and overall versatility of both implants.

Technical Approach:

All patients selected will be approved by both the Prosthodontic Service and the Oral Surgery Service, WBAMC. Active duty personnel must have a minimum of 12 months remaining prior to anticipated ETS or PCS. Dependents or retired personnel must be residents of the El Paso area and agree to a minimum of two years followup. The patient will have a minimum of 7mm vertical osseous height for the ramus frame and 9mm for the mandibular staple as measured on a lateral cephalometric radiograph. The oral soft and hard tissues will be free of active disease of pathology. The ramus frame implant will be primarily utilized for those patients who are medically contraindicated for general anesthetic. Patients who are candidates for the mandibular staple will have all pre-implant surgical preparation done a minimum of three months prior to placement of the implant. These include alveoloplasty and vestibuloplasty with skin grafting for lowering of mucosal and muscle attachments. Medical assessment of the patient will be accomplished by the Oral Surgery Svc or by WBAMC medical staff when indicated.

The patient will be counselled on the investigational nature of the procedure, to include expected results and possible complications. The patient will be required tosign an agreement concerning his participation in the study and the required followup.

Patients will complete post-operative questionnaires during the six month postop followup visit.

PROGRESS

Principal investigator has been reassigned. No other investigator has chosen to assume this project and it has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/22 Status: Ongoing

Title:

Mandibular Lingual Vertical Releasing Incision

Start Date: Est Comp Date:

Principal Investigator:
LTC T.J. Lynch, DC

Facility:
Dental Clinic #1
Ft Huachuca, AZ 85635

Dept/Sec: Dept Dentistry

Assoc Investigators

Key Words

Mandibular incision

MAJ W. Ekuall Dental Clinic
COL A. Ficara Ft Gordon, GA

Accumulative MEDCASE Cost

Est OMA Cost:

Periodic Review Results

Study Objective:

To document the immediate postoperative sequelae of two types of incisions used in periodontal surgery, neither one of which is experimental, but one of which may have superior long-term results.

Technical Approach:

Subjects selected for the study will be adult patients who require bilateral mandibular periodontal surgery as part of their dental treatment. The lingual vertical releasing incision will be used to reflect a flap on one side of the mouth and the envelop flap will be used at a different time on the opposite site. The subjects will not know which procedure is the one being studied and will be given the same analgesic for both postoperative periods. Subjects will be given a Symptom Data Log to complete each day for 14 days postoperatively and will rate the level of pain from 0-4 (none, slight, moderate, severe, excruciating). They will also be asked to make any comments they feel appropriate during the postoperative period. Written postoperative instructions will be given to each patient at completion of the surgery.

Patients will be seen one week postoperatively, at which time the sutures and periodontal dressing will be removed, the surgical area cleaned and color slides taken. At two weeks postoperatively the surgical area will be cleaned again, color slides taken and the Symptom Data Log collected. The Symptom Data Log will be kept separtely from the dental records in a locked file. Responses on the logs will be statistically evaluated in order to determine whether any differences in postoperative pain exist between the two procedures and whether such differences are statistically significant. The Chi-square and Student's t-test will be used for statistical analyses.

Postoperative healing will be subjectively compared by observing the degree of inflammation at the surgical areas at the two postoperative appointments. These slides will also be compared with those taken immediately after sutures were placed to compare, clinically, the degree of postoperative inflammation with completeness of flap closure.

Patients will be excluded from the study if they present with exostoses in the surgical area; a shallow lingual sulcus; an immune deficiency; diabetes; recent (within two months) antibiotic or steroid therapy; a bleeding disorder. It is hoped that 25 to 30 patients can be included in the study.

Progress:

Five cases have been completed to date. Completion of the project is expected by Spring 1986 with submission of a publication.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/22 Status: Terminated

Title:
Use of Topical Steroid Cordan Tape (Fluorandrenolide) in the Management of Skin Reactions

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ S. Ting, MC

Dept/Sec: Dept Medicine Assoc Investigators

Key Words:

Fluorandrenolide

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine whether locally applied cordan tape suppresses the histamine release, eosinophil migration and ultrastructural changes of mast cells in human allergic skin reaction.

Technical Approach:

Ten volunteers from the Allergy Clinic will be skin tested with ragweed and 48/80. Injections will be 0.02 ml of ragweed 1000 PNU/cc and 48/80. Skin blister technique will be employed and cordan tape placed over both forearms for 24 hours, then skin biopsy to determine measurement of histamine release.

Progress:

Principal investigator has been unable to solicit volunteers. The project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/19 Status: Terminated

Title:
Characterization of Bronchodilator Activity of Inhaled Dyphylline

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC L.E. Mansfield, MC

Dept/Sec: Dept Medicine/Allergy Cl Assoc Investigators

Key Words:

Dyphylline

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine if dyphylline can be used as an inhaled bronchodilator and to characterize the response for possible clinical application.

Technical Approach:

Ten adult asthmatic, nonpregnant, and not of child bearing potential subjects will be entered into this study. Their asthma will be sufficiently moderate so that they can withhold their usual morning dose of bronchodilators. They will report to the Allergy Clinic at 0800. Baseline pulmonary functions, including conventional spirometry, flow volume curves, and total respiratory resistance will be measured. Serum will be drawn for a theophylline level. The subject will then inhale to completion through a nebulizer (Devilbis 646) with a pulmonaid compressor a solution containing 1 mg/kg of dyphylline (with normal saline added to make a 5 ml total volume). Patients will be observed for any possible adverse reactions such as tachycardia, nausea, or headache. Pulmonary function will be remeasured immediately after finishing the treatment, and at 15, 30, 45, 60, 90, 120, 180, 240 minutes post-treatment. A repeat theophylline level will be obtained at 30 minutes post-treatment. In as many individuals as technically possible, determinations will be continued for 300,360,420, and 480 minutes. Where this will not be possible, a portable peak flow meter will be given to the subject to record PEFR at these time intervals. At any point where the subject notices distress, or in the opinion of the physicians further bronchodilation is indicated, then inhaled albuterol will be used.

In each of the subjects, the same procedure will be repeated at a dose of 3 mg per kg, 5 mg per kg, and 7 mg per kg. Rather than randomize the sequence of doses, it is the investigator's opinion that for the safety and comfort of the volunteers, this progressive dose exposure is more prudent. Therefore, on three other separate individual occasions, the same methodology and parameters will be used to determine the response to these larger doses.

It is estimated that the nebulization system used will deliver between 5-10 percent of actual dose to the patients, so that the effective delivered dose will be 0.1, 0.3, 0.5, 0.7 mg/kg. The usual systemic oral or parenteral doses are between 5-10 mg/kg q6-8h for dyphylline.

During each session subjects will be closely observed for tolerance of the treatment, the side effects and adverse reactions as described above. The unique taste of dyphylline makes the use of a placebo of doubtful value. Data for the expected response of a group of moderate asthmatics to placebo (saline inhalation) is available in the medical literature.

Dose response and durations of effect curves will be plotted.

Progress:

No patients were entered into this study. The principal investigator resigned and no other investigator has pursued the study. The study has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/51 Status: Ongoing

Title:

Biodistribution of Tc-99m-Folic Acid in 30 Normal Rabbits

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ Albert J. Moreno, MC

Dept/Sec: Dept Medicine/Nuc Med Assoc Investigators

Key Words:

Tc-99m-Folic Acid

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To radiolabel folic acid (pteroylmonoglutamic acid) with Technetium-99m and to characterize the tag using a physical description and chromatographically; to determine qualitatively and quantitatively the biodistribution of Tc-99m-folic acid in healthy rabbits.

Technical Approach:

An investigation will be conducted to determine the optimum labeling conditions for Tc-99m-folic acid. The major factors to be considered are pH. Past experience has shown that the percent of tagged material which will pass throiugh a 0.22 u millipore filter is pH dependent. Also, folic acid appears to be labeled at either basic pH's or acidic pH's. Imaging of sheep with the apparent Tc-99m-folate demonstrated different biodistribution depending on whether the folate was labeled basic or acidic. Additionally at more physiologic pH, the Tc-99m-folate compound apparently disassociated. To isolate the tagged material at varying pH, paper chromatography will be used. The isolated material will further be characterized by U-V spectroscopy and the HPLC with the help of a chemist. The specific procedures for tagging Tc-99m as sodium pertechnetate to folic acid uses a modified stannous chloride method. After a satisfactory radiolabeled folate is achieved, biodistribution studies will be performed using a rabbit model.

Progress:

Work has not begun on this project as yet due to time limitations of the principal investigator.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/04 Status: Terminated
Title:

Evaluation of the Systemic Allergic Reaction to Tetanus Toxoid

Start Date: Est Comp Date:
Principal Investigator: Facility:
MAJ S. Ting, MC

Dept/Sec: Dept Medicine/Allergy Assoc Investigators
Key Words:
Tetanus Toxoid

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To determine the nature of the systemic allergic reaction caused by tetanus toxoid immunization.

Technical Approach:

Using the residual serum collected from the patients, the following assays will be performed. Enzyme linked immunoassay (ELISA) determination of specific tetanus antibodies of the IgE, IgG, and IgG, IgM, IgD, subclass antibodies .

Progress:

No patients have been entered during this FY, the project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/09 Status: Ongoing

Title:

Amiodarone Treatment for Severe, Refractory Cardiac Arrhythmias.

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL James H. Wilkin, MC

Dept/Sec: Cardiology Assoc Investigators

Key Words:

Cardiac Arrhythmias

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To assess long-term efficacy and adverse effects of amiodarone hydrochloride in the control of malignant, potentially malignant, or symptomatic arrhythmias in patients who are either uncontrolled by or experience limiting adverse effects to the standard available and antiarrythmic drugs.

Technical Approach:

Amiodarone has been used as a potent anti-arrhythmic agent in Europe for many years. It does however possess several unusual properties which present problems with its utilization. The drug is a benzofuran derivative originally developed as an anti-anginal agent. The 1/2 life of this agent is very long, being in excess of 25 days. There are no reliable blood levels for monitoring the dosage of the patients. Because of these factors side effects have been chronic. It is important to have a long-term followup of patients on Amiodarone for side effects as well as efficacy. This study will provide data regarding these problems.

Progress:

Four patients have been entered with no adverse reaction. These patients have been very successful in terms of arrhythmia abolishment.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/11 Status: Ongoing

Title:

Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III (SWOG 8001)

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Lymphoblastic Leukemia

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To evaluate the effectiveness, as determined by the complete remission rate of the LIO protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of adult ALL in a group-wide study.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

One patient was entered but since deceased.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/12 Status: Ongoing

Title:

Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs FOMi CAP, Phase III SWOG 8012.

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To evaluate by pairwise comparison the response-rate, duration of response and survival of 3 regimens FOMi, CAP and FOMi/CAP in patients with advanced (TMN Stage III M_1) adenocarcinoma and large cell undifferentiated carcinoma of the lung. To evaluate the degree of non-cross resistance of FOMi in CAP failures and of CAP on FOMi failures. To compare the toxicities and side effects of FOMi and CAP.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients were entered during FY85.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/13 Status: Ongoing

Title:

SWOG 8110: Treatment of Advanced Germ Cell Neoplasms of the Testis.

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Neoplasms

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To compare in a randomized fashion the effectiveness of the drug combination Vinblastine, Cis-diamminedichic platinum (Cis-Platinum) and VP-16 213 versus Vinblastin Bleomycin and Cis-Platinum in the remission induction patients with disseminated germ cell neoplasms of testis origin.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

Two patients were entered into the study, but decided to quit the study.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/14 Status: Ongoing

Title:

A Comparison of Aggressive Radiotherapy Plus Chemotherapy Versus Aggressive Chemotherapy in the Treatment of Limited Carcinoma of the Pancreas (SWOG 8210)

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Carcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine whether aggressive therapy with combination radiotherapy/chemotherapy or chemotherapy alone yields superior survival in patients with incurable localized pancreatic cancer. To compare the toxicities of the two program.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/15 Status: Ongoing

Title:

Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy.

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Multiple Myeloma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Comparison of two different methods of giving the six best chemotherapy drugs that fight cancer.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

Three patients have been entered on this protocol. One has died, and two are still being followed.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/17 Status: Terminated
Title:

Use of in vitro Labeled 99mTc Red Blood Cells (RBC) Blood Pool Imaging and Computer Aided Acquisition and Processing in Localization of Upper Gastrointestinal (UGI) Bleeding Sites.

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ Bill F. Byrd, MC

Dept/Sec: Medicine
Key Words:
99mTc Imaging

Assoc Investigators
CPT H. Bogus
COL G. Turnbull,
Maj A.J. Moreno
LTC Tommy Brown

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the clinical utility of in vitro labeled 99mTc RBC blood pool imaging and computer aided acquisition and processing in the localization of UGI bleeding sites as compared to endoscopy, contrast radiography and angiography.

Technical Approach:

Patient selection: To be included in the study, the following criteria are necessary:

a. The patient must be eighteen years of age, or older.

b. The patient must give informed consent.

c. The patient must clinically have acute upper gastrointestinal hemorrhage manifested by a history of hemetemesis or positive gastric aspirate.

d. Participation must be approved by the Gastroenterology Service.

e. All female patients age 18-45 who may be at risk for pregnancy will have pregnancy screening test prior to procedure.

Upon admission into the study, the patient will undergo blood pool labeling per our standard technique as quickly as possible.

The patient will be imaged as soon as feasible. Feasibility will be determined by the attending physician who will consider the patients condition and the urgency for other diagnostic or therapeutic modalities. Imaging will initially be done for 90 minutes with repeat images as necessary to document the bleeding site for up to 24 hours after labeling.

The Nuclear Medicine Service will not be apprised of the results of other diagnostic procedures, if any, until an interpretation has been recorded. The attending physician will be apprised of the Nuclear Medicine report immediately.

Data Base: The following will be collected:

Name
Age
Sex
SSN
Complete history and physical
Results of endoscopic, radiologic and surgical procedures
All serial lab data obtained on admission
Transfusion requirements
Clinical course of the patient.

Data will be collected until 30 patients have been studied. Data will be stored via the clinical chart and all computer studies will be collected and maintained on diablo disc until the study is complete.

Scintigraphic results will be compared to the other diagnostic modalities. These patients with definitive endoscopic or roentgenographic studies will be used to determine the sensitivity and specificity of the scintigraphic procedure. In those patients whose endoscopic and roentgenographic studies are inconclusive, the clinical course of the hospitalized patient will be followed and compared to scintigraphic findings

Progress:

No patients were entered into this study. The principal investigator has been transferred and the project terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/20 Status: Terminated
Title:

Efficacy of Weekly Pulse Methotrexate in the Treatment of Rheumatoid Arthritis: A Double Blind Crossover Study

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ M.W. Nelson, MC

Dept/Sec: Rheumatology Assoc Investigators
Key Words:

Rheumatoid Arthritis

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results
Study Objective:

1. To evaluate the effectiveness of weekly pulse methotrexate therapy to control the activity of rheumatoid arthritis by subjective and objective criteria by means of a 27-week double blind, crossover study against placebo in patients with active rheumatoid arthritis who have failed therapy with gold salt and D-Penicillamine.

2. To evaluate the potential of long-term weekly pulse methotrexate therapy to halt or decrease the progression of destructive changes of the articular cartilage and periarticular bone by means of sequential x-ray evaluation.

3. To evaluate the potential for hepatic toxicity of weekly pulse methotrexate by sequential analysis of biochemical liver function studies (AST, ALT, alkaline phosphatase, GGT, LDH, and total bilirubin)and liver biopsy. Additionally, careful evaluation of longitudinal evaluations of hepatic morphology will allow for close monitoring of potential changes to prevent progression of methotrexate induced fibrosis to cirrhosis.

Technical Approach:

Flow sheets for laboratory parameters and clinical measurements will be maintained. Medication records will be maintained for all medications to include intra-articular medication. Laboratory

parameters and clinical measurements from week 14 and week 27 will be paired with average baseline values and analyzed using the paired t-test. If analysis does not substantiate parametric assumptions, nonparametric analyses will be substituted. Total scores for each patient will be compared for variance from baseline scores at each interval. Frequency of hepatic injury will be calculated. Comparison of clinical features, medications and dosage levels will be compared to patients without evidence of hepatic injury.

Progress:

Principal investigator was reassigned. No current staff is interested in pursuing this study. Two patients were entered in the study uneventfully.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/22 Status: Completed

Title:

Effect of Cromolyn on Immune Functions

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ S. Ting, MC

Dept/Sec: Dept Medicine/Allergy Assoc Investigators
CPT C.S. Serio, PhD

Key Words:

Cromolyn

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To assess the immunomodulating effects of cromolyn.

Technical Approach:

a. Animals: C57BL mice will be utilized as the animal model.

b. Dosage and Injecting Schedule: Dose levels and administration of cromolyn will be determined in preliminary experiments. We will examine a wide range of doses (all below reported toxic levels) and measure different immune functions at various times after injection to establish the time and dose kinetics.

c. Immunological measurements.

1. Lymphocyte stimulation. These assays will be utilized as an in vitro correlate of cell mediated immunity, mouse splenic, lymph node and thymic lymphocytes will be collected, separated and purified at various days after cromolyn injection (IP). T-cell responses will be anlyzed by specific T-cell mitogens such as phytohemagglutinin and concanavalin A. B-cell responses will be analyzed by poke weed stimulation.

2. Antibody production. The effects of injected cromolyn on antibody production will be analyzed by using a modified plaque assay in which sheep red blood cells (SRBC) and cromolyn will be

administered interperitoneally at various times before harvesting splenic lymphocytes. Control animals will receive only SRBC.

Progress:

This study has been completed and a manuscript in preparation.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/27 Status: Ongoing

Title:

Incidence of Mitral Valve Prolapse in Syncope

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT D.R. Wood, DO
CHANGE INVESTIGATOR TO Stephen Atchley, DO

Dept/Sec: Cardiology Assoc Investigators

Key Words:
Mitral Valve Prolapse

LTC S.T. Coleridge, DO
COL J.H. Wilkin, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine the incidence of mitral valve prolapse in patients presenting to a military Emergency Room with a chief complaint of syncope and to see if this incidence varies from a similar group of age-sex-matched controls.

Technical Approach:

The study population will consist of all patients being seen in the Emergency Room at this hospital complaining of "passing out". The patients to be studied will be ages 18-45.

A control population will consist of an age-sex-matched population presenting to the Emergency Room with either upper respiratory symptoms or acute gastrointestinal symptoms. It is anticipated that a study population of 100 subjects will be needed with 200 control subjects.

The study and control population will be obtained as follows: (a) All ER records will be screened for the complaint of "passing out". Patients meeting the criteria will be contacted by telephone. The project will be explained and if they consent, an appointment for evaluation will be set up.

If a patient presents for evaluation, two age-sex-matched controls will be selected from the ER sheets with the two diagnoses mentioned above. Studies to be obtained on all patients include a questionnaire and a m-mode echocardiogram.

Progress:

Approximately 200 patients have been entered into the study to date. The project is currently being carried out at Brooke Army Medical Center under the auspices of CPT D.R. Wood, MC. This project is being done in conjunction with COL J.H. Wilkin, MC, Chief, Cardiology Service, WBAMC. Results to date have shown no increased incidence of mitral valve prolapse in the patients presenting with syncope. However, what has been shown of interest is that patients with a history of fainting have a marked increase in mitral valve prolapse. As anticipated, the project will be completed within the next year as outlined in the original proposal.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/30 Status: Ongoing

Title:

Correlation Between Progesterone Receptor and Response to Tamoxifen in Patients with Newly Diagnosed Metastatic Breast Disease (SWOG 8228)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To define the prognostic role of progesterone receptor in patients with newly diagnosed metastatic breast disease by correlating progesterone receptor levels with objective response rates in women treated with Tamoxifen.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/31 Status: Ongoing

Title:

MEL 82 323 National Intergroup Protocol for Intermediate Thickness Melanoma 1.0 to 4.0 MM - Evaluation of Optimal Surgical Margins (2 vs 4 cm) Around the Primary Melanoma and Evaluation of Elective Regional Lymph Node Dissection. (SWOG 8393)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Melanoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

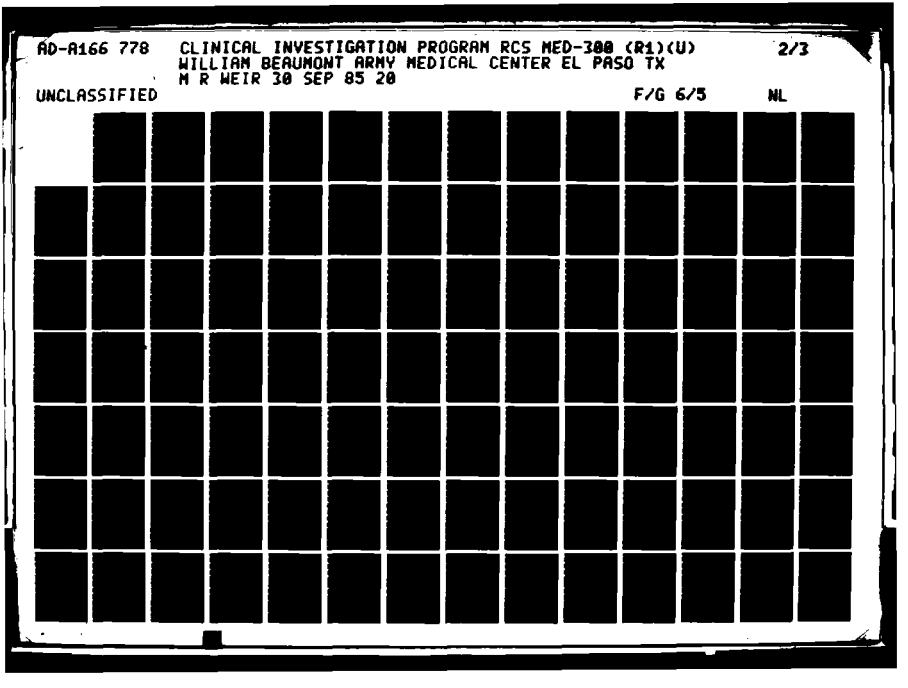
Determine the safest excision margins around the primary melanoma. Evaluate the management of the regional lymph nodes. Evaluate the relative prognostic value of various histopathological parameters of melanoma. The objective is to compare different histopathological criteria for their relative value in predicting the patient's clinical course and the risk of local recurrence.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.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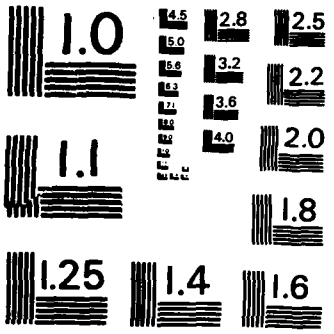

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/32 Status: Ongoing
Title:

Combined Chemotherapy with Cis-Platinum, Vinblastine and Methylglyoxal Bis (Guanylhydrazone) (MGBG) in Epidermoid Carcinoma of the Esophagus (SWOG 8311)

Start Date: Est Comp Date:
Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators
Key Words:

Carcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To define the response rate and duration, as well as survival duration, in patients with advanced epidermoid carcinoma of the esophagus when treated with Cis-platinum, Vinblastine and MGBG. To determine the toxicity of this regimen in the treatment of epidermoid carcinoma of the esophagus.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/33 Status: Ongoing

Title:

Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain Grade I and II (SWOG 7983)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Gliomas

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

The major objective of this study is to compare the survival of patients with incompletely resected Grade I and II Gliomas treated with radiation alone versus radiation and CCNU. To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission. Because many of these patients will have poorly or nonmeasureable disease, this will only be a secondary objective.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/34 Status: Ongoing

Title:

Treatment of Limited Small Cell Lung Cancer with VP-16/Cis-Platinum, Alternating with Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy (SWOG 8232)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To compare the efficacy of alternating noncross-resistant, multidrug regimens with concurrent combination chemotherapy as remission induction in patients with limited small cell lung carcinoma. To determine the toxicity of these treatment programs.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/35 Status: Ongoing

Title:

Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma (SWOG 7804)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Adenocarcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the efficacy of adjuvant chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/36 Status: Ongoing

Title:
Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma (SWOG 8208)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:
Carcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To study the response of functioning and nonfunctioning Islet Cell carcinoma chlorozotocin (CTZ) and 5-fluorouracil (5-FU). To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/37 Status: Closed
Title:

5-FU Adriamycin, Streptozotocin and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors (SWOG 8017)

Start Date: Est Comp Date:
Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators
Key Words:

Carcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To determine whether combinaton chemotherapy employing 5-Fluorouracil, Cyclophosphamide, Adriamycin and Streptozotocin is effective in the management of metastatic carcinoid. To study the duration of survival of patients with metastatic carcinoid tumor treated with combination chemotherapy regimens. To provide further information concerning the response and/or survival of patients with metastatic carcinoid originating in different sites and having different metastatic patterns.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date, and the study has been closed to registration.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/38 Status: Ongoing

Title:

Combined Modality Therapy for Breast Carcinoma (SWOG 7827)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus combination chemotherapy and oophorectomy.

To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, for combination chemotherapy plus tamoxifen, tamoxifen alone, and combination chemotherapy alone.

To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

To correlate the ER status with disease-free interval and survival.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

Six patients have been entered to date with no adverse reactions encountered.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/48 Status: Terminated

Title:

The Possible Importance of Chrysosporium Tropicum as an Aeroallergen in the El Paso Area

Start Date: Est Comp Date:

Principal Investigator: Facility:
Robert W. Haverly, DAC

Dept/Sec: Dept Medicine/Allergy Assoc Investigators
Key Words LTC Lyndon E. Mansfield, MC
Chrysosporium Tropicum Gordon Roberstadt, PhD UTEP

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To ascertain if the fungus Chrysosporium Tropicum is an important allergen in the El Paso area.

Technical Approach:

Chrysosporium tropicum cultures grown on enriched media will be obtained from the mycology laboratory of GR. The hyphae and spores will be removed from the media. This material will be defatted with ether. An aqueous extract of the defatted material will be made and freeze dried. The material will be reconstituted and cold sterilized through a .22u Millipore filter. The protein concentration of the extract will be adjusted to equal the protein contents of the usual fungal allergen extracts. The final extract will be tested for sterility (fungal and bacterial) by culture technique. After sterility has been established the irritancy of two-fold dilutions of the extract will be tested in normal nonallergic volunteers chosen from investigators and staff of the Allergy/Immunology Service and the Department of Clinical Investigation.

Once a nonirritant prick puncture method concentration is established, a 50-fold dilution of this will be tested for nonirritation after intradermal injection. If this concentration is irritating, further two-fold dilutions will be made until a nonirritating dose is achieved.

Five hundred patients found allergic by skin test reaction to some allergen will be tested. Skin test negative patients to all aeroallergens will be selected also. It is estimated that between 50 to 100 such patients will be seen during the survey for 500 skin test positive patients.

The incidence of positive skin tests to Chrysosporium in the "skin test reactive" patients will be compared to the incidence of skin test reactions to Bermuda grass, Mulberry and Mesquite, Russian Thistle, and Altenaria extracts, the most common grass, trees, weeds, and mold allergens found among our patients. Special note will be made of patients, if any, who react only to Chrysosporium .

The patients who have a 3+, 4+ or 4+ ID reaction to prick skin testing will be asked toi donate a 10ml blood sample for serum evaluation. If no positive reactions occur, then the second phase of the study will not be undertaken.

In Phase II, pooled sera from the responding volunteers will be used in a previously described ELISA and enzyme linked nitrocellulose immunoprint technique to characterize the nature of the antibody response to Chrysosporium Tropicum (i.e. IgE, G_1, G_2, G_3, G_4) and the proteins which are recognized as allergens.

Ten patients who have a positive skin test to Chrysosporum and a history of allergic rhinitis will be asked to return to the clinic for a nasal challenge. Briefly, the nasal challenge involves the inhalation of increasing concentrations of Chrysosporum extract into the subject's nostrils until symptoms such as sneezing, rhinorrhea, conjection, or ithcing occur.

Fungal extracts from Chyrsosporum may be included in the routine aeroallergen testing performed at the Allergy/Immunology Service, WBAMC.

Progress:

This protocol was discontinued due to lack of human resources.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/49 Status: Terminated

Title:

A Study of the Efficacy of Pyridine Extracted Alum Adsorbed Extracts in the Treatment of Allergic Rhinitis

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ Stanislaus Ting, MC

Dept/Sec: Dept Medicine/Allergy Assoc Investigators
Key Words: Robert Harverly, BA
Pyridine Extract

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine if pyridine extracted alum precipitated allergen extracts are suitable for allergen immunotherapy.

Technical Approach:

Forty patients, 18 years or older, will participate in this study. They will all have seasonal allergic rhinitis with a 3+ or 4+ skin test to Mesquite and Mulberry, and a clinical history which correlates with the skin tests. They will not have received immunotherapy for at least one year prior to the study. The patients will be entered into the study during the months August through October 1984.

At baseline, before beginning therapy, the following tests will be performed:

a. Carefully done titrated prick skin tests to Mulberry and Mesquite pollen with reconstituted freeze dried extracts, the same lot of which will be used for retesting late in the study. Histamine controls of 1.0mg, 0.5mg, 0.25 mg/ml and DHM controls of 1.0 ng/ml, 0.5 ng/ml, 0.025 mg/ml will be tested at the same time.

b. Nasal challenge: The patients nasal reactivity will be established by responsiveness to histamine solutions sprayed into the nose. The endpoint will be sneezing, rhinorrhea, itching or congestion. The patient will be allowed to recover and will then

have a similar challenge with Mulberry/Mesquite pollen mixture. The same endpoint determination will be used.

c. Serum will be drawn for total serum IgE, specific IgE and IgG subclass antibodies to Mulberry and Mesquite allergens.

After these tests are performed, the patients will be assigned to one of two treatment methods, aqueous extracts of Mulberry and Mesquite, or pyridine alum Mulberry and Mesquite extracts. Assignment will be selection to match groups based on the control findings.

An attempt will be made to have the patients receive 2 to 3 therapy injections weekly. During this time the patients will be carefully monitored for side reactions. When they have reached maintenance therapy, defined as 2500 PNU of each allergen per injection, and have successfully received three such injections without problems, the original baseline testing will be repeated. At this point, if other allergen immunotherapy is required for the patient's care, it will be begun and given in the alternate arm weekly, or alone during the period of increasing dosage of these other allergens. The Mulberry/Mesquite maintenance dose will be given weekly.

The study will be continued during March when the patients will fill out a daily symptom medication diary. During this time the patients in both groups will be given chlorpheniramine 4 mg tablets. A nasal decongestant (Afrin), and a topical eye preparation (OPConA) to use on a prn basis in treatment f their allergic symptoms as they occur. Daily pollen counts will be performed.

A final serum specimen for specific serum IgE, IgG subclasses to Mulberry/Mesquite will be collected. The contents of the pyridine extract, and the aqueous extract will be compared in the laboratory by isoelectric focusing and an enzyme linked immunoprint technique.

The following comparisons will be made with parametric and nonparametric statistical methods:

a. The skin titration endpoint of the reaction to the allergens, corrected for skin test reactivity as determined by histamine and DMH skin test controls.

b. The concentrations of allergen extract which cause the development of nasal symptoms at each time in the study corrected for histamine nasal reactivity.

c. The amount of total serum IgE, specific antimulberry and mesquite IgE and IgG subclass antibodies will be compared from each time specimens are collected.

d. The number and nature of side reactions, the time to reach maintenance dose of immunotherapy of each extract type will be compared (aqueous versus pyridine alum).

e. The symptom scores will be compared for each treatment group.

f. The medications use will be compared.

g. Both e. and f. will be compared to the daily pollen count.

h. The immunoprint technique will be used to denote the proteins in each extract compared to freshly extracted pollen. The number of proteins which are recognized as allergens in each extract will be compared to the fresh pollen using the pool of 40 allergic sera. The specific proteins to which the IgG subclass antibodies are formed will also be compared.

Progress:

Test material was not obtained and the project was terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/51 Status: Ongoing

Title:

Evaluation of Continuous Infusion Vinblastine Sulfate in Pancreatic Adenocarcinoma (SWOG 8237)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Adenocarcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the clinical response rate of a five-day continuous infusion of vinblastine sulfate in pancreatic adenocarcinoma.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/52 Status: Ongoing

Title:

Study of Doxorubicin, Mitomycin-C and 5-Fluorouracil in the Treatment of Metastatic Adenocarcinoma of the Prostate, SWOG 8302

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Adenocarcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To test the effectiveness and toxicity of DMF (Doxorubicin, Mitomycin-C and 5-Fluorouracil) in the treatment of stage D_2 adenocarcinoma of the prostate.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/53 Status: Ongoing

Title:

Evaluation of Continuous Infusion Vinblastine in Gastric Carcinoma SWOG 8235

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the response rate, response duration, and duration of survival of gastric carcinoma treated with continuous infusion vinblastine. To define the qualitative and quantitative toxicities of continuous infusion vinblastine administered in a Phase II study.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients entered into the study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/54 Status: Ongoing

Title:

Immediate Post-Operative Adjuvant Chemotherapy in Patients with Operable Breast Cancer, SWOG 8364

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Cancer

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To assess the toxicity of immediate chemotherapy with Cyclophosphamide, Methotrexate, 5-Fluorouracil, Vincristine and Prednisone beginning at the time of surgery in patients with Stage II carcinoma of the breast

Technical Approach:
The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients entered into the study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/56 Status: Terminated
Title:

A comparison of Zaditen with an H_1 and H_2 Antihistamine, and with a Combination of an H_1 and H_2 Antihistamine in the Inhibition of Dermographia, IND #13,303

Start Date: Est Comp Date:
Principal Investigator: Facility:

LTC L.E. Mansfield, MC (Resigned)
Change of Investigator to MAJ S. Ting, MC

Dept/Sec: Allergy/Immunology

Assoc Investigators
Stanislaus Ting, MC
Ruth Hulse, LVN

Key Words:

Zaditen

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To compare the inhibitory effects of a new agent Zaditen with a classic H_1 antihistamine or the combination of H_1 and H_2 antihistamine.

Technical Approach:

Forty patients, 18 years or older, and practicing contraception or not capable of childbearing, will be entered into the study. They will have a dermographic skin test response to 150g of pressure or less as determined by a special testing device. A positive response for dermographia is defined as a 3mm or greater wheal at the scale site. For clinical purposes, absence or presence of dermographia is important in evaluating cutaneous responses to allergen. The initial screening for reactive patients will be performed during the routine allergy skin testing performed in Allergy/Immunology Clinic, WBAMC.

After the patients understand the nature of the study, and the fact that Zaditen is an IND drug, the 40 patients will be divided into two groups. Baseline dermographic responses will be reconfirmed and transferred by a scotch tape technique.

The medication schedule for the groups will be

GROUP A

First week	CTM 4 mg bid
Second week	CTM 4 mg qid
Third week	CTM 4 mg qid & Cimetidine 300mg qid
Fourth week	" " "

GROUP B

First week	Zaditen 1 mg bid
Second week	Zaditen 1 mg qid
Third week	Zaditen 1 mg qid
Fourth week	Zaditen 1mg qid

The subjects will receive their medication as an opaque white capsule which will contain the entire dose. They will receive a new supply of medication at the second week testing. The investigator performing the dermographia testing will be blinded to group identity of the subject. One person will perform all the testing in dermographia. The testing will be performed at the same time of day in each person to avoid any effect of the recognized circadian rhythm of skin reactivity.

Testing for dermographia will be performed after the first two weeks of the study, with the final testing at four weeks when the study will end.

At each testing the dermographic response will be traced and transferred to the patient's experimental record by a cellophane technique. Three concentrations of histamine will be applied by intradermal prick skin testing (0.10,0.05,0.025 ng/ml)in the same area of the skin to serve as a control for skin reactivity. Similarly three concentrations of DMH (0.10,0.05,0.025 ng/ml)will be applied to control for mast cell mediator "releasibility".

The differences, if any, between the degree of suppression of the dermographic response by Zaditen will be compared to the H_1 and the combination for each period. The Zaditen effect, if any at two weeks, will be compared also to the four week response. A similar analysis will be performed on the histamine and DMH skin tests.

Non-parametric methods will be used for statistical analysis. The analysis will be of the least pressures which cause a 3mm wheal or greater and the lowest concentration of histamine or DMH, which cause a 3mm or greater wheal on prick puncture testing.

There will be no useage of concomitant antihistamines or systemic corticosteroids during the study period.

Zaditen and the placebo capsules will be provided by Sandoz Pharmaceuticals under IND #13,303.

Progress:

This study was terminated upon resignation of Dr. Lyndon Mansfield, who took the study with him and completed it in his private practice.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/59 Status: Competed
Title:

An Evaluation of Twice Daily Nedocromil Sodium in the Therapy of Mild to Moderate Asthma.

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ Stanislaus Ting, M.C.

Dept/Sec: Dept Medicine/Allergy Assoc Investigators
Key Words:
Nedocromil sodium

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To determine if nedocrimil sodium is a useful and tolerated therapy for mild to moderate asthma when given by intubation twice daily at a 4mg/ dose/

Technical Approach:

Thirty mild to moderate asthmatic patients will be selected for this study. They will be from 18 to 60 years of age, not capable of becoming pregnant, with baseline FEV_1 greater than 60%, and a 15% improvement in FEV_1 after 180 ug inhalation of albuterol, when other bronchodilators have been withheld (24 hours for theophylline, six hours for beta adrenergic agents by inhalation). They will be well controlled by routine use of bronchodilator, but will not require corticosteroid (oral or inhaled) therapy. They will be instructed in and demonstrate

1. Proper use of the meter dose inhaler.
2. The ability to properly complete the the symptoms/medication diary.

Patients who were using cromolyn or corticosteroids will have discontinued these medications for a month. Excluded will be females of childbearing potential, or who are breast feeding, patients younger than 18 years or older than 60 years, and those with any evidence of significant clinical or laboratory abnormalities.

Baseline CBC, SMA12, routine urinalysis and pulmonary functions will be obtained (Spirometry only FEV_1, FVC, FEF_{25-75}, PEFR). Each patient will participate in the study for eight weeks. The first two weeks will provide a baseline for future comparisons. At the beginning of the third week the patients will enter a six week random double blind trial, wherein many will receive either Nedocrimul 4 mg bid by inhalation or placebo. To enter this phase of the study, the patient must have demonstrated at least a total symptom score of 2 or more on 7 of the 14 days, and have demonstrated the ability to complete the symptom diary satisfactorily, and proper use of a meter dose inhaler.

Schedule of Study (Attachment #1)

VISIT #1: Entrance, entrance physical assessment examination, PFTS, Laboratory data issued diary card, issued PEFR meter to perform arising and retiring PEFR determinations. Instructed in use of MDI, PEFR meter, and how to record such data on telephone communication Seven days by monitor to evaluate progress.

Visit #2: Fourteen days: Return to Clinic, repeat PFTS, laboratory values assessed for normality, diary sheets check, 2nd instruction in use of MDI, PEFR meter with demonstration. Issued medication by Pharmacy after reassessment of suitability to enter study.

Twenty-one days: Telephone communications by monitor.

Visit #3: Twenty-eight days: Repeat of Visit #2.

Visit #4: Forty-two days: Repeat of Visit #3.
Forty-nine days: Telephone communication by number

Visit #5: Fifty-six days: End of study, repeat laboratory tests in addition to other assessments, physician assessment of overall effect of treatment on each patient.

Physician assessment.

Final Patient Assessment: 7.29 in the Fison Protocol.

Medication recording will be on symptoms diary with both OTC and prescription drugs.

Statistical analysis will compare these daily PEFR, bi-weekly spirometry) and subjective symptoms diary scores and medications use in the active and placebo groups. Changes within the group as well as difference between the groups will be evaluated using appropriate parametric and nonparametric tests for analysis.

The Pharmacy WBAMC will be responsible for maintaining the test agent in a secure location, for issuing the agents and for recording such activity in a log. Unused agents will be returned to the Pharmacy.

Severe adverse drug experience will be reported to the IRB and to Fisons within ten working days oif the discovery by the investigator. Any such experience will cause the patient to be withdrawn from the study with a full written report furnished by the investigator.

Progress:

Twenty-five patients completed the study. Baseline values were comparable in both groups. There were significant differences (Wilcoxon rank sum) between treatments as follows: For the bid centers (NS, n=45; P, n=42), a daytime and nightime scores (p=0.002), symptom severity (p=0.02), MD assessment (p=0.002); for the qid centers (NS, n=39; P, n=41), daytime score (p=0.04), symptom severity (p=0.01). There were no significant adverse effects reported. We concluded that inhaled nedocromil sodium is very effective in controlling the symptoms of chronic asthma; it is safe and very well tolerated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/68 Status: Ongoing

Title:

Measurement of Plasma Histamine Levels in Nonatopic and Atopic Individuals

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ S. Ting, MC

Dept/Sec: Dept Medicine/Allergy Assoc Investigators

Key Words:
Histamine David O. Rauls, PhD

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Using a new laboratory clinical investigation technique to establish baseline plasma histamine levels in nonatopic and atopic individuals.

Technical Approach:

Blood drawing is a routine procedure in the Allergy Clinic for all new patients undergoing evaluation for allergic or nonallergic diathesis. In this proposed study, 2cc of blood will be collected during routine venipuncture and the plasma separated for histamine assay.

Progress:

This study has resulted in two abstracts, with presentation at the American Academy of Allergy in March 1986. One hundred samples were collected for plasma histamine. Histamine values were evaluated in conjunction with T-IgE levels and total eosinophil count (TEC). Laboratory and skin test data were then compared within the study population (SP). The study population was further divided into three groups. (1) 64% Allergic rhinitis(AR) (2) 26% Vasomotor rhinitis (VR) (3) 10% Asthma (A) Preliminary results indicate that skin test reactivity is diminished in those individuals w/VR when compared to A or AR. T-IgE and TEC may serve as distinguishing factors between VR and AR.

One hundred thirteen samples were collected for plasma histamine (H). H levels were evaluated in conjunction with multiple other laboratory parameters for their predictive ability of skin test reactivity. Agc, T-IgE and H were consistantly selected by multiple regression formulas with F-ratio=4 as best predictors of skin test reactivity. This preliminary data suggests that 30% of skin test variability can be attributed to a combination of age, T-IgE and H.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/72 Status: Ongoing

Title:

Intergroup Phase III Protocol for the Management of Locally or Regionally Recurrent but Surgically Resectable Breast Cancer SWOG 8293

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Cancer

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To better define the relative roles of systemic and local treatments in the care of resectable locally or regionally recurrent cancer of the breast in patients who have no evidence of disease after resection. To assess the effects of chemotherapy, radiation therapy, singly or in combination, administered immediately after surgical resection on local control, disease-free interval, and pattern of re-recurrence. To determine the effect of the administration of systemic chemotherapy or radiation therapy which has been delayed until local, regional, re-recurrence upon local and regional control, disease-free survival, patterns of relapse and survival. To determine the influence of disease free interval, size, and extent of local or regional recurrence on the effectiveness of treatment with chemotherapy, radiation therapy, singly or in combination.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients entered into the study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/82 Status: Ongoing

Title:

Combination Chemotherapy with O,P-DDD and Cis Platinum in Metastatic Adrenal Patients, Phase III(SWOG 8325)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Chemotherapy

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To study the responsiveness of adrenocortical carcinoma to combination chemotherapy consisting of Cis-platinum (DDP) and Mitotane (O,P'-DDD). To study the prognostic features of patients with metastatic and/or resectable adrenal carcinoma receiving chemotherapy. To document the toxicity of chemotherapy in this group of patients.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/83 Status: Ongoing

Title:

Phase II Study of PAC (Cis-Platinum, Adriamycin and Cyclophosphamide) in Treatment of Invasive Thymoma, Intergroup Study (SWOG 8490)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Thymoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the objective response rate in extensive and limited invasive thymoma treated with PAC (Cis-platin, Adriamycin, Cyclophosphamide). To determine the duration of remission of patients with limited invasive thymoma treated with split course radiotherapy plus PAC and in patients with extensive disease treated with PAC alone.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 8 Prot No: 84/86 Status: Ongoing

Title:

Intergroup Adult Soft Tissue Sarcoma Study #1. Randomized Trial of Adjuvant Doxorubicin vs Standard Therapy(SWOG 8291)

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL Ray O. Lundy, MC

Dept/Sec: Oncology Assoc Investigators

Key Words:

Carcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

This prospective randomized study is designed to evaluate the efficacy of adjuvant Adriamycin compared to standard treatment (a delay of chemotherapy until the time of demonstrated relapse) in the management of patients with Stages IIB, IIIA-C and tissue sarcoma in terms of local recurrence rate, disease-free interval, and survival.

TECHNICAL APPROACH:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

One patients has been entered into this study to date with no adverse effects.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/88 Status: Completed
Title:

SQUID Magnetocardiograph - A Pilot Study

Start Date: Est Comp Date:
Principal Investigator: Facility:

COL James Wilkins, MC

Dept/Sec: Dept Medicine/Cardiology Assoc Investigators
Key Words:

Magnetocardiography

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To determine the utility of SQUID magnetocardiography in the assessment of cardiovascular disease.

Technical Approach:

The SQUID magnetometer is housed in a radio frequency shielded room of the Engineering Building of UTEP. Therefore, all studies will be done at that location. It is anticipated to use six study subjects. Three will be normals, one will be left bundle branch block, one will be anterior myocardial infarction, and one will be left ventricular hypertrophy. The criteria for selecting the patients will relate primarily to the ease of obtaining the needed studies.

The subjects will receive an electrocardiogram, an echo, and a vectorcardiogram prior to the magnetocardiogram. Magnetometer will be positioned to correspond with the location of normal ECG positions.

The resultant studies will be compared. The major comparison will be in terms of the instrument's ability to define either the patient's normalacy or abnormalcy.

The technology is totally noninvasive. It does not place the patient in any kind of radio-frequency field. The other preliminary tests are noninvasive. The patients selected will have full informed consent.

Progress:

The work has been completed on the pilot project for the SQUID Magnetocardiography. A total of ten subjects were studied, six with normal hearts and four with cardiovascular disease. The tracings were obtained at the Engineering Building at UTEP as was outlined in the original proposal. It was demonstrated that reproducible tracings could be obtained with a satisfactory signal to noise ratio. Differences in QRS and T wave vectors were noted between abnormals and normals. The purpose of this study was to assess the adequacy of the obtained signal. It is hoped that we can study a specific disease process with an upcoming protocol which is currently in the drafting stage.

A paper has been accepted to the J Magnetocardiology.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/01 Status: Ongoing

Title:

Skin Test Reaction Variability in Human Skin Induced by Single Strength Antigen

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ S. Ting, MC

Dept/Sec: Medicine/Allergy Svc Assoc Investigators

Key Words:

Skin testing

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine if the incidence of variability in skin test reaction as a function of skin test site.

Technical Approach:

One hundred patients from the Allergy/Immunology Clinic population at WBAMC will be asked to participate in the study. Each patient will be prick skin tested on a preselected single antigen to which they have a known hypersensitivity. The concentration of the extract will be 1:200 w/v. Skin testing to antigen, saline and histamine and DMH control will be done on the back in the upper right and left and lower left and right quadrants. The resulting wheal and flare reactions will be outlined and recorded by cellophane tape technique for later evaluation. Data will be analyzed with a SPSS package specifically analysis of variance.

Progress:

Preliminary data suggest that 30% of skin test variability can be directly attributed to a combination of age, T-IgE and H. The study is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/02 Status: Completed
Title:

Skin Test and Measurement Technique Employed in Allergy Skin Testing

Start Date: Est Comp Date:
Principal Investigator: Facility:

Robert Haverly

Dept/Sec: Medicine/Allergy Svc Assoc Investigators
Key Words:

Skin testing

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

Investigate the various skin testing and measurement techniques used among allergists in the United States.

Technical Approach:

A survey sheet will be mailed out to practicing military and civilian allergists. Data will be coded and analyzed with SPSS package, looking specifically at frequency and distribution.

Progress:

Six hundred and five questionnaires were returned and 518 were used for study purposes. There exists a significant degree of variability among the types of skin tests used, methods of recording and interpretation of results. Of the respondents 88.6% used a positive control reagent such as histamine (94%) or codeine (6%) in routine allergy skin testing; 11.4% did not apply any positive control reagent. Preliminary data support the need for the reporting of skin test data in actual units of measure to avoid pitfalls of oversimplified rank system used by the majority of respondents. Data will be presented at the American Academy of Allergy in New Orleans, March 1986.

Detail Summary Sheet

Date: 1 Oct 85 | Prot No: 85/04 | Status: Ongoing

Title:

A Comparative Study Between Prick Skin Testing and in vitro Measurement of Serum Specific IgE by an Immunofluorescent Assay

Start Date: | Est Comp Date:

Principal Investigator: | Facility:

MAJ S. Ting, MC

Dept/Sec: Medicine/Allergy Svc | Assoc Investigators

Key Words:

Immunofluorescent assay

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Investigate whether serum specific IgE determined by an immunofluorescent assay correlates with prick skin test results.

Technical Approach:

One hundred patients with allergic rhinitis/conjunctivitis with/without asthma will be skin tested to 32 local allergens. In addition to routine blood lab work, one additional red-top tube will be drawn, serum will be separated and stored at -80°C. Antigen specific IgE levels will be measured by IgE-FAST technique. Data will be analyzed using a SPSS package.

Progress:

Over 1200 individual determinations have been made. Preliminary data reinforces the concept that skin test reactivity is not solely IgE dependent. It is also suggested that significant skin test reactions are possible in the absence of any measureable level of S-IgE.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/05 Status: Completed

Title:

Effects of Beta-2 Agonist & Naloxone on Codeine-Induced Skin Reactions

Start Date: Est Comp Date:

Principal Investigator: Facility:

LTC A. Shelton, MC

Dept/Sec: Medicine/Allergy Svc Assoc Investigators

Key Words:

Codeine-induced skin reaction MAJ S. Ting, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Determine whether locally applied B_2 agonist/Naloxone (N) suppresses the histamine release induced by codeine (C) in human allergic skin reactions.

Technical Approach:

Twenty atopic and nonatopic volunteers will be tested intradermally with (A) C 1.0 ug, (B) C 1.0 ug + N 1.0 ug, (C) C 1.0 ug + N 2.0 ug, (D) C 1.0 ug + N 3.0 ug, (E) C 1.0 ug + 4.0 ug, and (F) N 4.0 ug. Data will be analyzed with a SPSS package.

PROGRESS:

C-induced skin wheal and flare reations were not inhibited by N at all doses tested. Plasma histamine levels were determined from venous effuent 10cm proximal to the C and C + N induced skin reaction site of the forearm. Peak plasma histamine levels induced by C and C + N were very similar. X $\pm$ SEM pg/ml 1308 $\pm$ 85 vs 1342 $\pm$ 96. Baseline: 242 $\pm$ 18 vs 212 $\pm$ 22. No differences were noted between C and C + N induced ultrastructural alteration of mast cells. These results suggest that codeine-induced cutaneous mast cell degranulation is not mediated by opiate receptors.

Results of the study will be presented at the XII International Allergy-Clinical Immunology Meeting in Washington DC, October 20-25, 1985.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/07 Status: Ongoing

Title:

SWOG 8300: Treatment of Limited Non-Small Cell Lung Ca Radiation vs Radiation & Chemotherapy

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL R.O. Lundy, MC

Dept/Sec:Medicine/Oncology Assoc Investigators

Key Words:

Lung Carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To compare combination chemotherapy (FOMi/CAP: 5-Fluorouracil, Vincristine and Mitomycin-C alternating with Cyclophosphamide, Adriamycin and Cis-platinum) plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, response duration and survival duration. To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC. To evaluate the responsivness of smaller tumor burdens to FOMI/CAP (i.e., less than metastatic disease). To determine the pattern of relapsing disease in each treatment arm and in subgroups of patients determined by histology and response to FOMI/CAP. To determine if prophylactic brain irradiation will decrease the chances for brain metastases and influence toxicity or survival.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patient has been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/08 Status: Ongoing

Title:

SWOG 8410: Combination Chemotherapy of Intermediate and High Grade Non-Hodgkins Lymphoma with BACOD

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL R.O. Lundy, MC

Dept/Sec:Medicine/Oncology Assoc Investigators

Key Words:

Lymphoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine an approximate complete remission rate and remission duration for the treatment program of cyclophosphamide, doxobubicin, vincristine, dexamethasone, and bleomycin with intervening moderate dose methotrexate and leukovorin rescue (m-BACOD), in patients with intermediate and high grade non-Hodgkin's lymphoma. To assess the feasibility of using this regimen in the Southwest Oncology Group with the intent of using m-BACOD in a future Phase III trial.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/09 Status: Ongoing
Title:

SWOG 8411: Evaluation of DTIC in Metastatic Carcinoid

Start Date: Est Comp Date:
Principal Investigator: Facility:

COL R.O. Lundy, MC

Dept/Sec: Medicine/Oncology Assoc Investigators
Key Words:

Carcinoma

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To determine the effectiveness of dimethyl triazenoimidazole carboxamide (DTIC) in the treatment of metastatic carcinoid. To determine the survival of patients with metastatic carcinoid receiving DTIC.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/10 Status: Ongoing

Title:

SWOG 8415: Evaluation of Tamoxifen in Unresectable and Refractory Meningioma

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL R.O. Lundy, MC

Dept/Sec:Medicine/Oncology Assoc Investigators

Key Words:
Meningioma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the antitumor activity of Tamoxifen in meningiomas not amenable to surgery or radiotherapy. To estimate the response rate and response duration experienced by these patients.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

No patients have been entered into this study to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/20 Status: Ongoing

Title:

SWOG 8294: Evaluation of Adjuvant Therapy & Biological Parameters in Node Negative Operable Female Breast Ca, Intergroup Study

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL R.O. Lundy, MC

Dept/Sec: Medicine/Oncology Assoc Investigators

Key Words:

Breast Carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Assess the impact of short-term intensive chemotherapy wth CMPP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumors and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm. Assess the impact of surgical procedures, ER status, menopausal status and tumor size. Develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival. Assess the value to CEA in predicting recurrence and survival rates. Assess the natural history of a subgroup with N-, ER+ small tumors.

Technical Approach:

The details are lengthy and specified in the SWOG protocol. Duplicates are kept on file in the Department of Clinical Investigation and are available upon request.

Progress:

Three patients have been entered with no adverse effects.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/21 Status: Ongoing

Title:
Treatment of Grave's Ophthalmopathy With Cyclosporin (Sandoz)

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ Leonard Sanders, MC

Dept/Sec: Medicine/Endocrinology Assoc Investigators

Key Words:

Cyclosporin, Grave's Ophthalmopathy

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To assess the efficacy of cyclosporin treatment on the ophthalmopathy of Graves' Disease.

Technical Approach:

Approval to undertake this project was first requested at WRAMC with collaborative studies in Endocrinoogy Services at other MEDCENs on a slightly more limited bases in order to enroll as many patients as possible with this relatively rare problem and attain an earlier completion date.

The study will be composed of a random cross-over design comparing Cyclosporin treatment to the most commonly employed current therapy, high dose oral prednisone. Due to the nature of these drugs and their potential side effects, a double-blind design is not feasible. Since responses tend to be seen rapidly (if they occur at all) with steroids, and the favorable responses to Cyclosporin in the recent reports by both Weetman et al., and Nussenblatt et al., were seen within seven to ten days, we plan to administer each drug for three weeks. Each patient's response to one drug will be compared to their own response to the other drug. A total of 20 patients will be initially evaluated with random alternating allocation to either:

Group A: 1) Prednisone 40 mg t.i.d. x three weeks
2) Full evaluation of response (see below)
3) Cyclosporin 5-10mg/kg/day x three weeks

Group B: Reverse order of Group A

Progress:

No patients have been entered into this study since none have meet the entry criteria. Dr. Wartofsky at WRAMC will try to extend the time for the study.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/30 Status: Ongoing

Title:

The Value of Routine Ileoscopy During Colonoscopy

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ E. Washington, MC

Dept/Sec: Dept Medicine Assoc Investigators

Key Words:

Ileoscopy

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Assess the benefit of routine ileoscopy during the evaluation of occult gastrointestinal bleeding.

Technical Approach:

No more than 100 consecutive patients, referred to the gastroenterology clinic for evaluation of unexplained hemoccult positive stools, will be selected for the study. After history and physical examination, all patients who need evaluation of the colon and small bowel will have a proctosigmoidoscopy, colonoscopy, and small bowel followthrough x-rays. Barium enema will be obtained in all cases, whenever possible. If a barium enema or a small bowel followthrough has been done within the previous 12 months, another study will not be requested. Patients must be at least 18 years old to enter the study. Patients whose bleeding requires admission due to volume depletion, patients with poor general medical condition prior to colectomy, and poor cardiopulmonary status, will not be included in the study. The data recorded on each patient will include age, sex, duration of symptoms, symptoms, results of stool hemoccult, findings on proctoscopy, colonoscopy, ileoscopy, ileal biopsy results, and interpretation of the terminal ileum by small bowel x-rays. The data will be recorded on report sheets and stored on the TRS 80 computer.

Progress:

Fourteen patients have been entered to date. Preliminary results indicate that only inflammatory bowel disease patients benefit from ileoscopy. Full data analysis is under way. The study is ongoing, but limited to patients with inflammatory bowel disease.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/45 Status: Ongoing

Title:
Evaluation of Bronchodilator Effect of Nebulized Cromolyn

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ S. Ting, MC

Dept/Sec: Allergy/Immunology Assoc Investigators

Key Words:

Cromolyn nebulized

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:
To investigate whether nebulized cromolyn has bronchodilating activity on methacholine induced mild bronchospasm.

Technical Approach:

Methacholine inhalation challenge test is a routine procedure performed daily at both Allergy and Pulmonary Clinics for the diagnosis of reactive airway disease in both children and adults. Twenty percent drop of FEV_1 from the normal baseline FEV_1 by 100 inhalation units is considered a positive methacholine inhalation test and the diagnosis of reactive airway disease is supported. In this proposed study, nebulized cromolyn sodium will be given to adult patients who show a positive methacholine inhalation test. Repeat FEV_1 value will be measured at 5-15 minutes. If no significant change in FEV_1 is observed, inhaled beta 2 agents will be given. A total of 20 subjects with positive methacholine inhalation tests will be invited to participate in this study. As suggested, half of the study group patients will receive placebo (saline) instead of active drug cromolyn.

Progress:

This is a newly activated protocol with no results reported to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/46 Status: Ongoing

Title:
Effect of Vitamin C on Asthma

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ S. Ting, MC

Dept/Sec: Allergy/Immunology Assoc Investigators

Key Words:

Vitamin C, Asthma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To investigate whether asthmatic patients will benefit from oral vitamin C supplementation.

Technical Approach:

About 20 stable, asthmatic adult patients attending the allergy clinic will be invited to participate in this study. Baseline spirometry, metha choline response, plasma histamine level, skin test response to histamine, allergens and dextromethorphan will be recorded. Vitamin C, 1000 mg, bid x 3 weeks will be prescribed. The patient will be advised not to add supplemental "over-the-counter" type of vitamins to their diet during the testing period. Similar skin tests and laboratory tests will be repeated after vitamin C treatment. Multiple data points obtained from this study will be analyzed by Student's t-test for paired data.

Progress:

This is a newly activated protocol and no results are reported to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/47 Status: Ongoing

Title:
Effect of Vitamin B-6 on Asthma

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ S. Ting, MC

Dept/Sec: Allergy/Immunology Assoc Investigators

Key Words:

Vitamin B6, Asthma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To investigate whether asthmatic patients will benefit from oral vitamin B-6 supplementation.

Technical Approach:

Fifty stable, asthmatic adult patients attending the Allergy Clinic will be invited to be participants in this study. Baseline spirometry, plasma histamine, B6 level and skin response to histamine DMH and allergens will be recorded. Oral vitamin B6, 50mg bid, will be given for three weeks. The patient will be advised not to add supplemental "over-the-counter" type of vitamins to their diet during the testing period. Similar lab test and skin test will be repeated. Various data points obtained pre- and post-B6 treatment will be analyzed by paired Student's t-test.

Progress:

This is a newly activated study, no results have been reported to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/48 Status: Ongoing

Title:
Evaluation of Echosine in the Diagnosis of Sinusitis

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ S. Ting, MC

Dept/Sec: Allergy/Immunology Assoc Investigators

Key Words:

Sinusitis, Echosine

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To evaluate whether echosine can replace x-ray in the diagnosis of sinusitis.

Technical Approach:

Approximately 50 adult patients with history and clinical findings of sinusitis will be evaluated by both echosine and sinus x-ray. Antibiotic treatment will be initiated on the basis of clinical and x-ray findings. At the end of the study, echosine findings will be evaluated against sinus x-ray findings and echosine findings will be analyzed by appropriate statistical analysis, to include x-squared, sensitivity, specificity, positive and negative predictive values and percent agreement.

Progress:

This is a newly activated study with no results reported to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/49 Status: Ongoing

Title:
Gentamicin Clearance by Hemofiltration in a Dog Model

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT G.M. Davis, MC

Dept/Sec: Medicine/Renal Assoc Investigators

Key Words:

Hemofiltration

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To develop an animal model for continuous arteriovenous hemofiltration and to use this model to study the drug clearance characteristics of this system.

Technical Approach:

Five healthy dogs will be surgically rendered anephric. The dogs will have column disc peritoneal catheters placed and be maintained on peritoneal dialysis using the methods of Thornhill. A unilateral external shunt will be created in each dog. For each study a dog's peritoneal dialysis will be suspended and the animal placed on continuous arteriovenous hemofiltration. After the hemofiltration system has been primed with a liter of 0.9% saline containing 2000 units of heparin, the dog will be connected to the system with the arterial line connected to the femoral artery and the venous line connected to the femoral vein. The animal's arterial blood pressure will be measured periodically using a manometer via the arterial port.

Each study will involve a 10 mg/kg intravenous loading dose of gentamicin. After the loading dose is given, ultrafiltrate will be collected and measured for volume at 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330 and 360 minutes; at a 10cc aliquot of ultrafiltrate will be saved at each interval. Three cc blood samples will also be collected simultaneously from the arterial and venous sampling ports at 0, 30, 60, 90, 120, 180, 210, 240, 270, 300, 340 and 360 minutes.

Ultrafiltrate and blood will be assayed for gentamicin using the TDX fluorescope polarization method that is routinely used in our laboratory.

Data will be analyzed using non-compartment kinetics that have been well characterized. This analysis generates clearance data using the area under the curve for a drug concentration vs time graph.

Each animal in the study will be maintained alive indefinitely by peritoneal dialysis and will be used in other drug clearance studies relating to renal failure and peritoneal dialysis.

Nephrectomy will be performed by either bilateral flank incision or intra-abdominal approach. At the same time, peritoneal catheter will be placed. General anesthesia will be used. Prior to hemofiltration, vascular access will be placed under local anesthesia.

Progress:

This is a newly activated study with no progress to report as of this date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/60 Status: Completed

Title:

Can Individualized, Detailed Preoperative Instruction Decrease Anxiety and Enhance Recovery in the Mastectomy Patient?

Start Date: Est Comp Date:

Principal Investigator: Facility:

LTC W. Mika, ANC

Dept/Sec: Nursing Service Assoc Investigators

Key Words:

Pamela Smith, RN

Preoperative Anxiety, Mastectomy

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

This investigation focuses on the preoperative instruction relative to the unique needs of the mastectomy patient. The goal of this research is to collect data relative to the effectiveness of preoperative instruction as perceived by the patient. This knowledge will support the hypothesis that nursing is in an ideal position to meet some of the unique needs of the mastectomy patient through preoperative instruction.

Technical Approach:

The investigator will explain to each prospective participant that each answer sheet will be coded to assure anonymity. Following collection and analysis of data, a debriefing will be arranged. Prospective subjects will be approached regarding participation regardless of military status and age. Those women who are unable to read and write English will not be asked to participate. The prospective participants will be identified by the investigator following their admission to Wards for mastectomy. Fifteen women in each group and other participants will be designated into the control group.

Progress:

At the conclusion of the data collection, ten women were included in the study. Due to small sample size, trends were minor and the results were not statistically conclusive. However, some trends were evident such as the completeness of preoperative instruction by staff (MDs and RNs) and the overwhelming fear of cancer and death in all the participants.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/62 Status: Completed
Title:

An Assessment of Consumer Health Education Needs at William Beaumont Army Medical Center

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ Jane Yaws, ANC

Dept/Sec: Nursing Service Assoc Investigators
Key Words:

MAJ Betsy Kemp, ANC
Health Education MAJ Barbara Parry, ANC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To identify the perceived health education needs of consumers at William Beaumont Army Medical Center so that future patient education programs could be directed towards meeting some of these needs.

Technical Approach:

Three separate surveys will be administered by volunteers during a designated time frame. After the data has been collected it will be analyzed to examine:

1. Identify what patients perceive their health education needs to be.
2. Examine demographic data to determine if relationships exist between various items.
3. Identify what situations/methods patients identify as providing the best learning situation.

Progress:

Data is being analyzed and results will be written.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/84 Status: Terminated

Title:

Do Nurse Anesthetist's Credentials Affect Preoperative Patients Anxiety?

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT D. Gaston, ANC

Dept/Sec: Nursing Assoc Investigators

Key Words:

Anxiety

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine what effect an explanation of the Army CRNA's credentials and training will have on patient anxiety.

Technical Approach:

The sample population will be 50 ASA I adult elective preoperative patients. The patents will be given, as a pre-test, the State Trait Anxiety Inventory (STAI) test prior to pre-anesthetic interview. Twenty-five of these patients will receive added information concerning credentials and training of Army CRNA's in their pre-anesthetic interview. A repeat STAI test will be given as a post-test to assess the effect of the added information. The samples will be statistically analyzed, using the Student t-test for paired data. Demographic data will be collected for group comparison.

Progress:

Principal investigator was transferred with no progress reported.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/87 Status: Ongoing

Title:

Postpartum Nipple Care - Techniques to Prevent Sore Nipples in the New Breastfeeding Mother

Start Date: Est Comp Date:

Principal Investigator: Facility:

LTC W.V. Mika, ANC

Dept/Sec: Dept of Nursing Assoc Investigators

Key Words:

Nipple Care MAJ W.L. Farace, ANC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To evaluate the effectiveness of three different nursing approaches on the prevention of sore nipples in new breastfeeding mothers in the immediate postpartum period.

Technical Approach:

Mothers will be instructed on an individual basis by the nurse investigator on breastfeeding techniques. All mothers will be taught seven principle methods to prevent nipple pain, and two of the three experimental methods to be studied.

Mothers will be asked to fill out the subjective rating of nipple tenderness form immediately after each feeding for the first seven postpartum days. This form requires the mother to evaluate the amount of nipple pain she experienced on each breast each feeding session on a one to three scale.

Progress:

No progress has been reported to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/14 Status: Ongoing
Title:

Domestic Violence and Child Abuse

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ B. Parry, ANC

Dept/Sec: Nursing Assoc Investigators
Key Words:

Child abuse

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results
Study Objective:

To determine the incidence of medical indications of child abuse in families in which there is documented spouse abuse.

Technical Approach:

Reports of spouse abuse are substantiated by Social Work Service. All medical records of children living in homes where spouse abuse has been substantiated are reviewed for medical indications of abuse or neglect.

Progress:

Data collection is incomplete.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/25 Status: Completed
Title:

Comparison of Cardiovascular Stability in Two Age Groups of Patients Receiving Atropine vs Glycophrrolate iv during Induction of Halothane, Nitrous Oxide/Oxygen Indotracheal Anesthesia

Start Date: Est Comp Date:
Principal Investigator: Facility:

CPT R.E. Haas, ANC

Dept/Sec: Dept Nursing Assoc Investigators
Key Words:

Anesthesia

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results
Study Objective:

Compare cardiovascular stability after the intravenous administration of an equivalent dose of atropine or glycopyrrolate during the induction of general anesthesia. These effects will be measured from administration of the agent through induction and including intubation of the patient.

Technical Approach:

Instrument for data collection will be the Ohio 2105 noninvasive adult/pediatric blood pressure monitor with printer. The indices measured will be pulse and blood pressure. Pediatric patients scheduled for elective surgery requiring general anesthesia will be studied. Sample population will be randomly assigned to one of two study groups by a sealed envelope, or even/odd first digit of last four numbers in SSAN. Group I will receive atropine while Group II will receive glycopyrrolate. Both drugs are routinely used in anesthetizing pediatric patients and in no way deviates from standard anesthetic practice. Patients will receive appropriate milligram per kilogram dosages of chloral hydrate preoperatively. Measurements of pulse and blood pressure will be made at the preoperative interview and throughout induction and intubation with the Ohio 2105 noninvasive blood pressure monitor. Two-way analysis of variance and two sample T-test for variance of means will be utilized to analyze the data.

Progress:

We found that atropine and glycopyrrolate provided equal cardiovascular stability in subjects ranging from six months of age to ten years of age treated at the time of induction of halothane, nitrous oxide, and oxygen general endotracheal anesthesia. Minor differences were seen in the onset of action of the anticholinergic agents, with atropine being more rapid in its onset of action than glycopyrrolate. Greater cardiovascular stability was seen in subjects under two years of age as compared to subjects ages two to ten years. This may be explained by increased sympathetic tone in older children as a consequence of greater nervous system development when compared to younger children. No control group was utilized in this study for comparison. Such a group could further elucidate the factor that development plays in the response of children to induction of anesthesia, intubation, and administration of anticholinergic medication. Our findings indicate that the administration of anticholinergic agents at the time of induction of anesthesia and intubation may provide greater cardiovascular stability in the child under two years of age than in the child aged two to ten and, in fact, may not be advantageous in those children two to ten years of age undergoing general endotracheal anesthesia.

We recommend that further study of this possibility be investigated utilizing control groups of subjects under two years of age and two to ten years of age who receive no anticholinergic at the time of induction of anesthesia and intubation, in comparison to the treatments as administered in this study. A larger sample size would also be recommended.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/40 Status: Ongoing

Title:
A Comparison of Manual vs Computerized Nursing Documentation

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC W.V. Mika, MC

Dept/Sec: Nursing Assoc Investigators

Key Words:

MAJ Patricia Borup, ANC

Nursing Documentation

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To examine nursing documentation to determine the completeness of the information contained in manually written versus computer generated nurses notes.

Technical Approach:

A tool has been developed to use in examining the nursing notes. Fifty manually written and fifty automated records will be compared using the developed tool.

Progress:

A pilot study was conducted examining eleven manually written and eleven automated records. There was evidence that the computerized records may be more complete. Based on the pilot study, changes have been made in the tool and in the methodology to improve the study.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/41 Status: Ongoing

Title:
Relationship of Hospitalized Children's Cognitive Level, Painful or Fear Provoking Procedures/Treatments and Misperceptions of a Hospital Experience

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ B.A. Parry, ANC

Dept/Sec: Nursing Assoc Investigators

Key Words:

Cognitive levels, hospital experience

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine the relationship of hospitalized children's cognitive level, painful or fear provoking procedures/treatments and misperceptions of a hospital experience.

Technical Approach:

The child is administered the Piaget Test battery to determine cognitive level of functioning. The child is then asked to draw a picture of his/her hospital experience and participates in a 20-60 minute unstructured play session with hospital equipment.

Progress:

Data is being collected.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/42 Status: Completed

Title:
Evaluation of Discharge Planning Document in Cerebrovascular Accident Patients

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC W.V. Mika, ANC

Dept/Sec: Assoc Investigators

Key Words:

CPT Lynn Baldvins, ANC

Discharge planning

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To evaluate the nursing documentation on discharge planning for patients with CVA and to develop a discharge planning tool to improve the continuity of care.

Technical Approach:

To evaluate the documentation of discharge planning done with the population of CVA patients we would request access to 40 patient records. We will be looking specifically at the discharge planning documentation in the nursing care plans, nursing notes, progress notes and discharge form.

There will be no identifying data collected which could be used to identify any patient, and the patient will be identified only by a code number. The principal investigator will coordinate with PAD the review of all records, ensure no identifying data is recorded, and that records are not removed from PAD.

Progress:

Results of the study indicated that structured discharge education did not significantly reduce anxiety state in the experimental group. The experimental group did score significantly higher on the post-test relating to knowledge of the treatment regimen. Data analysis further revealed significant difference in anxiety trait and anxiety state by gender. Female subjects had higher anxiety trait on admission, after surgery and one week following discharge. Females also demonstrated significantly higher anxiety state on the post-surgery measurement. This researcher believes that structured discharge education is one of the most critical components of the discharge planning process.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/43 Status: Terminated

Title:
The Incidence of Skin Problems in Very Low Birthweight Neonates

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC W.V. Mika, ANC

Dept/Sec: Nursing Assoc Investigators

Key Words:

Sara Wood, RN

Skin problems, neonates

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Determine if there is a significant incidence of skin problems in very low birthweight neonates.

Technical Approach:

Review of delivery statistics will supply data to establish the portion of live births weighing less than 1500gm. Review of medical records on all admissions to the Neonatal Intensive Care Unit weighing less than 1500gm will establish the incidence of skin problems. The size of this problem population will determine if the third purpose, ascertaining common contributing factors, is addressed in this study or becomes the topic of a future study. Access to delivery records, NICU, admission records and medical records of neonates weighing less than 1500 gm is required.

Progress:

LTC Mika was reassigned. Associate investigator has failed to furnish a progress report. Project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/51 Status: Ongoing

Title:
Effect of Structured Patient Education and Discharge Planning on State Anxiety and Life Satisfaction in Post-Surgical Patients

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC W. Mika, ANC

Dept/Sec:Nursing Assoc Investigators

Key Words:
Education/Anxiety CPT Lyn Baldvins, ANC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Focus on the relationship of patient education and discharge planning and its effect on state anxiety and life satisfaction. The goal of this research study is collection of data relative to the effectiveness of a structured patient education and discharge planning program.

Technical Approach:

Subjects will be selected from the population of adult preoperative patients and the nonprobability sample selected will be randomly assigned to the control and experimental group. Investigators will meet with and explain to each prospective participant the coding utilized in data collection to assure anonymity. Potential subjects will be identified after admission for surgery. The goal is to include forty subjects in this study. Following completion of data collection and analysis the investigator will notify participants in this investigation of the time and location of a debriefing session.

Progress:

This is a newly activated study with no progress to report at this date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/54 Status: Ongoing

Title:
Incidence of Postoperative Nausea for Cataract Extraction: Comparison of Nubain and Stadol as Intraoperative Sedatives

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT N. Garrett, ANC

Dept/Sec: Nursing Assoc Investigators

Key Words:

Nubain, Stadol, sedatives

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To find if there is a difference in the incidence of postoperative nausea following cataract extraction when comparing nalbuphine and butorphanol as intraoperative sedatives.

Technical Approach:

Subject population will be individuals undergoing unilateral cataract extractions in the age range of 55 years and older. All subjects will be ASA 2 or 3. No subject will have medically treated gastrointestinal disorders or currently under treatment for cancer. A computer generated random numbers table will be utilized. The course director will maintain this table and the numbers will then be assigned exclusively and in order of appearance for each subject with sequential progression down the list. This number will be added to the last digit of the recorded social security number. Even totals will be designated to receive butorphanol and odd totals will receive nalbuphine. All subjects will receive preoperative assessment. They will be NPO after midnight and receive no premedication prior to surgery. The investigator will administer an initial dose of butorphanol or nalbuphine intraoperatively prior to local anesthesia and titrated until the patient is mildly sedated, but awake. Following the procedure the patient will be observed for a period of four hours postoperatively for any incidence of nausea. An "incidence of nausea" frequency distribution table will be constructed comparing Stadol and Nubain groups. Chi-square analysis will be utilized to determine variance significance.

Progress:

This is a newly activated study with no progress to report as of this date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 81/44 Status: Completed

Title:
Effect of Intravenous Terbutaline on Phospholipid Content of Adult Dog Lungs

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL L.L. Penney, MC

Dept/Sec: Obstetrics-Gynecology Assoc Investigators

Key Words:

Terbutaline; Surface active phospholipids

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

This study is designed to determine if intravenously administered terbutaline will cause a change in the concentration of phospholipids known to be important in the surfactant system of adult lungs.

Technical Approach:

Two groups of 8 mixed sex adult beagle dogs each will be used in the study. One group will receive 250 ml of 0.9 percent NaCl intravenously over a 30-minute period; these will serve as controls. One-half of these animals will be sacrificed at one hour, and the other half at four hours. The other group will receive 250 ml of 0.9 percent NaCl containing 0.5 mg of terbutaline intravenously over a 30-minute period and will be similarly sacrificed. Portions of lung and alveolar washings from each animal will be freshly obtained and studied for content of total phospholipid, lecithin, sphingomyelin, phosphatidyl inositol and phosphotidyl glycerol. We will then compare the groups to determine any changes in the phospholipid content over the period of time that we investigated.

Progress:

Preliminary data was presented at the Armed Forces District of the American College Obstetricians and Gynecologists in 1981. After the initial presentation additional experiments have been completed, but data reduction has not been accomplished to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 81/47 Status: Completed

Title:

Variability of Estradiol Induced Increases in Uterine Blood Flow as a Function of Time Post-oophorectomy

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL L.L. Penney, MC

Dept/Sec: OB-GYN Assoc Investigators

Key Words:

17b estradiol; uterine blood flow

Accumulative MEDCASE Cost Est OMA Cost: $650(650) Periodic Review Results

Study Objective:

To establish the lack of responsiveness of uterine blood flow to estradiol stimulation in rabbits oophorectomized longer than 60 days.

Technical Approach:

We have recently completed a study of the effects of Actinomycin D on estradiol-induced increases of uterine blood flow in oophorectomized rabbits. During that experiment a delay in shipping labeled microspheres necessitated study of a small group of control animals 60 days post-opertively as opposed to between 1-5 weeks as had been the case. At 60 days an increase in uterine blood flow two hours following estradiol, 10 ug/kg, was no longer demonstrable. Such a change with time has not previously been reported. We wish to repeat the study with sufficient numbers of animals to confirm or refute this observation.

Progress:

Ten rabbits were studied, indicating failure to respond as a function of time post-oophorectomy. Principal investigator has retired and the final data will be published at a later date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 81/48 Status: Terminated

Title:

Variability in Quantifiable Uterine Cytosolic and Nuclear Estrogen Receptors as a Function of Time Following Oophorectomy in Rabbits

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL L.L. Penney, MC

Dept/Sec: OB-GYN Assoc Investigators

Key Words:

17b estradiol; estrogen receptors

Accumulative MEDCASE Cost | Est OMA Cost:0($618) | Periodic Review Results

Study Objective:

To correlate the amount of receptor present with the degree of blood flow response to 17b estradiol.

Technical Approach:

If protocol 81/47 confirms a diminished response of uterine blood flow to 17b estradiol, as a function of time following operation, this study will be conducted. Since a decreased response is in a sense natural inhibition, a quantification for the receptors should aid in elucidating the basic mechanism. In addition to the cytosolic receptor, eosinophilic and a-adrenergic receptors, as well as any others suggested by Protocol 81/46 will be examined by standard techniques detailed in the references. For each receptor 6-8 animals will be studied at 20-40 days following operation and another 6-8 at 60-80 days.

Progress:

Principal investigator had no time to work on this project during the last fiscal year, and is now retiring. The study has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/14 Status: Completed

Title:
Serum and Urinary Electrolyte and Steroid Concentrations During Danazol Administration

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL L.L. Penney, MC

Dept/Sec: Assoc Investigators

Key Words:

Danazol

Accumulative MEDCASE Cost Est OMA Cost:$657(647) Periodic Review Results

Study Objective:

To further define electrolyte changes occurring during danazol administration and to examine indirectly potential sites of inhibition in the metabolic pathways involved.

Technical Approach:

Standard methods of testing the mineralocortioid pathway are available. The effects of danazol will be tested on days 6 and 12 to coincide with references in which testing was done on day 6. Our observation has been significant cramps and edema are noted 10 days to 2 weeks after starting therapy. Patients will receive 200 mg of danazol four times a day. Only those patients with documented endometriosis who will be treated as part of this therapy with danazol will be asked to participate. In addition to the battery of tests outlined in the flow chart (see below) patients will be asked to submit a serum sample at 8 a.m. for deoxycorticosterone (DOC), aldosterone (A), plasma renin activity (PRA), Na and K and to collect a 24-hour urine specimen on days 3 and 9. Aliquots of serum will be kept frozen for possible analyses of 18-hydroxycorticosterone (18OHB), corticosterone (B) or other steroids. Na, K, and possibly aldosterone will be determined on each urine collection and aliquots will be frozen for subsequent analyses (by GC-MS) as might be suggested by the serum results. Results will be collated and data analyzed by appropriate t-test after 5-6 patients have been entered to determine the need and direction of further testing.

Study Plan and Flow Chart:

Day (-10): Subjects begin 120 mEq Na and 80 mEqK diets after 24 hour urine Na and K (Day 1 of menstrual cycle).

Day (-5): 24-hour urine Na and K

Day (0) :

A) 24-hour urine Na and K completed by 0700

B) Baseline serum Ca, P, K, DOC, B, 18-OHB, A, PROG, 17OHP, F, DHEA and PRA.

C) Infusion of 25 units (0.25 mg) of ACTH intravenously at 0900. Patient supine from 0700 until 1030.

D) Serum drawn at 0930, 1000 and 1030 from arm opposite the infusion. All serum to be frozen and baseline and 1000 samples to be analyzed; otherwise samples to be studied if needed. Patient starts danazol. at conclusion of sampling.

Day (6): Repeat Day (0). Patient on danazol.

Day (12): Repeat Day (0). Patient on danazol.

Progress:

Access of patients is completed but data is still being analyzed.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/32 Status: Completed

Title:
Effect of Verapamil on Gestational Length in Rabbits

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL L.L. Penney, MC

Dept/Sec: OB-GYN Assoc Investigators

Key Words:

Verapamil

Accumulative MEDCASE Cost Est OMA Cost:$1440(1440) Periodic Review Results

Study Objective:

This is the second in a series of projects designed as preliminary studies to evaluate the potential value of verapamil as a tocolytic agent in the prevention of premature labor.

Technical Approach:

Pregnant rabbits whose time of conception is known within two hours will be used. The rabbits will be randomly divided into two groups and one group will receive oral verapamil in three equally spaced doses beginning on the 22nd day of gestation. The length of gestation will be recorded in all animals. Observations will be made regarding their respiratory status and survival of the pups. The control group will receive placebo in place of verapamil. A second cohort of rabbits will be similarly treated, but will also receive subcutaneous oxytocin 0.5 units every day at 0800, beginning on the 24th day of gestation.

Progress:

Forty rabbits were studied. Verapamil did not increase length of gestation in normal pregnancy; however it did delay time of delivery in oxytocin-induced labor as compared to controls.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/33 Status: Terminated

Title:
In vitro Effects of Spironolactone on Gonadotropin Production by the Rat Pituitary and Androgen Formation by the Rat Ovary

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL L.L. Penney, MC

Dept/Sec: OB-GYN Assoc Investigators

Key Words:

Spironolactone; Hormones

Accumulative MEDCASE Cost | Est OMA Cost: $90(90) | Periodic Review Results

Study Objective:

This project is designed as a preliminary study to determine if spironolactone, acting either primarily or secondarily, inhibits gonadotropin production from the pituitary in this animal model.

Technical Approach:

Estrous rats will be sacrificed and the anterior pituitary removed for culture by established techniques. Similarly, the ovaries will be removed and separated into granulosa cell and remaining theca and stroma as published. FSH and LH will be determined by radioimmunoassay with reagents obtained from the NIH. The gonadotropins will be measured in the media of the cultured pituitary glands as a baseline and with spironolactone in concentrations of 0.15, 1.0 and 2.0 X 10^{-6}M respectively. Glands will also be cultured in physiological concentrations of testosterone, estradiol, and estrone. Once these control levels of gonadotropin release into the media are determined, the experiment will be repeated with spironolactone combined with testosterone, estradiol and estrone individually. The effects of these same concentrations of spironolactone will also be determined on basal and gonadotropin stimulated sex steroid production from the cultured granulosa cells and ovarian stroma.

Progress:

Support personnel PhD biochemist was reassigned. Project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/57 Status: Completed

Title:
Cardiovascular Effects of Delta-9-Tetrahydrocannabinol in the Pregnant Conscious Sheep

Start Date: 1 Est Comp Date:

Principal Investigator: Facility:

COL L.L. Penney, MC

Dept/Sec: OB-GYN Assoc Investigators

Key Words:

Delta-9-THC; Cardiovascular effects

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To delineate the effects of intravenous delta-9-THC on cardiovascular acid base parameters in the conscious pregnant sheep comparing variable doses and rates of administration.

Technical Approach:

Twelve pregnant sheep at approximately 135 days' gestation will be studied. An indwelling Swan-Ganz catheter and a carotid arterial catheter will be placed under pentobarbital anesthesia. These catheters will be maintained open with a heparin lock and the sheep will be given antibiotics. Utilizing a paired t-test and randomized block (or appropriate variance as per consultation with statistician) design the sheep will be treated 24 hours postoperatively with either 0.25 mg/kg, 0.5 mg/kg, or 1 mg/kg of delta-9-THC injected in the pulmonary artery. Baseline recordings will be obtained prior to injection and cardiac output will be monitored at 3,5,15 and 60 minutes and at hourly intervals thereafter until recovery occurs. CVP will also be monitored at the same times. Continuous monitoring of the heart rate and blood pressure will be conducted and blood gases will be drawn at 5,15 and 60 minutes and thereafter until recovery has occurred. Following rest periods of 48 hours, each sheep will be studied at the next dose in its scheme until all sheep have been studied with each of the three doses. Forty-eight hours after the final study, a continuous infusion of 10 ugm/kg/min for three hours will be conducted and monitoring continued at hourly intervals until recovery occurs. The sheep will be salvaged, if possible. Serum samples will be saved at each blood gas sampling for possible analysis of THC concentration.

Progress:

Forty-two experiments with 30 sheep were completed. Manuscript is in preparation.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/26 Status: Terminted
Title:

Effects of Maternal Orgasm on Fetal Heart Rate

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ Eugene Rudd, MC

Dept/Sec: OB-GYN Assoc Investigators
Key Words:

Fetal Heart Rate

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To determine the safety (as reflected in fetal heart rate pattern) of sexual stimulation resulting in orgasm in the third trimester of pregnancy in both a normal and high risk population.

Technical Approach:

Ten to 15 patients from the routine OB Clinic will be selected for the initial phase of the testing. Patients must be low risk as defined by 1) being normotensive, 2) with appropriate fetal growth clinically, 3) single gestation and 4) with no risk factors for carbohydrate intolerance or if risk factors exist, diabetic screening must have been negative. There must also be no maternal disease to place the fetus at risk of placental insufficiency for the patient to qualify for Phase I of the study. This study is designed to determine indirectly if there is any compromise of fetal oxygenation during sexual stimulation and orgasm in a normal group of pregnant patients at 36 weeks or beyond. Following the first group of normal patients, the study will be performed using a group of patients at risk of uteroplacental insufficiency.

Progress:

Principal investigator was reassigned, the project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/58 Status: Terminated

Title:

Precision and Efficiency of Fundal Height Measurements During Pregnancy

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ E.G. Rudd, MC

Dept/Sec: OB-GYN Assoc Investigators

Key Words:

Fundal Height Measurements

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

The precision and accuracy of fundal height measurements made in a clinic consisting of multiple examiners will be evaluated in regard to documenting gestational age and uterine growth. Differences in an examiner's measuring techniques among examiners and between measurements made with and without prior knowledge of gestational age will be determined.

Technical Approach:

Patients presenting to the routine and complicated obstetrical clinics at least 16 weeks's of gestation. Gestational age will be presumed accurate when two or more of the following parameters agree: 1) reliable menstrual history, 2) first trimester exam of uterine size, 3) fetal heart tones negative to auscultation before and positive between 18-20 weeks, and 4) ultrasound dating before 26 weeks.

Progress:

Principal investigator was reassigned, the project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/75 Status: Terminated

Title:
Efficacy of Administering a Nonsteroidal Agent Prior to Hysterosalpingography

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ Cesar Rosa, MC

Dept/Sec: Dept OB-GYN Assoc Investigators
COL L.L. Penney, MC

Key Words:
HSG, Analgesia

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine whether the administration of a nonsteroidal anti-inflammatory (Ibuprofen) is effective in reducing the pain or discomfort associated with hysterosalpingography.

Technical Approach:

Patients from the Gyn Infertility Clinic, having a HSG as part of their evaluation will be invited to join the study. Ibuprofen tablets, or placebo, will be administered to the participants two to four hours prior to the HSG. Whether the patient gets the active ingredient or the placebo will be determined by the Pharmacy Svc using a table of random numbers. Medication and placebo will be of identical appearance and they will be dispensed by the Pharmacy Svc, keeping both patient and staff unaware of the nature of the medication dispensed.

Prior to the HSG each participant will be asked to complete a questionnaire that will include the following data: Age, gravity and parity, history of gynecological surgery, history of endometriosis, history of dysmenorrhea with degree and nature if any, and whether patient requires medication for dysmenorrhea.

Shortly after the procedure the participants will be asked to answer a second questionnaire. The following information will be obtained:
Was the procedure painful and, degree of pain, if any.

If painful, was pain associated mostly with the grasping of the cervix or with the injection of the contrast media.

If painful, nature of pain and for how long after the procedure did the pain last.

The day after the procedure patients will be called. The following information will be requested:

Any pain after leaving the hospital.
Was any medication necessary to relieve the pain.
Any other occurrences.

We want to determine whether administration of a nonsteroidal agent prior to hysterosalpingography helps to decrease the pain or discomfort associated with the procedure and if that was the case, whether there is any subgroup of patients that would benefit more.

Statistical Methods: Contingency tables using chi square analysis to compare placebo vs Ibuprofen; improvement or not in pain score.

The following individuals will be excluded: Patients with history of peptic ulcer disease; patients with bleeding diathesis; patients using analgesics; or patients with a history of allergy to Ibuprofen. Patients allergic to iodine, seafoods, or x-ray contrast material will be excluded.

We anticipate needing 200 individuals (100 placebo, 100 active ingredient). All patients will be referred from the Gyn Infertility Clinic. This group is composed of both active duty and dependent females in the reproductive ages of 18-40. All patients undergoing hysterosalpingography will be invited to participate except patients with the conditions previously described. The main support needed will be from the Pharmacy Svc in maintaining randomization list and codes.

The estimated duration of the study will be 1-2 years.

Progress:

The pharmaceutical company did not make good on an offer to supply placebo tablets. Over the past few months another group published on basically the same clinical project.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/76 Status: Ongoing

Title:
Improved Pregnancy Rates after using Oil-Soluble Contrast Media (OSCM) for Hysterosalpingography(HSG)

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ Cesar Rosa, MC

Dept/Sec: OB-GYN Assoc Investigators
COL L.L. Penney, MC

Key Words:
HSG, Pregnancy Rates, Contrast Media

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine whether OSCM used for HSG improves pregnancy rates in patients with patent fallopian tubes and no other major cause for infertility.

Technical Approach:

Patients from the Gyn Infertility Clinic will be invited to participate. After a complete initial evaluation which includes history, physical exam, semen analysis, documentation of adequate ovulatory function by BBT and serum progesterone, and postcoital test; patients will be scheduled for HSG to evaluate tubal patency as is routine in the evaluation of these infertility cases.

All HSGs will be done using water soluble contrast media (WSCM) in order to establish tubal patency and to evaluate presence or absence of rugal marks. Those individuals with a normal study as evidenced by unilateral or bilateral spillage, without evidence of distal obstruction in either tube, will then be randomized to receive 5ml of OSCM injected through the HSG cannula, or no OSCM at all. For this purpose a table of random numbers will be used assigning each group to odd or even numbers. No effort will be made to blind the study as far as the f/u will be similar in both groups and the measured parameter will be an objective, all or none end result - pregnancy.

Patients with normal studies will be followed expectantly for a minimum of four menstrual cycles during which they will be encouraged to maintain BBT charts and to time intercourse with

ovulation. After this period of time, those patients with persistent infertility will be progressed through their infertility evaluation as otherwise indicated.

Participation in this study will not change in any way the couple's infertility evaluation. The proposed waiting period after a HSG is presently the norm after any normal study; so no unnecessary or extra delay is being introduced into these patient's evaluation.

The HSG will be performed by residents from the Dept Obstetrics and Gynecology, under the direct supervision of one of the principal investigators, as is the norm for all HSGS performed presently.

Generally, whether OSCM or WSCM is used for HSG is a matter of personal choice by the operator. Both contrast media to be used WSCM (Renografin-Squiff Pharmaceuticals, Princeton NJ) and OSCM (Ethiodol-Savage Co, Missouri City, TX) have been in common use for a number of years and are accepted as safe. Patients allergic to iodine, seafoods, or x-ray contrast material will be excluded from the study.

Statistical Methods: Contingency tables, using chi-square analysis, comparing OSCM vs no OSCM; pregnancy rates in one group vs the other.

SUBJECTS: The subjects to be considered will be healthy females in their reproductive years, attending the Gyn Infertility Clinic due to involuntary infertility of more than one year duration. This group is heterogenous in terms of military status and age range 18-36.

Additional Support: Facilities to be used will be the same fluoroscopy room in the x-ray department which presently is alloted to the Gyn Dept for HSGs one afternoon a week. The maximum number of studies per day will be six, as is the norm presently. We do not anticipate the use of any additional facilities or resources other than the one routinely used for HSGs.

Progress:

Two patients have been added to the protocol, bring the total number to three. Due to staff shortage, this protocol has not been implemented to the full extent. It is expected that during calendar year 1986 a significant number of patients will be added.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/18 Status: Terminated

Title:

Human Chorionic Gonadotropin Titers and Ultrasound During Early Pregnancy

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ A.S. Maslow, MC

Dept/Sec: Obstetrics/Gynecology Assoc Investigators

Key Words:

Ultrasound, pregnancy

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To establish institutional normative data on human chorionic gonadotropin (HCG) titers and ultrasound (U/S) images during early pregnancy.

Technical Approach:

U/S examination was recognized as an appropriate and reasonably safe procedure during pregnancy. All epidemiological studies support the safety of diagnostic U/S exposure in humans; however, after all available information was reviewed, the concensus was that ultrasound examinations during pregnancy should be performed for a specific medical indication.

Pregnant patients having ultrasound examination of the pelvis for obstetrical indications during their first trimester of pregnancy will be invited to give a 3-5 ml blood sample. The latter will be assayed for b-HCG immunoreactivity in our RIA laboratory, utilizing a RIA system presently in routine use. This RIA system is based on a monoclonal antibody specific for the bHCG subunit for HCG. It has been shown to be highly specific and sensitive for HCG.

U/S examinations will be performed in the ultrasound section of the Department of Obstetrics/Gynecology. One ultrasonographer will be utilized in order to limit interobserve differences.

Progress:

Principal investigator was reassigned and the project was closed with no progress.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/19 Status: Terminated
Title:

A Comparison of PO Vibramycin with IM Cefazolin Prophylaxis in Vaginal Hysterectomy

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ K. Kiley, MC

Dept/Sec: Obstetrics/Gynecology Assoc Investigators
Key Words:

Vibramycin, Cefazolin

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

To compare the effectiveness of a cephalosporin to tetracycline in vaginal hysterectomy.

Technical Approach:

Approximately 100 patients undergoing vaginal hysterectomy will be included in the study. Patients will be counselled as to the need for antibiotic prophylaxis and the nature of the study. Each will then sign an informed consent. Upon entering the study the patient will be randomly assigned to one of the two antibiotic regimens by the pharmacy. On call to the OR, the patient will receive both an injection and capsules with either 200 mg Vibramycin or 1 gm Cefazolin. The study will be doubly blinded with respect to the physicians, nurses and patients. Patients with allergies to either antibiotic will be excluded from the study.

Progress:

Principal investigator was reassigned and the project was terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/38 Status: Completed

Title:
Prolactin and Thyrotropin Responses to Nursing During Early Puerperium

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT D. Gehlbach, MC

Dept/Sec: OB-GYN Assoc Investigators

Key Words:

Prolactin, Thyrotropin

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To investigate whether thyrotropin-releasing hormone acts as a physiologic prolactin-releasing factor by measuring prolactin and thyrotropin levels during nursing in the first postpartum month.

Technical Approach:

Women with normal physical exams, who have no active medical problems, are on no medication other than vitamin or iron supplements, and who plan to breastfeed a minimum of five weeks, will be invited to participate. A scalp vein needle will be used in a suitble forearm vein. Two baseline samples will be collected and serial samples will be obtained every 15 minutes for 45 minutes during the nursing episode (total blood collected will be approximately 50 ml). After clotting at room temperature, serum will be separated by centrifugation and stored at -20°C until sent as a single batch for assay of prolactin and TSH in the WBAMC RIA laboratory.

Each patient will be studied during three separate time intervals: postpartum days 2-3, 10-14, and 28-35. Total blood collection per patient for this study will be 150 ml (3cc/g). Additional support will include use of blood sampling materials stocked on Ward 4P, and hormonal assay by the WBAMC RIA laboratory. Two-tailed Student's t-test for comparison of means will be used for data collection. The experimental phase of the study should encompass approximately three months to study between ten and fifteen subjects.

Progress:

Thirteen lactating women with uncomplicated pregnancies and deliveries were recruited. Blood samples were drawn at -15, 0, 15, 30, and 45 minutes during nursing on three separate occasions. Period 1 on postpartum days 2 or 3; Period 2 on days 7-10; and Period 3 on days 28-35. Serum was removed by centrifugation and stored frozen at -20°C. All samples were assayed in single batch for PRL and TSH. Comercially available, hormone specific, RIA kits were utilized.

Of the 31 sampling sessions, 19 (61%) showed a rise in PRL greater than 100% over its baseline value. A marked variation in PRL release was noted among individuals and between sampling periods. TSH showed no significant rise over baseline during nursing in any of the sampling sessions, even when the sessions with a high PRL release were considered independently.

Our data fails to show any increase of TSH during suckling in the early postpartum period. This finding fails to support the contention that TRH is a physiologic PRL-RF.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/57 Status: Ongoing

Title:
Histopathologic Grading of Squamous Cell Carcinoma of the Cervix

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC R.J. Stock, MC

Dept/Sec: OB/GYN Assoc Investigators

Key Words:

Cervical carcinoma

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Evaluate Stendahl's histopathologic malignancy grading system for squamous cell cancer of the uterine cervix. Modify Reagan's classification for squamous cell carcinoma of the cervix and compare with Stendahl's system. Use the two systems to see if there exists a better means for assessing the potential aggressiveness of squamous cell carcinoma of the human cervix as relates to stage of disease and age at presentation.

Technical Approach:

Review of all histologic materials and classify as to adequacy of histologic material. Modification of Reagan and Wentz classification in large cell nonkeratinizing and large cell keratinizing. The two classification systems will be evaluated with respect to age, presenting stage of the lesion and equated with the prognosis.

Progress:

This is a newly activated study with no progress to report as of this date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/60 Status: Ongoing

Title:
Interactions Between Aminoglycoside Antibiotics and Vitamin B6 *in vitro* and *in vivo*

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ R.C. Keniston, MC

Dept/Sec: Dept Pathology Assoc Investigators

Key Words:

Aminoglycosides; Vitamin B_6

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To develop a method for isolating and quantitating aminoglycosidepyridoxal-5'-phosphate complexes. To isolate these complexes from the urine of patients receiving the aminoglycoside antibiotics. To determine if depletion of vitamin B6 occurs in patients receiving aminoglycoside antibiotics, and if so, how this depletion correlates with morbidity and mortality.

Technical Approach:

Subjects will be patients who are to be given aminoglycoside antibiotics for clinical indications (sepsis, serious gram-negative infections, etc). These patients should also have SMAC 20 chemistry screens and monitoring of their aminoglycoside levels (procedures already routinely performed). The blood and urine samples from at least 30 patients will be examined.

Progress:

Mortality rate for patients who were monitored but not toxic was 12 times the mortality for the unmonitored patients; the mortality for those monitored patients who were toxic was 36 times the mortality of the unmonitored group. The higher mortality for the monitored persisted across 7 of the 9 patient groups (Chi squre, $p = 0.010$ or less). Furthermore, the mortality for patients who were toxic but not infected (6/30 or 20%) was equal to the mortality for the patients who were bacteremic but who did not receive aminoglycosides (34/170 or 20%). Thus, it appears that aminoglycoside toxicity is associated with increased mortality rate, independent of severity of illness or infection status.

Detail Summary Sheet

Date: 1 Oct 85 Prot No:83/34 Status: Ongoing

Title:

Utilization of Robotics in the Laboratory

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT P.H. Cordes, MC

Dept/Sec: Dept Pathology Assoc Investigators

Key Words:

Robotics

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To investigate the uses of a simple robot in application to menial and repetitive tasks within the laboratory. To determine whether such applications might be cost effective. To determine what other applications might be feasible and cost effective in the laboratory with more sophisticated robots.

Technical Approach:

a. Purchase robot.
b. Build robot (time frame 1-2 weeks).
c. Begin investigation.

(1) Develop application to routine histological staining. A routine and repetitive task requiring only simple programming sufficient for familiarization with the machine (time frame 2-3 weeks).

(2) Develop application to production of microbiological media. A routine and repetitive task requiring more detailed manipulation of the robot arm and more than one program in order to deal with more than one media type (time frame 1-2 months).

(3) Develop and test application for delivery of laboratory specimens from receipt to the appropriate section. A routine task requiring intensive programming in robot navigation, obstacle avoidance, motion detection and voice output (time frame 3-6 months).

(4) Implement other possible uses that become apparent during utilization of the robot, but which are unforeseen at this time.

d. Evaluation.

(1) Reliability: The ability of the robot to perform a task more than once without reprogramming. Also an estimation of mean time between failures of the hardware.

(2) Suitability: Is this particular robot suitable for this job and/or environment? Would a more sophisticated robot be suitable?

(3) Cost effectiveness: Is the robot cost-effective in each of the above implementations? Would a more sophisticated robot be cost effective?

e. Reporting of results: Writing of an article for publication and/or presentation to laboratorians at a conference.

Progress:

Preliminary experimental work has begun with special stains and ultrasonic ranging.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/11 Status: Completed

Title:

Equal Employment Opportunity Attitudes of Laboratory Technicians Working Under a Stress Factor

Start Date: Est Comp Date:

Principal Investigator: Facility:

K. M. Hudry, DAC

Dept/Sec: Pathology Assoc Investigators

Key Words:

Stress, EEO LTC William York, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

This study is a comparison between the male and female attitudes of laboratory bench workers concerning EEO. The stress factor under investigation is the shortage of personnel.

Technical Approach:

A survey will be distributed to approximately forty laboratory bench workers at William Beaumont Army Medical Center. These workers will be civilians and military ranging in age from 18-50 years. The only distinction between the workers that will be evaluated is the sex of the workers. The data will be collected and compiled into rank averages and a T-test will be computed by the investigators.

Progress:

The t-statistic for a two-tailed test at a 95% confidence level is approximately 2.030. The calculated t-statistic was -0.2490. Further calculations indicated that the probability of a value occurring greater than -0.2490 was less than 80.018%. Therefore, using the averages for each question, the null hypothesis, H_0 $u_1 = u_2$, cannot be disproved at this level.

The questionnaire response was evaluated from the overall response. In general, positive responses were received from the EEO section of the questionnaire. The respondents felt that there was virtually no sex, age, or racial discrimination. It was also felt that handicapped personnel were not discriminated against and provisions were made for special accommodations. Laboratory

personnel felt comfortable with EEO policies. They were aware of grievance procedures. They realized that supervisors complied with EEO regulations as well and that EEO representatives were accessible to all personnel.

One of the areas that showed a negative response was the question that dealt with promotions due to merit and ability. Personnel indicated, on the average, that promotions were not due to merit. Moreover, the question of being promoted on senority drew a middle of the road response. The answers obtained from the survey did not determine how promotions were received.

The stress questionnaire revealed some interesting attitudes and problems in the laboratory. The survey indicated that there was a lot of tension and worry on the job. Other responses indicated that there were also annoying distractions in the work area.

Personnel indicated that they were uncomfortable at work. This was indicated when negative responses were received regarding ventilation, temperature, layout of the work area. Even with these types of problems in the laboratory, males and females indicated they they were able to discuss problems with their supervisors.

Even though it has been assumed that male and female responses were the same on the survey, the Standard Deviation Index indicated that there were differences in the strength of male and female responses. The three questions the males felt strongly about were examined closely.

Regarding the questions dealing with the idea that the organization provided opportunities for women, it was interesting that the males felt more strongly than the females that the organization had made progress in providing opportunities for women.

The males indicated that the layout of their work space was convenient. They also felt more comfortable discussing personal problems with their supervisors.

The females indicated strong feelings in the areas of age and minority discrimination. The females felt that there was little age discrimination and that job opportunities were provided for minorities. The SDI also indicated that females felt more irritation at work than males.

The SDI between civilian and military workers also yielded interesting results. Civilian workers indicated strong response regarding age and minority discrimination. They felt there was little of this type of discrimination occurring in the laboratory. The civilian workers also emphasized that they were more aware of the formal method for filing grievances.

There were four strong military responses regarding the stress questions. The military indicated that the work they performed did not interfere with their personal lives, they were fairly free from distractions, and their work space was convenient.

One of the most interesting comparisons between military and civilian responses was the question regarding discussing personal problems with their supervisors. With the high SDI of 12.084, the military strongly indicated that they were able to discuss personal problems with their supervisors easier than the civilians.

CONCLUSION:

According to Giordano and Everly, a few indicators of stress include changes in one's mood or disposition. These can be demonstrated by worry, nervousness, or overexcitability.

The survey indicated that some of these symptoms are apparent in the WBAMC laboratory. Worry and tension on the job are examples of this. There are ways to control stress in the work area. These can include the following: 1) Effective time management. 2) Delegation of responsibility. 3) Reduction of the task. 4) Know the optimal stress level. 5) Avoid exposure. 6) Enlist support of others. 7) Accept falibility.

Currently the laboratory at WBAMC is hiring additional personnel to reduce the workload per person. Re-arrangement of the work areas is being planned to increase the effectiveness of individuals. Reorganization of the management structure is being effected so that more effective delegation of responsibility will be made.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/09 Status: Terminated

Title:
An Evaluation of the Effects of Theophylline and Beta Adrenergic Medication on the Auditory Processing Ability of Children

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT G.V. Gwinn, MC
CHANGE INVESTIGATOR TO MAJ A.W. Atkinson, MC

Dept/Sec: Dept Pediatrics Assoc Investigators

Key Words:

Theophylline

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine if the use of theophylline or beta adrenergic medications qualitatively or quantitatively affect the auditory processing abilities of children.

Technical Approach:

Twenty asthmatic children currently requiring continuous therapy with theophylline will be entered into the study. Serum theophylline levels will be checked to ensure that they are in the generally accepted therapeutic range of 10-20 micrograms per milliliter.

Each child will be evaluated using the Revised Token Test administered by personnel from the University of Texas at El Paso Speech, Hearing and Language Center. The reliability in the administration of this test is verified to be greater than 98%. The testers will be unaware of which medical regimen the children are on during any of the testing encounters.

Patients will then have their theophylline therapy discontinued and be placed on an inhaled beta-2 agent (Albuterol 180 micrograms) four times daily. Clinical experience suggests that most patients do equally well on this regimen. After one week on this new regimen, the testing will be repeated.

Patients whose clinical condition suggests that their asthma would be adequately controlled on inhaled beta-2 medication taken on an as needed basis will be placed on Albuterol every four to six hours as needed. After one week, they will be retested.

During the fourth week, the subjects will have the inhaled bronchodilators discontinued and once again be placed on their

theophylline regimen. After one week they will be tested once again.

The patient's pulmonary condition will be monitored by a diary sheet and twice daily Peak Expiratory Flow Rates. Conventional spirometry and flow volume determinations will be determined weekly.

After the results are analyzed each child will be placed on the regimen which gave best control of asthma and the least CNS effects.

The theophylline preparations used in this study will be whichever preparation the patient is taking on initiation of the study.

Statistical analysis will be done with nonparametric and parametric testing as deemed proper by our statistical consultant.

Progress:

Dr. Gwinn has been transferred and MAJ A.W. Atkinson, MC, has been unable to pursue the study, the project has been terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 82/43 Status: Completed

Title:
Adolescent Immunity to Varicella and Cytomegalovirus

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC M. Schydlower, MC

Dept/Sec: Dept Pediatrics Assoc Investigators

Key Words:

Varicella; Cytomegalovirus

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the immune status of adolescents age 13-17 years to varicella and cytomegalovirus.

Technical Approach:

Each year, May through August, days are set aside at WBAMC for school and sport physical examinations for military dependent children and adolescents as required by the local schools. Approximately 300 adolescents are examined on these days. Sera will be collected from approximately 150 adolescents and analyzed for seronegativity for varicella by complement fixation and neutralization tests. Sera will also be tested for cytomegalovirus by complement fixation and anticomplement immunofluorescence. The laboratory of Dr. Philip Brunell at the Department of Pediatrics, University of Texas Health Science Center, San Antonio, will test for varicella, and the laboratory of Dr. Martha Yow, Department of Pediatrics, Baylor University in Houston, will test for CMV. Both are experts in the study of these viruses. The data obtained will be correlated with age, sex, ethnic background, rank (as an index of economic background) and history of disease. Approximately 5 cc of blood will be obtained by venipuncture after obtaining appropriate informed consent.

Progress:

During recent school physical examinations 32 of 107 military dependent American adolescents had a negative history for varicella. Twenty-one were female and 11 were male, ranging in age between 12 and 19 years. Serum samples from those with negative histories were assayed with the FAMA technique. Varicella

fluorescent antibody to membrane antigens. All samples were positive for varicella specific antibody at screening dilutions of 1:4 and 1:8. Our data suggest that up to 100 percent seroreactivity is reached by mid-adolescence in some urban subpopulations. Also a negative history for chickenpox is not reliable in determining susceptibility to varicella infection.

This was presented as a poster session at the American Academy of Pediatrician Meeting, October 1985.

Table

Title: Seroepidemiology of CMV in Texas teenagers

Category	No. of subjects	No. CMV-seronegative (%)	No. CMV-seropositive (%)
Income			
Lower	58	15(26)	43(74)
Middle	133	97(73)	36(27)
Girls			
Pregnant	83	32(39)	51(61)
Nonpregnant	62	43(69)	19(31)

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/48 Status: Terminated

Title:
Use of an Enzyme-Linked Immunosorbent Assay(ELISA) for Detection of Microabluminuria

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC Richard A. Banks, MC

Dept/Sec: Dept Pediatrics Assoc Investigators

Key Words:

ELISA; Serum albumin

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To evaluate the reliability of an ELISA in measuring microalbuminuria in patients with insulin-dependent diabetes mellitus (IDDM), in an effort to detect early changes in renal integrity.

Technical Approach:

There will be several phases in the overall investigation which is proposed. The initial phase will be the development of a reliable and sensitive ELISA for urinary albumin in the range of 10-1000 ng/100 ul. ELISA has been shown to detect antigen concentrations down to 1 ng/ml. Specifically, an attempt will be made to develop both a direct competition and double antibody sandwich assay as described in a standard methods manual for ELISA.

A direct competition ELISA will be performed by attaching anti-human albumin to the microplates with a coupling buffer, and then overlaying these with an unknown amount of unlabelled albumin and a known quantity of horse-radish peroxidase (HRP)-tagged albumin. In the double antibody sandwich technique, goat anti-human albumin is attached to the plates, overlayed with an unknown quantity of albumin. This is washed off after a fixed period and rabbit anti-human albumin antibody added. After incubation, this is removed and goat anti-rabbit immunoglobulin antisera tagged with HRP is added. In both assays a substrate is added and the color change, which occurs, is quantitated. Standard curves are then drawn up.

After the procedures have been established, reproducibility and recovery studies using the scheme outlined by Barnett et al will be performed. This consists of 20 once-a-day analyses of a standard aqueous solution of human albumin, and recovery studies in triplicate at three different levels. A protein determination using the BIORAD Kit will be done at the same time to serve as the reference method. Once sensitivity and reliability have been investigated, one of the techniques will be selected for the next phase.

If the initial phase is successful, urine samples obtained from patients with IDDM will be studied. To ensure the availability of adequate samples, aliquots of 24-hour urine collections will be obtained on pediatric patients with IDDM who are followed by the Pediatric Endocrine Clinic WBAMC and University of Florida, Gainesville. These samples will be submitted ao analysis of microalbuminuria, creatinine, and beta-2-microglobulin. A separate protocol will be submitted prior to initiation of this phase of the study.

Progress:

Study is terminated due to reassignment of principal investigator to Tripler AMC.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/08 Status: Ongoing

Title:

Effects of Ritalin on Self-Concept of Children with Attention Deficit Disorder and Hyperactivity.

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ Melvin L. Cohen, MC
Change of Principal Investigator to MAJ A.W. Atkinson, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

MAJ P.C. Kelly, CO

Ritalin
Attention Deficit Disorder

MAJ A.W. Atkinson, MD
DR. Owen Caskey, PhD

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Objectively measure the effects of Ritalin on the self-concept of children with Attention Deficit Disorder and hyperactivity over a short period of time.

Technical Approach:

In a double-blind approach, patients are treated with Ritalin or placebo for one month and then crossed over. They are tested for self-concept, teacher and parent ratings, and performance on the Gordon Diagnostic System and Central Auditory Processing functions before any medication is given, as well as while on both Ritalin and placebo.

Progress:

Data continues to be accummulated. Project is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/25 Status: Completed

Title:

Adolescent and Pediatric Care Delivery at Army Medical Treatment Facilities

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ W.K. Imai, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

Care Delivery

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

This study will characterize health care delivery to dependent children in Army Medical Treatment Facilities. It will delineate the extent to which we make care available to adolescents, and in so doing, serve as a guide to pediatric training programs and treatment facilities.

Technical Approach:

We proposed to study the current status in order to better prepare the training programs and the trainees for the future, as well as an aid to individual MTF's for optimum provision of adolescent and pediatric health care.

Subjects: Fifty-seven Pediatric and Family Practice Services at MEDDAC's and six medical center Adolescent Medicine Services.

Phases: Survey distribution and collection. Collation and interpretation of results. Service specific survey forms will be utilized. No controls are necessary.

Progress:

The study has been completed, results were presented informally. A manuscript is in preparation.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/64 Status: Ongoing

Title:

Use of the Gordon Diagnostic System to Measure Changes in Attention Deficit Disorder Treated with Ritalin.

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ Melvin L. Cohen, MC
Change Principal Investigator to MAJ A.W. Atkinson, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

MAJ P.C. Kelly, DO

Attention Deficit Disorder MAJ A.W. Atkinson, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

It is often difficult to determine, clinically, the appropriate dose of Ritalin for children with Attention Deficit Disorder. This study will assess the ability of the Gordon Diagnostic System to measure improvement or deterioration in children with ADD who are treated with Ritalin.

Technical Approach:

Thirty children with ADD and hyperactivity will be given either placebo or Ritalin in double blind fashion. In addition to studies already planned, each child will be tested with the GDS at the time his diagnosis is initially confirmed. He will be tested again after one month of Ritalin or placebo, and a third time one month after the crossover occurs. Using a special commercial computer program, both tasks of the GDS will be analyzed for variation of performance during the test period. Results will be compared for the following parameters: Delay task - (a) rewards, (b) responses, (c) efficiency ratio; and for the vigilance task - (a) correct responses, (b) omissions, (c) commissions, and (d) task monitoring data. These data will be compared for response on or off medication.

Progress:

A total of 21 patients were enrolled prior to the end of the last school year. Statistical analysis of those data are underway. Departure of the principal and one associate investigator will result in a new principal investigator being assigned. The study is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/65 Status: Ongoing

Title:

Diagnosis of Attention Deficit Disorder Using a New Objective Measure of Impulsivity and Sustained Attention

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ A.W. Atkinson, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

MAJ P. Kelly, MC

Attention Deficit Disorder MAJ B. Ting, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To assess the ability of the Gordon Diagnostic System (GDS) to diagnose attention deficit disorder (ADD) compared to standard, customary procedures used in developmental pediatrics.

Technical Approach:

Military dependent children between six and eleven years of age referred to the Developmental Pediatric Clinic by parents, physician, or school for evaluation of school or behavior problems will be voluntarily enrolled in the study. In addition to customary evaluation procedures, the child will be evaluated with the GDS (approximately 17 minutes). Developmental and medical history, neurodevelopmental examinations, observations, teacher, and parent behavioral questionnaires, and consultations, as needed, will be used to make the diagnosis (according to the DSM III) and formulate a management plan as usual. Use of stimulant medication will be based solely on customary diagnostic criteria. Testing with the GDS will be repeated twice at two month intervals, and once more six months from the start. Using a special commerical computer program, both tasks of the GDS will be analyzed for variation of performance during the test periods (four, two minute blocks for delay and three, three-minute blocks for vigilance tasks). Results will be printed in numerical lists as well as bar graphs for the following parameters. Delay task - (a) rewards, (b) responses, (c) efficiency ratio; and for the vigilance task - (a) correct response, (b)

omissions, (c) commissions, and (d) task monitoring data. These data are used in identifying differential responses of individual patients. Response to management will be judged in the routine fashion using standardized questionnaires as well as history and performance in school. The project will run until a minimum of fifty children with the diagnosis of ADD/ADD-H have been evaluated and followed for six months. At that time data will be collated from all patients to assess the following: (1) comparison of clinical diagnoses of ADD/ADD-H with performance on GDS, (2) comparison of all children 'diagnosed" by GDS as ADD with their clinical assessment, (3) for all children treated with stimulant medication, a comparison of their GDS scores before and after treatment, looking for correlations with positive and adverse responses, and (4) correlation of teacher/parent questionnaires with results on the GDS. Data will be analyzed statistically by a multivariate analysis of variants.

Progress:

Data continues to be accumulated on this study. The project is ongoing.

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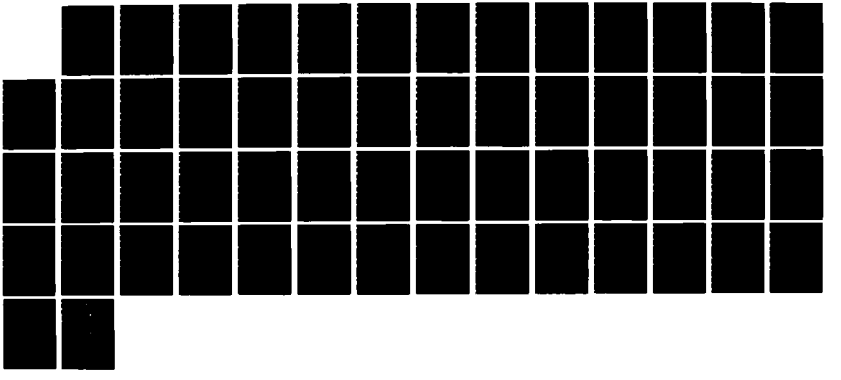

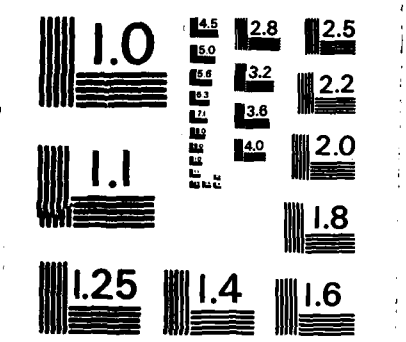

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/06 Status: Completed

Title:
Skin Testing for Penicillin Allergy: A Collaborative Study

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT C.A. Borchert, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:
Penicillin, Allergy

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine whether penicillin skin testing can induce penicillin sensitivity in nonpenicillin allergic subjects. To determine whether oral penicillin treatment can induce penicillin sensitivity in patients with past history of penicillin allergy and negative penicillin skin tests.

Technical Approach:

All dependents less than 21 years of ago who have a positive history of allergic reactions to penicillin or its analogs, will be the study group, approximately 300 subjects.

After informed consent has been obtained, the patient will be skin tested in the Allergy Clinic where experienced personnel and emergency medicines and equipment exist. Those who have a positive skin test will be considered allergic to penicillin and no further testing will be done. Those who are skin test negative will then be given 4×10^4U of penicillin suspension orally and observed for 30 minutes. If there is no reaction to oral penicillin, then those greater than three years of age will be given 4×10^5U penicillin suspension and those less than three years of age will be given 2×10^5U penicillin suspension and observed for 45 minutes. At this time, if there is still no reaction, they will be given a ten-day oral challenge of penicillin (2 or 4×10^5U penicillin suspension or tabs tid). Parents and patients will be instructed to discontinue the penicillin and notify the Allergy Clinic if any reaction occurs during therapy. After the ten-day course, they will be requested to return 4-6 weeks later to be skin tested again.

Progress:

Data has been gathered and analysis is pending. Over 200 patients were enrolled in the study with no adverse reactions.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/13 Status: Completed

Title:
Clinical Efficacy of Latex Agglutination Reagent for Detection of Group A Streptococcus

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL R. Lampe, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:
Streptococcus detection

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the efficacy of the Culturette Brand 10-minute Group A Strep ID on pharyngeal swabs by comparison to the identification of Group A Streptococci by the standard laboratory methods. The second objective will be to compare the usefulness of this test in the clinical setting with rapid detection versus the labortory setting.

Technical Approach:

Children who are seen by the three physician investigators in whom it is felt a throat culture is necessary will have a throat swab performed and the throat swab placed on blood agar plates and streaked; then the throat swab will be processed according to the Marion Laboratories recommendations. The number of Group A Streptococci will be read at 24 and 48 hours after aerobic incubation at 35°C. Beta-hemolytic colonies will be subcultured onto blood agar plates with a bacitracin disc (0.04U) and any zone of inhibition will be interpreted as presumptive Group A Streptococci. Approximately 100 positive Group A Strep throat cultures will be compared in this fashion. It is planned that the first 50 will be carried out principally in the Pediatric Clinic. The remaining 50 will be done by the Laboratory. Marion Laboratory will analyze the results comparing the rapid Group A Strep ID versus throat culture results and William Beaumont AMC will compare the usefulness and problems encountered, having the rapid Group A Strep ID test available in the clinic versus the standard culture system as it presently exists. It is not intended that the rapid test will be used in making clinical therapeutic decisions as a part of this study.

Progress:

Results of this study will be presented at a professional meeting in March 1986. Two thousand one hundred and sixty-five throat cultures have been studied. Three hundred and twelve throat swabs were positive by the standard culture method and confirmed by grouping. The Group A Strep I.D. was positive in 203 of these (sensitivity 65.1%). One thousand eight hundred and fifty-three were negative by the standard culture method. The Group A strep I.D. was negative in 1,822 of these (specificity 98.3%). The positive predictive value (PPV) of the Group A strep I.D. was 203/234 (86.8%) and the negative predictive value (NPV) was 1822/1931 (94.4%). A comparison between the Group A strep I.D. and bacitracin results with serogrouping as the standard is presented in the table. Eighty-five of 109 (80%) of the false negatives with the Group A strep I.D. had growth of less than 50 colonies and possibly represent colonization

	Sens	Spec	PPV	NPV	Accuracy
Group A I.D.	65.1	98.3	86.8	94.4	93.5
Bacitracin	81.4	98.8	91.7	96.9	96.3

The failure of the Group A strep I.D. to identify these patients with light growth contributed to the low sensitivity of the Group A strep I.D. The Group A strep I.D. is simple and easy to perform. The Group A strep I.D. technique was useful in a large ambulatory setting. The accuracy is comparable to culture and bacitracin disc methods of identification. Rapid identification eliminates the need to contact and have patients return for appropriate therapy. The likelihood of continued streptococcal spread pending standard culture results is also reduced.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/17 Status: Terminated

Title:
Serological Survey of Epstein-Barr Virus Infections Followed Over a 12-Month Period

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT C.A. Borchert, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

Epstein-Barr Virus

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the incidence of positive Epstein-Barr virus (EBV) serology among adolescents in a military population. To determine the rate and nature of seroconversion over a one-year period.

Technical Approach:

Adolescents, 13-21 years of age, who seek medical care through the Adolescent Clinic at WBAMC, will be the patient population. The average yearly census of adolescents seen in our clinic is 17,000. It is expected that 100 patients will be needed for this study. These patients include male/female, caucasian/black/hispanic, and a wide range of socioeconomic classes. A questionnaire will be used to determine if symptoms of past exposure to EBV has occurred and if any symptoms or signs of chronic infection exist. Informed consent will be obtained for entry into the study. Sera is to be collected on all groups and sent to University of Texas at San Antonio, for analysis of EBV serology. These patients will then be divided into four groups: (1) negative serology, (2) convalescent serology (IgG-VCA and IgG-EBNA positive), (3) acute serology (IgM-VCA, IgG-VCA, IgG-EA positive), and (4) chronic infectious serology (IgG-VCA, IgG-EBNA, IgG-EA, and/or IgM-VCA positive). Those in Group 1 will then be restudied (IgG-VCA, -EBNA, -EA) at the end of the twelve months to determine seroconversion. Those in Group 2 will be restudied at three, six, nine, and twelve months to determine if serology changes. Those in Group 3 will be studied at one, three, six, nine, and twelve months. Those in Group 4 will be studied at one, two, three, six, nine, and twelve months to examine the immune response over time. Throat washing will be obtained on

all groups at the same time intervals as specified, and sent to the University of Texas at San Antonio, for tissue culture of EBV. The data will be used for a descriptive analysis of serologic status at inception of the study and for frequency and direction of seroconversion.

Progress:

Reluctance of volunteers to consent to repeated venipunctures precluded completion of this project.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/28 Status: Completed
Title:

Duration of Group A Streptococcal Antigen in the Pharynx of Patients with Group A Streptococcal Pharyngitis

Start Date: Est Comp Date:
Principal Investigator: Facility:

COL R. Lampe, MC

Dept/Sec: Pediatrics Assoc Investigators
Key Words:

Streptoccal antigen

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

Determine the duration of Group A streptococcal antigen in the pharynx of patients with Group A streptococcal pharyngitis. This will be done by detecting the presence of Group A streptococcal antigen as detected by a latex agglutination reagent on sequential days in patients who are initially diagnosed as having Group A streptococcal pharyngitis by both latex agglutination and by standard throat culture. This information is important since the detection of antigen in the pharynx of patients under treatment may allow the etiologic diagnosis of the pharyngitis to be made while patients are on antibiotics.

Technical Approach:

Patients who present to the Pediatric Clinic with pharyngitis will have a throat swab performed, swabbing the left tonsil or left tonsillar area, the posterior pharynx, and the right tonsil or right tonsillar area. The swab will then be plated on blood agar and streaked and the throat swab will be processed according to the Marion Laboratories recommendation for the latex agglutination detection. The number of Group A streptococci will be read at 24 hours after aerobic incubation at 35°C. Beta hemolytic colonies will be subcultured onto blood agar plates with a bacitracin disc (0.04 units) and any zone of inhibition will be interpreted as presumptive Group A streptococci. Approximately ten patients with 4+ latex agglutination reactions will be studied. In addition, ten patients with 3+ latex agglutination reactions will be studied; ten 2+ and ten 1+ will be studied. After proper informed consent, these

patients will be treated with oral penicillin, 25,000 units per kilogram per day in three to four divided doses for ten days. If the patient is allergic to penicillin, they will be treated with erythromycin, 40 mg/kg/day in three to four divided doses. The patients will be asked to return daily for repeat throat culture. After two consecutive throat cultures which are negative for Group A streptococcal antigen by the latex agglutination reagents, there will be no further throat cultures. The data analysis will be to compare the duratrion of antigen and the positive throat cultures in each category of treated patients.

Progress:

Thirty-nine patients were completely studied. All patients were treated with antibiotics (31 oral penicillin, 3 erythromycin, 3 amoxicillin, 1 clindamycin, and 1 benzathine penicillin). Group A streptococcal antigen was present in 2 of 39 patients on the day following initiation of treatment. One of 39 patients grew Group A streptococci on the day following the initiation of treatment and this patient was positive also for Group A streptococcal antigen. On the second day none of the 23 patients examined had Group A streptococcal antigen detected nor a positive culture. The conclusions were that duration of detectible Group A streptococcal antigen is brief (less than 24 hours in 37 of 39 patients) in treated patients. Group A strep ID Kit should not be used to exclude Group A streptococci as an etiology of pharyngitis in patients on antibiotic therapy.

DURATION OF GROUP-A STREPTOCOCCAL ANTIGEN IN THE PHARYNX OF PATIENTS WITH GROUP-A STREPTOCOCCAL PHARYNGITIS

Patients had a throat culture performed, swabbing left and right tonsil and the posterior pharynx. This culture was plated on blood agar and incubated aerobically at 35°C overnight. Serogrouping with Phadebac (Hersteller Pharmacia Diagnostics) was used to confirm presumptive group-A.

Group-A streptococcal antigen presence was determined using the commercially available Culturette Brand 10-minute Group-A Strep ID Kit (Marion Scientific Corporation, Kansas City, MO).

Thirty-eight patients were studied. All patients were initially positive for group-A streptococcal antigen and were treated with antibiotics (30 penicillin, 3 erythromycin, 3 amoxicillin, 1 clindamycin, 1 benzathine penicillin).

Group-A streptococcal antigen was detected in the throat culture of only two of 38 patients on the day following initiation of treatment, and one of the 38 throat cultures was positive for group-A streptococcus. On the second post-treatment day, none of 23 patients examined had group-A streptococcal antigen detected, nor a positive culture.

The duration of detectable group-A streptococcal antigen in patients initially positive and treated with appropriate oral antibiotics is brief (less than 24 hours in 36 of 38 patients).

The Group-A Strep ID Kit should not be used to exclude group-A streptococci as an etiology of pharyngitis in patients on appropriate oral therapy.

EXHIBITORS: Richard M. Lampe, M.D., FAAP, Robin Goodman, M.D., Michael Shoemaker, M.D., Department of Pediatrics; Ann Brady, SP5, Michael R. Weir, M.D., FAAP, Department of Clinical Investigation; and Ed Morales, DAC, Microbiology Service, Department of Pathology, William Beaumont Army Medical Center, El Paso, TX 77920-5001

Poster presentation at the American Academy of Pediatrics, San Antonio, TX,

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/29 Status: Ongoing

Title:

Serologic Response Among Patients with Non-Group A Beta-Hemolytic Strep Throat Infections

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL R. Lampe, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

Strep Throat Infections

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Examine the serologic response among patients who have positive throat cultures for beta hemolytic streptococci that are non-Group A. Certain groups of streptococci are recognized to cause pharyngitis in addition to the most common Group A streptocci. Principally, these streptococci are Group C and rarely Group B. There are no studies indicating the serologic response to streptococcal antigens among patients with throat infections due to streptococci other than Group A. We propose to examine the serologic response of these patients based on acute and convalescent titers to determine whether there is a serologic response to infection.

Technical Approach:

As part of an ongoing study of the Group A strep infections in children in the Pediatric and Adolescent Clinic, a rapid latex agglutination for Group A streptococci is employed and, in addition, this technique is compared to standard throat culture. As part of the quality control to assure that the beta hemolytic streptococci isolated from the throat are Group A, serologic grouping is done on all beta-hemolytic streptococci isolated from throat cultures. Group B, Group C, Group G, Group F, and nongroupables are thus identified. We propose to obtain blood samples acutely and three weeks later from patients who have non-Group A beta-hemolytic streptococci isolated from their throat. The decision with regards to therapy will be a clinical decision based on the attending physician. If treatment is employed, it will be penicillin 25,000 u/kg/day in 3-4 divided doses for ten days. If the patient is allergic to penicillin, they will be treated with erythromycin, 40 mg/kg/day in 3-4 divided doses for ten days.

The acute and convalescent sera will be stored at -20° and subsequent determinations of the following streptococcal serology will be performed: (1) streptozyme, (2) ASO antistreptolysin O, (3) anti-DNA'se B, (4) anti-hyaluronidase, (5) anti-NAD'se B, and (6) group specific antibody. It is anticipated that ten patients with Group B, ten patients with Group C, ten patients with Group G, and twenty patients with non-groupable beta-hemolytic streptococci isolated from their throat cultures will be studied in this fashion.

Progress:

Eighteen acute and 11 convalescent sera have been drawn. Progress has been slow but steady. This project is not likely to be completed without personnel from DCI in Pediatrics to support the project.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/31 Status: Ongoing

Title:

ECG Standards for Adolescents Based on Tanner Staging

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT E. Stafford, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

ECG Standards

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To establish ECG standards for healthy adolescents based on Tanner staging which measures biologic age rather than chronologic age. The new standards will allow a more narrow definition of normal.

Technical Approach:

We propose to obtain ECGs on all consenting patients presenting to the Pediatric and Adolescent Clinics for school or sports physicals, between 10 and 21 years old. Tanner staging will be assessed by examiners with drawings of Tanner stages. Complete physical exams will be performed and subjects with evidence of chronic illness or heart or lung disease will be excluded. Furthermore, a questionnaire is to be completed by each subject which elicits additional information on athletic activities and tobacco exposure. Patients will be sent to the Cardiology Clinic upon completion of the physical exam for ECG to be performed by trained ECG technicians.

Progress:

Statistical analysis of the pilot study in 150 subjects has been completed. An additional 300 subjects will be entered for further statistical analysis. The study is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/39 Status: Ongoing

Title:

Efficacy of the CHILDPACE Developmental Inventory Compared to Denver Developmental Screening Test Battery

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ S.W. Brown, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

CPT Graham Pereira, MC
Developmental Screening LTC Richard Banks, MC
MAJ A.W. Atkinson, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine the reliability of a newly available computerized child development inventory which is administered by the parent, as compared to the Denver Developmental Screening Test (DDST), the Denver Prescreening Questionnaire (PDQ) and the Denver Developmental Screening Test-Revised (DDST-R). These three tests are standardized and widely utilized by health care providers.

To determine the feasibility of using this computerized instrument in the outpatient setting of a busy Pediatric Service with the goal of maximizing available manpower.

Technical Approach:

Those subject evaluated by CHILDPACE will also be screened by the PDQ, DDST-R, and DDST. The pstient population will be volunteers taken from the Beaumont Well Baby Clinic and the General Pediatric Clinic whose ages fall within the appropriate confines. In addition, select patients from the Special Well Baby Clinic will be screened as a high risk sample population. For this study, standard training techniques will be employed with attainment of interrater reliability of greater than 85%. All evaluations will be done on the same day to provide for concurrent correlation. The CHILDPACE and Denver battery will be presented in a counterbalanced order. After a representative sample has been collected, (N=10 per age group, i.e. 6,12,18,24,36,48 and 60 months) the results will be compiled and statistically analyzed. Chi square analysis will be done by each of the four sections of the CHILDPACE, comparing each

test result with the DDST as the final standard, within each age group and for all ages combined. Factors which will be addressed will include patient convenience, interest, and adaptability. The questions that the study will be seeking to answer are the following: (1) Is CHILDPACE a more efficient means of screening for developmental delays in the general population than is currently available; (2) Does this technique meet with better patient compliance with respect to ease of administration and, therefore, test results; (3) At what level of screening does this tool exist - a highly sensitive but very nonspecific test versus a better correlation with the more specific DDST.

Progress:

Computer acquisition has been a problem. Pilot observations with borrowed equipment have not shown any barriers to the study as detailed. No formal entries to date. The project is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/44 Status: Ongoing

Title:
A Survey of Texas Pediatricians on Corporal Punishment in Schools and "Latchkey" Issues

Start Date: Est Comp Date:

Principal Investigator: Facility:
COL R. Fearnow, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

Corporal Punishment, Latchkey

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine the current opinions of pediatricians in the State of Texas on the issues of corporal punishment in schools and the "latchkey" practice.

Technical Approach:

A questionnaire was developed which will be distributed to approximately 1,500 pediatricians in Texas. The data collected will be utilized for comparison with opinions of military parents collected in our previous studies. Statistical analysis will include descriptive statistics and analyses of variance (ANOVA's).

Progress:

From the response to the questionnaire we concluded that there is a remarkable similarity of opinion in our military community between pediatricians, military police, and parents on "latchkey" age issues. We further conclude that variables involving parental experience, socioeconomic status, ethnic background, family structure, and working situations of the parents do not significantly influence stated "latchkey" opinions. We offer this survey as a starting point in the investigation of the practice and the development of guidelines for this complex issue. Since working status and number of parents were not factors in stated opinions, we encourage a broader based approach addressing the basic issue of adult supervision of children rather than one envisioning the child alone as simply a reflection of prevalent parental employment and marital status.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/50 Status: Ongoing

Title:
Pediatric Intubation Training Utilizing the Feline Model

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ R. Allen

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

Intubation training

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

This training is designed to teach physicians and other health care professionals basic knowledge and endotracheal intubation skills required to resuscitate a neonate (newborn) or infant.

Technical Approach:

The laboratory exercise will concentrate on developing the health professional's confidence in establishing an airway. Each new house officer will be required to intubate two cats employing a laryngoscope and endotracheal tube

Progress:

This is a newly activated protocol.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/58 Status: Ongoing

Title:
Serologic and Side Effects of Hemophilus Influenza Type B

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT A.I. Rivera, MC

Dept/Sec: Pediatrics Assoc Investigators

Key Words:

Influenza Type B

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the side effects and serum response to the administration of the Hib vaccine to our patient population. The side effects will be evaluated at 24 and 48 hours post-vaccination. Effects particularly evaluated will be fever and other systemic complaints as well as local reactions. The serologic response will be evaluated by a pre- and three weeks post-vaccination serum antibody level. Patients who receive the immunization at 18 months of age will receive an additional serum antibody determination at 24 months of age. This information is important since it will provide more data on the safety and efficacy of the Hib vaccine in our population.

Technical Approach:

Approximately 2,000 children receiving the Hib vaccine at the Pediatric Clinic, the Immunization Clinic or the Well Baby Clinic will be given a questionnaire and a stamped, self-addressed envelop to be returned to the investigators. The questionnaire is to be completed by the child's caretaker at 24 and 48 hours post-vaccination, listing the side effects experienced by the child. Five age groups (18 months, 2-3 years, 3-4 years, 4-5 years, and 5-6 years) will be delineated and sample populations will be randomly selected. The 18-month-age group will consist of approximately 150 children. The remaining age groups will consist of approximately 30 children each. These patients will have a pre-vaccination serum sample obtained followed by an additional sample three weeks post-vaccination. Patients in the 18 month sample will have a repeat serum sample obtained at 24 months of age. The data will be analyzed by ANOVA.

Progress:

This is a newly approved study with no progress to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/67 Status: Ongoing

Title:

Psychological and Physiological Effects of Didactic Instruction and Relaxation Training with Essential Hypertension Patients

Start Date: Est Comp Date:

Principal Investigator: Facility:

LTC T.B. Jeffrey, MSC

Dept/Sec: Psychology Svc Assoc Investigators

Key Words:

Relaxation Training

MAJ G.R. Greenfield, MSC
MAJ C.L. Ferguson, MC
Randy G. LaGrone, M.A.

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To compare the relative effects of didactic instruction and relaxation training on the systolic and diastolic blood pressures of essential hypertension outpatients.

Technical Approach:

Subjects will be randomly assigned to one of three groups: didactic instruction only, didactic instruction with relaxation training, and no treatment control. The two treatment groups will receive eight sessions of didactic instruction four times weekly for 30 minutes. Lectures will be presented on stress management, diet, exercise, and substance abuse. This instruction is intended to modify dysfunctional behaviors known to be associated with essential hypertension. The didactic instruction only group will participate in an additional 45 minutes each day of discussion on each lecture topic and supportive counselling. The didactic instruction with relaxation training group will receive an additional 45 minutes each day of discussion on each lecture topic, supportive counselling and relaxation training. In addition, this group will be provided with a modified progressive relaxation audio tape for home practice. The control group will receive no treatment or instruction. The dependent variable measure, BP, will be recorded independently of the treatment conditions (pre-, post, and followup) by staff in the hypertension clinic at routine appointments. Psychological measures will be administered at pre (MMPI, Medication side effect index, quality of life scale, Harvard group scale of hypnotic

susceptibility) and post-treatment (Jenkins activity survey). Demographic and psychological data will be studied for their relationship to differential treatment effects. A health habits questionnaire will be used at followup to assess the impact of didactive instruction on targeted behaviors.

Progress:

Twenty subjects have been entered into the treatment protocol. Two-month followup has been conducted on approximately 12 of these subjects. Preliminary results indicate that a reduction in systolic and diastolic blood pressure is occurring in patients in each treatment condition. We are continuing to assign patients to treatment conditions and expect to complete the protocol during the next twelve months. A paper will be prepared for publication upon completion of the followup.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/79 Status: Ongoing

Title:

Burn-Out Prevalence in Health Care Personnel

Start Date: Est Comp Date:

Principal Investigator: Facility:

LTC T.B. Jeffrey, MSC

Dept/Sec: Psychology Svc Assoc Investigators

Key Words:
Burn-out

MAJ G.R. Greenfield, MSC
MAJ W.F. Barko, MSC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

To determine the prevalence of job-related burnout in health care personnel at William Beaumont Army Medical Center.

Technical Approach:

This prevalence study will use the MBI to measure three dimensions of burnout (emotional exhaustion, personal accomplishment, and depersonalization) among selected staff at WBAMC.

a. Random sampling of 50% of civilian, officer, and enlisted staff will be obtained from the authorized and assigned roster of all personnel and distributed through normal hospital channels. Questionnaires will be numbered for control purposes to assist in securing a 75% return rate, but all information will be reported anonymously.

b. Questionnaires will be analyzed through descriptive statistics. Parametric statistics will be employed to evaluate measures of central tendency and distribution of scores for:

(1) Prevalence of burnout.
(2) Comparative levels of burnout within sample populations.

Progress:

Approximately 700 WBAMC staff personnel participated in the Burn-Out Prevalence survey. The loss of both associate investigators and major reductions in staffing have delayed data analysis and paper preparation. This should be completed during the next 12 months.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/12 Status: Terminated

Title:
Neuropsychological Implications of Alcoholism

Start Date: Est Comp Date:

Principal Investigator: Facility:
SGT R.A. Butler

Dept/Sec: Psychology Assoc Investigators

Key Words:
Alcoholism

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Evaluate the nature, extent and permanence of brain deficits associated with alcoholism.

Technical Approach:

Forty alcoholic NCOs from the WBAMC Rehabilitation Training Facility will be evaluated with the following instruments: A questionnaire ascertaining the above demographic and substance abuse variables to include screening of medical records, the Russell Modification of the Wechsler Memory Scale (RWMS), Michigan Alcoholism Screening Test (MAST), Wechslet Adult Intelligence Scale (WAIS), and the HRB Category Test (CAT), Trail Making Test (TMT), Tactual Performance Test (TPT), Finger Oscillation Test (FOT), and the Minnesota Multiphasic Personality Inventory (MMPI).

Groups will be tested at different intervals during their rehabilitation treatment. Results will be factor analyzed and should yield four factors: 1) a language ability or verbal factor, 2) an abstraction or problem solving factor, 3) a perceptual motor skill factor, and 4) a memory for spatial relations factor. The factor loadings or weights will then be further analyzed by four 2 x 3 analysis of variance techniques comparing the alcoholics to controls on the three time intervals for each factor. I believe that by controlling all of the known "problem" variables, this study can address the questions: Are there neuropsychological deficits due to alcoholism? Are these deficits permanent? If deficits do exist, what is the improvement rate with six months' abstinence?

Progress:

SFC Butler was reassigned to HQDA and this project was terminated.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/16 Status: Completed

Title:

MMPI Restandardization Project: Active Duty Soldiers

Start Date: Est Comp Date:

Principal Investigator: Facility:

LTC T.B. Jeffrey, MSC

Dept/Sec: Psychology Assoc Investigators

Key Words:

MMPI

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Establish standardization data for the revised MMPI as determined by active duty Army soldiers.

Technical Approach:

Permission will be obtained from unit commanders to test members of their command. Groups of active duty soldiers will be administered a biographical history form, a life events form, and the MMPI. The materials will be numbered but will not be marked with any information which would specifically identify the subject. the biographical history form will document demographic characteristics of the population and permit noninclusion of subjects with histories of psychiatric disorders to achieve a "normal" sample population.

Progress:

Three hundred fifty volunteer basic trainees completed the study. The results are being written up for submission to a professional journal. Preliminary screening of the data suggest that trainees look like the normal population with the exception of some elevation on Scale G (hypomania) and some elevation on Scale K. These results will be combined with the results from active duty volunteers at several other military installations for ultimate data analyses and reporting.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/23 STATUS: Completed

Title:
Familial Interaction Patterns in First-Time Parents of Male Adolescents in Families of Different Religious Activity

Start Date: Est Comp Date:

Principal Investigator: Facility:
CPT D.B. Danser, MS

Dept/Sec: Psychology Assoc Investigators

Key Words:
Familial interaction

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Examine the discipline patterns of first-time parents of adolescents and the impact of those patterns on prepubertal male adolescent.

Technical Approach:

A sample of 40 families will be recruited. Each family will be measured for varying levels of religious activity (church attendance and religious commitment). Middle class families as defined by ratings of the father's occupation on the Duncan Socioeconomic Index (SEI) will participate. Pubertal status will be assessed verbally via parent reports of rapid recent growth and the development of secondary sex characteristics. Only families that are intact, with a middle class SEI, and their first-born child, a 10 to 11 year old prepubertal male will be accepted to the study. Families will participate in a structured interaction task. A questionnaire on family decision making will be completed by each person in separate rooms with the family convening and being instructed on the completion of the task. During the interaction time each family will be instructed to complete one questionnaire, following appropriate discussion, that will represent the family's opinion or view. The entire session will be videotaped. After the session, the family will be shown a portion of the videotape and debriefed as to the nature of the entire study.

Progress:

Nine families were seen at WBAMC with written informed consent during the months of March to June 1985. This sample was combined with a sample of families collected in Richmond, VA. All the data has been analyzed and the entire study is summarized in a forthcoming brief presentation submitted to the American Psychological Association for their annual meeting.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/24 Status: Terminated

Title:

Effect of Age and Education on Repeated Administration of Neuropsychological Test Battery

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT F. Brown, MS

Dept/Sec: Assoc Investigators

Key Words:

Neuropsychological Test

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Investigate the effects of the level of education, practice, and age on neuropsychological assessment instruments, using normal, neurologically intact individuals.

Technical Approach:

Subjects will be approximately 40 white individuals who do not report a history of head injury or significant illness which would interfere with cognitive functioning. In addition, subjects will be screened for a history of psychiatric or neurological disturbances. Subjects will be assigned to one of three age groups according to their chronological age at the time of the initial assessment: A 25-34 year old group, a 45-54 year old group, and a 65-74 year old group. All persons will be administered a brief neuropsychological test battery on two occasions with a three-month test, retest interval. The battery will include the Wechsler Memory Scale with the Russell Revision, the Trail Marking Test, the Stroop Color-Word Test, and the Wisconsin Card Sorting Test.

Progress:

No subjects from WBAMC were entered into the protocol. The study was completed at Texas Tech University. Recommend protocol be closed. A paper is being prepared for publication on the results of the study.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 78/03 Status: Ongoing

Title:
National Intraocular Lens Implantation Study

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ WILLIAM C. LLOYD, MD

Dept/Sec: Surgery, Ophthalmology Assoc Investigators

Key Words:

Intraocular lens

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To participate in the study of clinical results of implantations of intraocular lens organized by the Intraocular Lens Manufacturer's Association in response to directives of the Ophthalmic Classification Panel, FDA.

Technical Approach:

An intraocular lens is a prosthetic replacement for the eye's crystalline lens. It is placed in the eye at the time of cataract surgery, where it is fixated by a variety of means, with the intention that it remain permanently and correct the large refractive error remaining after conventional cataract surgery.

PROGRESS

One hundred seventy-one intraocular lenses were implanted in FY85 with no adverse effects due to implantation. During the coming year the Ophthalmology Service will initiate implantation of IOLs which are coated to absorb harmful UV radiation.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 83/16 Status: Ongoing

Title:
Size of the Abdominal Aorta: In vivo vs Ultrasonic Measurement

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC Silverio Cabellon,MC

Dept/Sec: Dept Surgery Assoc Investigators

Key Words:

Abdominal aorta

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the size of the normal abdominal aorta. To determine the accuracy of ultrasound in measuring the size of the normal abdominal aorta.

Technical Approach:

Measure by caliper the infrarenal aorta at surgery for other abdominal conditions; compare with size determined by ultrasound before or after surgery.

Progress:

Assignment will be made to another surgical resident to get this study going.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/43 Status: Ongoing

Title:

Outflow Pressure Regulation of Arthroscopic Knee Infusions.

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ Joseph Neustein, MD
CHANGE OF INVESTIGATOR TO LTC Michael Barwick, MD

Dept/Sec: Orthopedics Assoc Investigators

Key Words:

Arthroscopic knee infusion

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Development of an outflow pressure regulator to permit safe pressurized infusions during arthroscopy thus affording maximum visibility with minimal risk of fluid extravasation.

Technical Approach:

An experimental arthroscopy method will be developed as described below. It will be tested on a plastic hinge model knee to establish necessary parameters before being used in a controlled study.

For the controlled study patients are to be drawn from the elective surgery schedule. After informed consent they will be placed at random into a control group receiving standard treatment or an experimental group receiving treatment with the new device. Ten patients per group will be studied. Standard outflow tubing is connected to a large bore outflow portal placed in the suprapatellar pouch of the knee. This tubing is then connected in parallel and off the sterile field to #1 an air ballast, #2 a regulatory valve controlled by a pressure transducer, and #3 a manual outflow valve. A reservoir capable of delivering pressurized arthroscopic irrigation fluid (Sarns infusion pump) will be utilized. The regulatory valve on the outflow tubing will be set at 115mm of mercury, well below the minimum pressure required to rupture the knee capsule as determined by the previously quoted study. The system can be set to provide constant low flow pressure irrigation by setting the infusion pump pressure above the regulatory valve pressure. If static distension at a set pressure is desired the

infusion pump pressure will be set at or below the pressure of the regulatory valve. Quick clearing of cloudy fluid can be accomplished by opening the manual outflow valve. Both the regulatory and manual outflow valve will drain into a nonsterile collection device. The parameters measured will be the amount of time spent clearing a blurred field compared to total operating time. A Student's t-test will be used to compare control with experimental values. Complications with all procedures will be documented. No additional risks above those present during routine arthroscopy are foreseeable except the following:

1. Pressure regulation valve malfunction with failure to release pressure and subsequent extravasation of fluids through a ruptured capsule into the leg, or failure to maintain distension pressure with subsequent inadequate visualization.

Notation will be made after each case regarding any technical difficulties or advantages noted with this technique. A preliminary evaluation will be made after ten patients to determine whether continued utilization of this method is warranted.

Progress:

A prototype pressure regulator has been constructed. Departure of the principal investigator has delayed patient evaluation. A new principal investigator has been appointed and the study will resume. No patients have been enrolled, but the study is ongoing.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/55 Status: Ongoing

Title:

Radiolabeled Triazines for Evaluation of Soft Tissue Damage in Rabbits

Start Date: Est Comp Date:

Principal Investigator: Facility:

COL T.J. Scully, MC

Dept/Sec: Dept Orthopedics Assoc Investigators

Key Words:

COL M.J. Spicer, MC

Soft tissue damage

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Pilot study to synthesize and test a series of radiolabeled triazine compounds as nuclear imaging agents for soft tissue damage in rabbits.

Technical Approach:

Phase I: Synthesize stable complex of Indium with a chlorotriazine dye.
Phase II: Inject rabbits with radio-indium-labeled chlorotriazine dye after producing controlled soft tissue and bone lesions. Scan for radiotracer distribution within four hours.

Progress:

A stable complex of Indium and procian brilliant blue MRS has been prepared, but soluability has been a problem. Departure of the Chief of Chemistry, DCI, has delayed progress. After a six month hiatus, a new chemist is now on board and work will resume.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/63 Status: Completed

Title:

Comparison of Treatment Methods for Sterilization of Contaminated Free Bone Fragments Sustained in Type III Open Fractures - An Animal Study

Start Date: Est Comp Date:

Principal Investigator: Facility:

MAJ Joseph Neustein, MC

Dept/Sec: Orthopedics Assoc Investigators

Key Words:

Contaminated Bone Fragments

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Type III fractures often involve segmental loss of bone from the wound. The following two-phase study is proposed.

Determination of susceptibility to infection of cow metatarsals which have been contaminated by barnyard soil and then sterilized. Determination of pullout strength of screws inserted into bone.

Technical Approach:

Stage I: Cow metatarsals will be obtained from freshly slaughtered animals placed in plastic bags and preserved in an ice chest. The metatarsals will be harvested and will be cut into four sections of approximately one inch lengths. They will be incubated in barnyard soil for 16 hours and then treated by one of the following methods.

a. Mechanical cleaning with a 10-minute betadine scrub and sterile water.

b. Mechanical cleaning with betadine followed by autoclaving 20 minutes at 15 psi.

c. Mechanical cleaning with betadine and soaking with merthiolate 1:1000 for one hour.

d. Controlled specimen cultured after irrigation with sterile water.

e. Controlled culture of barnyard soil.

The specimens will be cultured by total immersion in thioglycolate broth for up to seven days with appropriate subculture for aerobic bacteria, anaerobic bacteria, and fungi.

Stage II: Four cow metatarsals will be cut into approximately two inch sections (four per metatarsal). Sections from each metatarsal will be treated by the following methods.

a. Autoclaving for 20 minutes at 15 psi.

b. Merthiolate 1:1000 immersion for one hour.

c. Irrigation with sterile water for 15 minutes.

A 4.5mm ASIF cortical screw will be inserted with standard technique using a 3.2mm drill through one cortex, depth gauge determination of cortical hole, and threading the hole with a 4.5mm tap. An appropriate size screw will be inserted. An Instron machine will be used to determine pullout strength of screw from the bone. Data will be evaluated to determine if there is a statistically significant difference in results of bone treated by these various methods.

PROGRESS:

The study is complete. A paper entitled Replacement of Contaminated Extruded Bone Segments was presented at the Western Orthopaedic Association and received the Vernon P. Thompson Award.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 84/85 Status: Completed

Title:

The Use of Gentamicin Impregnated Bone Cement in Total Hip Arthroplasty

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT P.M. Garcia, M.D.

Dept/Sec: Orthopedics Assoc Investigators

Key Words:

Arthroplasty

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To determine the efficacy of antibiotic impregnated bone cement in total hip replacement surgery. One particular patient at WBAMC is a prime candidate for the use of this procedure and will be the only patient.

Technical Approach:

A 54-year-old diabetic male who underwent closed reduction and internal fixation of a hip fracture. Subsequently he developed osteomyelitis (Staph epi.) and was treated with six weeks of IV antibiotics and then switched to oral medication. Now clinically the infection has resolved,, but collapse of the femoral head has occurred secondary to avascular necrosis. A total hip arthroplasty will be placed with the use of antibiotic impregnated cement. Use of antibiotic impregnated cement for total joint arthroplasty following infections is highly recommended on a protocol from EM Laboratories.

Progress:

The single patient entered into this study is doing very well, the project is completed.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/15 Status: Ongoing

Title:

A Multi-Center Study on Rehabilitation of the Hand Following Flexor Tendon Repair

Start Date: Est Comp Date:

Principal Investigator: Facility:

LTC J.J. Monsivais, MC

Dept/Sec: Surgery Assoc Investigators

Key Words:

Flexor Tendon Repair

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Development and implementation of a new postoperative management regime for Zone II flexor tendon injuries.

Technical Approach:

Primary repair is performed as soon as possible using a Tajima stitch with 3.0 or 4.0 Ethibond 6-0 nylon and meticulous repair or reconstruction of fibro-osseous tunnel.

Progress:

Fifteen patients have been entered into the study. Results of 85% in the excellent category have been obtained versus 30-40% reported in the literature.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/26 Status: Ongoing

Title:

Radionuclide Detection and Treatment of Pulmonary Contusions in the Pre-Clinical State. Phase I

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT M. Halpert, MC

Dept/Sec: Dept Surgery Assoc Investigators

Key Words:

Pulmonary contusion MAJ T.M. Reyna, MC

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results

Study Objective:

Investigate the use of strict fluid management of victims of pulmonary trauma prior to the development of a clinical adult respiratory distress syndrome.

Technical Approach:

Patients will undergo a 99m-Tc-HSA heart-lung study as soon as practicable after admission workup and initial diagnostic procedures have been accomplished, but no more than eight hours after injury. The study will be done at the bedside using a portable gamma counter and will involve negligible risk to the patient. Additional data to be recorded on each patient will include mechanism of injury, time interval between injury and scan, pre-existing lung disease and smoking history, and laboratory data at the time of the scan, including arterial and, when possible, mixed venous blood gas determinations, AaDO2, and data on intravenous fluid and blood product administration since the injury. Radiographic findings, serial vital signs, and when available, central venous or pulmonary capillary wedge pressures, will also be recorded. If the initial scan is negative, it will be repeated at 48 hours post-injury, or any time thee are changes in the patient's clinical or radiographic presentation that indicate the possible presence of a pulmonary contusion.

Progress:

Ten patients have been entered into the study without any adverse effects.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/32 Status: Ongoing

Title:

Arthrotomy and Irrigation vs Aspiration and Closed Irrigation in Treatment of Septic Arthritis in Rabbits

Start Date: Est Comp Date:

Principal Investigator: Facility:

CPT Paul Nitz, MC

Dept/Sec: Orthopedics Assoc Investigators

Key Words:

Septic Arthritis

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

Pilot study to determine if pyogenic septic arthritis managed by aspiration enclosed irrigation can yield articular joint surface histology comparable to that of an arthrotomy and irrigation.

Technical Approach:

The efficacy of arthrotomy and irrigation vs aspiration and irrigation in New Zealand white rabbits infected with either a Gram-negative (E. coli) or Gram-positive (Staphylococcus aureus) will be determined in an initial pilot study as follows: The animals will be divided into two groups of two animals each. Group I will receive an intra-articular infectous dose of 10^8 Gram-negative organisms in both knee joints. One additional animal will have one knee joint injected with the Gram-negative organism and the other knee joint injected with the Gram-positive organism, which will be used as an infected nontreated control. A noninfected normal control will require the use of one additional animal. Group II will receive an infectious dose of 10^8 organisms per joint of the Gram-positive organism in the three joints as described in Group I. Twenty-four hours after injection of the infectious organism, treatment of one hind joint by arthrotomy and irrigation (250cc lactated ringers solution) and aspiration and irrigation (250cc lactated ringers solution) of the other hind joint will be performed. Appropriate systemic antibiotics will be given intramuscularly according to weight and organism sensitivity thereafter for ten days. After this time the animals will be sacrificed by lethal injection of T-61. The joints will be

surgically removed and appropriate histological samples taken. Analysis of the articular cartilage will be performed on coded samples by a pathologist, The histology of the articular surfaces of the joints obtained will be studied for thinning of the cartilage, loss of chondriocytes, and erosive changes (fibrillation, etc.). Significance of the results will be determined by chi-square and one-way analysis of variance. If favorable histologic results are obtained, as determined by preservation of the articular cartilage in these diverse treatment modalities, the study will then be extended to include a larger number of animals to establish statistical significance.

Progress:

Rabbits are being sent from Fort Sill, OK, by Dr. Nitz to William Beaumont AMC to have their tissue examined. Fort Sill does not have the capability to examine the tissue as needed. The study will be completed at WBAMC within the next few months.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/33 Status: Ongoing
Title:

Bone Remodeling in the Femoral Heads of Rabbits Following Femoral Neck Osteomy with or without Epiphysiodesis

Start Date: Est Comp Date:
Principal Investigator: Facility:

MAJ R.J. Snyder, MC

Dept/Sec: Orthopedics Assoc Investigators
Key Words:

Bone remodeling

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To demonstrate pictorially, using tetracycline labelling, bone mineralization in the femoral head of a rabbit following various surgical procedures, in an attempt to show how the bony architecture is reconstituted. Clinically, these results may help explain why the subtrochangeric osteotomy is associated with less morbidity or perhaps show why the cuneiform osteotomy in conjunction with epiphysiodesis should be considered the procedure of choice.

Technical Approach:

The study will require forty skeletally immature rabbits as determined radiographically by the presence of a femoral head epiphyseal growth plate. Preoperatively, routine blood work will be obtained - sedimentation rate and alkaline phosphatase. The rabbits will be operated in groups of ten alternate right and left hip. Postoperatively rabbits will be administered tetracycline on the fifth postoperative day and weekly thereafter. A rabbit from each group will be sacrificed at one week intervals. At necropsy the femoral head will be split coronally, examined under fluorescent microscopy and photographed. The tetracycline marker will show new bone mineralization similar to rings on a cut tree and should show the directions from which new bone was formed. A rabbit from each group will be operated on weekly.

Progress:

To date approximately 12 of 40 rabbits have been operated. Due to technical problems of rabbits dislocating postoperatively the operated hip, only three rabbits could be followed correctly. The principal investigator is currently awaiting time to finish the protocol and will try to complete the operating within two months.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/34 Status: Ongoing
Title:

Effect of Continuous Low Dose Epinephrine on a Depressed Myocardium

Start Date: Est Comp Date:
Principal Investigator: Facility:
CPT M.G. Newbrough, MC

Dept/Sec: Surgery Assoc Investigators
Key Words:

Epinephrine, Myocardium

Accumulative MEDCASE Cost Est OMA Cost: Periodic Review Results
Study Objective:

Evaluate the effect of continuous infusion of low dose epinephrine on a depressed myocardium. Low dose epinephrine has selective beta-adrenergic effects which stimulate myocardial contractility (+ inotrope). The positive inotropic effect may optimize the Frank-Starling curve. Side effects include increased oxygen utilization, which may result in ischemic injury. The objective is to determine if the positive inotropic effects prove to be beneficial with only minimal side effects.

Technical Approach:

Evaluate a continuous infusion of low-dose epinephrine in a depressed heart model of a dog. Invasive monitoring, such as an A-line, Swanz-Ganz catheter, IV, EKG and general anesthesia would be applied. A Frank-Starling curve would be performed. The heart would then undergo depression (anesthetic) to be assessed by a depressed Frank-Starling curve. Low dose epinephrine (.02 - .04 meg/kg/min) would then be administered and the Frank-Starling curve would be optimized by titration of the epinephrine. Deleterious side effects, such as ischemia, injury or infarct to the myocardium, would be evaluated by EKG, ABG and cardiac enzymes.

Progress:

Adult foxhounds were given general endotracheal anesthesia and underwent monitoring for placement of intravenous line, Foley catheter and arterial line. Under sterile technique a 7FR thermistor tipped, triple lumen catheter was placed in the pulmonary artery. Measurements were then made 1) prior to myocadial depression, control, 2) after myocardial depression with

acepromazine, a known myocardial depressant, 3) during infusion of epinephrine (0.5 mcg/min, 1.0 mcg/min, 1.5 mcg/min, 2.0 mcg/min and 4) after discontinuation of the epinephrine infusion. Measurements were made at 10 minute intervals, after the initiation of each dosage schedule.

All animals showed a depression from baseline anesthetized hemodynamic parameters when given the acepromazine maleate. All animals showed improvement in cardiac output and systemic blood pressure in each of the four epinephrine treatment ranges. Total systemic vascular resistance was decreased in all treatment ranges. The heart rate was unchanged in all treatment ranges.

We have shown the epinephrine infused in doses which are in the range to affect only beta adrenergic receptors, reverses myocardial depression in animals with normal volume status. No effect on alpha adrenergic receptors was noted. No increase in heart rate was noted.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/55 Status: Ongoing

Title:
Evaluation of Low Dose Heparin in the Postoperative Management of Digital Reimplantation

Start Date: Est Comp Date:

Principal Investigator: Facility:
LTC J.J. Monsivais, MC

Dept/Sec: Surgery Assoc Investigators

Key Words:

Digital Reimplantation

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To investigate heparin therapy for improvement of the present survival rate on amputation reimplantation. Preoperative medications (ketamine and rompun) will be used according to the advice of the veterinarian.

Technical Approach:

Study animals will be randomly assigned to "heparin-first" or "heparin-second" group by Bioresearch personnel, without knowledge of the surgeon. The left ear will be amputated in a standard semitraumatic manner. The two surfaces will be surgically debrided and reattached by the investigators. At a latter date, the right ear will be similarly treated. The "heparin-first" animals will be given 50 units/kg of heparin every six hours by the intravenous route for 72 hours during the initial reimplantation and equal volume of normal saline during the second. The "heparin-second" animals will receive normal saline during the initial reimplantation and heparin during the second.

Success and failures for both groups will result in a 2x2 table for chi square analyses.

Progress:

This is a newly approved study with no progress to date.

Detail Summary Sheet

Date: 1 Oct 85 Prot No: 85/56 Status: Ongoing

Title:
Porocoat Synatomic Knee Device(DePuy IND #G830152)

Start Date: Est Comp Date:

Principal Investigator: Facility:
MAJ Wm Roberts

Dept/Sec: Surgery/Orthopedics Assoc Investigators

Key Words:
Synatomic Knee Device

Accumulative MEDCASE Cost | Est OMA Cost: | Periodic Review Results

Study Objective:

To demonstrate the safety and efficacy of the Porocoat Synatomic Knee System.

Technical Approach:

Investigators will follow the manufacturer's protocol, which has been approved by the FDA. This protocol is extensive and is available in the Department of Clinical Investigation.

Selection of subjects.

Approximately 60 patients will be selected for participation in this study according to the following qualifications:

Tricompartmental Replacement.

1. Significant arthritic diseases of tricompartmental tibio-femoral and patello-femoral surfaces.

2. Stable or reconstructable ligaments.

3. Physiologic or correctable axial alignment.

4. Intact quadriceps and hamstring mechanisms.

5. Cruciate retention as accommodated by use of the Porocoat Synatomic Standard Platform and polyethylene tibial bearings.

6. Posterior cruciate retention as accommodated by use of the Porocoat Synatomic Variable Fit Platform or the Porocoat Synatomic Standard Platform and polyethylene tibial bearings.

7. Patella suitable for accepting metal backed patella component.

The applicability of the following indications and contraindications for use of the Porocoat Synatomic Knee will be evaluated:

Indications: The prosthesis may be investigated for selected patients including elderly patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis and for patients concurrently suffering from correctable valgus or varus deformity and moderate flexion contracture. This prosthesis is also proposed in those patients with failed previous surgery where pain, deformity or dysfunction persists.

Porocoat total knee replacement may be considered for younger patients, under age 30, if an unequivocal indication outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate gain of knee mobility leads to an expectation of significant improvement in the quality of their lives.

CONTRAINDICATIONS:

Reasons for exclusion:

a. Active infection/local infection.

b. Loss of musculature, neuromuscular compromise or vascular deficiency rendering the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).

c. Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity.

d. Poor bone quality, such as osteoporosis, severe deformity or tumors of the supporting bone structures, not amenable to augmenting autogenous bone grafting, that would lead to the impaired anchorage or improper positioning of the implant.

e. Subjects with known hypersensitivity to implant materials.

f. Occupational hazards.

Distant foci of infection are a relative contraindication and the danger of hematogenous spread to the implant site versus the

advantages of the procedure to the patient must be weighed by the surgeon. The surgeon should be aware that in young, active, or overweight patients increased stress will be placed upon the device. Nevertheless, such a patient may be included in the study as the surgeon determines that this is in the best interest of the patient. The usual contraindications for cemented knee replacement are also applicable to the Porocoat Synatomic Knee System. The results of the clinical use of the Porocoat Synatomic Knee will be compared to the results of a control (comparison) group composed of other types of semi-constrained total knee prostheses. The comparison group data will be a historical control from previously published papers. These control groups will be chosen based on similar population demographics and length of followup. More than one comparison group may be needed to ensure that adequate comparison of complications and other parameters will be possible. Besides utilizing descriptive tables and graphs for the data analyses and comparisons, certain postoperative events will be analyzed and evaluated through the use of modified life tables (actuarial methods). Clinical assessments will be performed by the principal investigator or his designee at intervals specified in the enclosures. Enclosed forms for patient followup visit will be strictly adhered to. Copies will be retained by the principal investigator until the study is concluded and then sent to the Department of Clinical Investigation. Copies will be sent to the sponsoring company.

Data collected and results achieved at William Beaumont AMC will be compiled with results of other institutions by the sponsoring company and analyzed by complicated and appropriate actuarial methods.

Progress:

This is a newly approved study with no progress to date.

INVESTIGATORS

SUBJECT INDEX

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