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<tr>
<td>AUTHOR</td>
<td>SAMUEL A. CGOONLL, M.D., Ph.D., MC</td>
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<tr>
<td>PERFORMING ORGANIZATION NAME AND ADDRESS</td>
<td>Department of Clinical Investigation, Tripler Army Medical Center, Tripler AMC, Hawaii 96859</td>
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<td>CONTROLLING OFFICE NAME AND ADDRESS</td>
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**SUPPLEMENTARY NOTES**

The findings in this report are not to be construed as an official department of the Army position unless so designated by other authorized documents.

**KEY WORDS**

Clinical investigations; experimental projects; research protocols; in-house research; publications, presentations of research data; protocol status; experimental design.

**ABSTRACT**

Subject report identifies those individuals who are conducting investigative protocols at Tripler Army Medical Center. An abstract of each protocol giving abbreviated technical objectives, methods, and progress is presented.
FOREWORD

Contained herein are progress reports on research projects fostered by the Clinical Investigation Program at Tripler Army Medical Center (TAMC) during Fiscal Year 1981.

The Clinical Investigation and Human Use Committees reviewed all proposals for their scientific merit, medical applicability, and risk to human subjects. In conducting the research described in this report, the investigators adhered to the "Guide for Laboratory Animal Facilities and Care" as promulgated by the National Academy of Sciences/National Research Council, the criteria established by the American Association for Accreditation of Laboratory Animal Care, and the principles embodied in the Declaration of Helsinki.

This Annual Progress Report contains publications, presentations, awards, proposals, preliminary findings, unit staffing, and fiscal data.

[Signature]

SAMAEL A. CUCINELL, M.D.
Colonel, MC
Chief, Dept of Clinical Investigation
DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: Previous to the provisions of 1981, the duty of the Department of Clinical Investigation (DCI) was the provision of support for medical research by the TAMC staff. Now DCI is responsible for the quality and administrative monitoring of the research as well. Emphasis on quality has required additional reviews and preparation of protocols; possibly this relates to the decrease in protocols. Unfortunately, zero of seven protocols submitted to the Human Subjects Research Review Board (HSRRB) this year have been approved in time for the work to be carried out, reflecting the increased demand for quality.

B. TECHNICAL APPROACH: All research, investigations, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-1E, and HSC Regulation 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

C. STAFFING:

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L. PROGRESS: 97 projects are reported, of which 23 have been terminated, 17 completed, and 57 ongoing. There have been 31 publications, 15 resulting from research projects, and 23 presentations at national and regional scientific meetings, 13 resulting from research projects. The detail sheets should be examined for specific information on the individual projects.

The number of publications has climbed steadily since the start of the DCI at T AMC in 1971. As a baseline from 1968 to 1970, there were nine publications per year. From 1971 to 1980 the average was 17.4 ± 5.9 per year. Even before DCI had any facilities at all in 1971, there was a sharp increase. This suggests that simply the idea of research encouraged by the command is valuable in stimulating effort (Fig. 1). Since 1979, DCI has taken responsibility for preparation of manuscripts throughout T AMC. The number of manuscripts prepared by DCI has increased during these past three years compared to the previous five years for which data is available. The number of publications prepared includes major rewrites. On the other hand, the number of manuscripts submitted for publication clearance has remained constant. This manuscript preparation service is believed to
be the single most important thing in increasing the publication rate, not any dramatic increase in research, money, or personnel.

If the measure of success is publication, then DCL does well. The following table compares the past three years. There has been an increase in the number of publications resulting from protocols. What is disturbing is that the same authors' names are repeated over again. These publications do not represent a cross-section of the hospital, but rather the efforts of a limited number of individuals. Considering the number of protocols which are not published each year, it is possible for TAMC to have 50 manuscripts per year output. Numbers of publications do not necessarily reflect quality of work or completion of the mission. But what other measure is there?

<table>
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<th>Year</th>
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<td>1979</td>
<td>14</td>
<td>2</td>
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<td>1980</td>
<td>73</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>1981</td>
<td>31</td>
<td>15</td>
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I. PROBLEMS: The main problems are delay and lack of interest, time, and money. During the past two years, 8 months have been required on the average for resolution of a protocol submitted to the HSPRL. Six months is the shortest interval, and one year to final approval has occurred. The delay involves the consultant reviewers to the HSPRL who always find imperfections in the protocols. The resolution of this problem is to prepare perfect protocols.

The number of protocols reported this year has decreased from 62 to 73 (noncancer) protocols. The total protocols submitted to the Clinical Investigation Committee were 30 in 1980 and 17 in 1981. Articles have been written on the decrease in physician research. There is no reason to suspect that military physicians should be any more research-minded than civilians. Although the reason for the decrease in the civilian sector is said to be an increased interest in primary care and increased debts from medical school, TAMC's problem is the limitation on time of the physician staff. This is compounded by the aging equipment in DCL. The x-ray equipment, sterilizers, anesthesia machines, and surgical tools are 10 years old. Since research is the new and the advanced, our equipment simply is not adequate to meet the demands of modern surgical technique and postoperative care. The veterinary section is struggling to maintain a basic animal colony, and major surgery and postoperative care are marginal. As the surgical procedures decrease, the veterinary personnel become less experienced.

A chronic problem continues to be that protocols have been completed and reached the preliminary publication stage when they are
abandoned because of PCS of the investigator. Previously, one-half of all completed protocols were left unpublished. This has been reduced to one-quarter.

During the past year we lost our full AAAAC accreditation. The HSC Inspector General's inspection team found the ICI deficient in the animal colony as well. Remarkable effort has been made to correct the deficiencies and accreditation is expected to be reinstated.

RESOLUTION OF PROBLEMS: A short-term solution of the problems of physician time and improvement of the quality of protocols is the preparation of protocols by more senior staff physicians with longer tours at TMC, and the incorporation of the house staff into ongoing established programs. This is the classical mentor system. It may discourage novel efforts by the house staff but novel efforts by house staff have not really succeeded.

The quality of the surgical support in TMC must be improved to make experimental surgery successful. This involves improving the maintenance of our equipment and improving our MEDCASE. Although we have been awarded $85,000 in MEDCASE funds in FY 81, not one item from these funds has arrived in Hawaii as of the submission of this report. MEDCASE support must be found to replace the X-ray system, since the radiologists cannot be expected to do advanced procedures with equipment from the 1960's.

The PCI of TMC is ten years old. It has continued to have the support of an involved commander, MG Edward Huyke, and our former HSC program director, COL Norman Peam.

The PCI is reorienting its administrative and research programs to meet new requirements.
Figure 1

Year

1968 69 70 71 72 73 74 75 76 77 78 79 80 81

Manuscripts cleared for publication (orignal and major revisions)
Manuscripts prepared by DCl

PUBLICATIONS

HISTORY OF TACI

STAFF OF TACI

Manuscripts

DCI prepareds
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21/81 Coussens, W. I. Postpartum Psychological Reactions to Childbirth Preparation and Experience. (T) 17
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Wan, S. P. Ureterogastric Urinary Conduits. (C)

Ohashi, D. K. Strain Differences of Staphylococcus aureus based on Lipid Analysis. (C)

Ohashi, D. K. Studies on the Bacteriology of Acid-Fast Isolates Isolated from Lepromatous Leprosy Patients. (C)

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PUBLICATIONS

DEPARTMENT OF CLINICAL INVESTIGATION


Dressendorfer, R. H., Wade, C. E., and Amsterdam, E. A.: Development of Pseudoenemia in Marathon Runners During a 20-Day Road Race. JAMA 246(11): 1215-1217, Sep 81. (C)


Mercado-Simnen, R., Goodwin, B., Ueno, M., Yamamoto, S., Bryant-Greenwood, G.: Rat Receptor in the Myometrium and Cervix of the Pig. Biol Reprod, in press. (C)


DEPARTMENT OF MEDICINE

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY


DEPARTMENT OF PEDIATRICS


DEPARTMENT OF PSYCHIATRY


DEPARTMENT OF RADIOLOGY


DEPARTMENT OF SURGERY


PRESENTATIONS

DEPARTMENT OF CLINICAL INVESTIGATION

Brooks, U. P. and Claybaugh, J. P.: Reduced Mean Arterial Blood Pressure (MABP) and Plasma ADH After Aldosterone Infusion into Dehydrated Conscious Dogs. 31st Annual Fall Meeting, American Physiological Society, Toronto, Canada, Oct 1980. (C)


Claybaugh, J. R.: Urinary Metabolites of Pressin: Consequences in Radioimmunoassay. 31st Annual Fall Meeting, American Physiological Society, Toronto, Canada, Oct 1980. (C)

Claybaugh, J. R.: Lack of Effect of Acetazolamide on Increase in ADH During First 24 Hrs at 13,600 Ft in Man. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 1981. (C)


Lotson, C. R.: Comparison of Antibiotic Susceptibility Patterns and Bacteriophage Types of Coagulase-Positive Staphylococci Isolated from Newborn Skin. Annual Meeting, American Microbiological Society, Dallas, TX, Feb 1981. (C)

Goodwin, B. S., Jr.: Hepatic Blood Flow Measurement and Blood Sampling Techniques in the Dog. 31st Annual Session, American Association for Laboratory Animal Science, Indianapolis, IN, Oct 1980. (C)


O'Brien, J. C., Jr.: Endotoxin Effects on Rat Hepatocytes in Monolayer Culture. 65th Annual Meeting, Federation of American Societies for Experimental Biology, Atlanta, GA, Apr 1981. (C)

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Rudd, E. G.: Intrauterine Irrigation with Cefamandole Nafate Solution at Cesarean Section. Armed Forces OB-GYN Seminar, Orlando, FL, Oct 1980. (C)
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Newell, J. D.: Computerized Tomographic (CT) Appearance of the Myocardium After Reversible and Irreversible Ischemic Injury. 29th Annual Meeting of the Association of University Radiologists, Apr 1981.

DEPARTMENT OF SURGERY


Rainey, R. K.: Compartment Syndrome. Annual Seminar, American College of General Practitioners, Ohio Chapter, Dellroy, OH, Aug 1981. (C)


OBJECTIVES: To obtain comparative gastric and cardioesophageal sphincter pressures during 24-hour pH testing for nocturnal reflux.

TECHNICAL APPROACH: For more exact analysis of causative factors of nocturnal reflux and its surgical correction, the direct measurement of gastric and cardioesophageal pressures are to be made simultaneously with pH in 24-hour studies. Reduction of errors due to perfused side-hole catheter pressure measurements in the cardioesophageal sphincter are to be made by utilizing a three-channel, semiconductor, gastro-esophageal probe presently available. This device is to be modified so as to incorporate both a Dent sleeve system in the center section and a pH probe.

PROGRESS: The Dent sleeve catheter has not proved to be of advantage in 24-hour pH/oesophageal pressure studies. In common with all water perfused side-hole catheter systems for intraesophageal pressure measurement, hydrostatic artifacts due to patient movement introduce uncertainties in recording interpretation. An additional research study for fabrication of a nonperfused catheter system is being instituted so as to eliminate this problem. Nonavailability of a suitable catheter system for these measurements has necessitated the suspension of this project for six months.


DATE: 5 Jan 82

PROJ NO: 34/79

STATUS: Ongoing

TITLE: Fabrication of a Catheter for the Determination of Liver Blood Flow in Dog and Man

Start Date: Oct 79

1st Comp Date: Sep 82

Principal Investigator:
Gordon H. Bryant

Facility:
Tripler Army Medical Center

Dept/Sec:
Dept of Clinical Investigation

Associate Investigators:
COL Samuel A. Cucinell, MC

Key Words:
Liver blood flow

CPT Clayton L. Hadick, VC

Accumulative MEDCASE Cost:

Est Accumulative OMA Cost: $2500

Periodic Review Results: Continue

OBJECTIVES: Development of a thermodilution catheter which will easily and repeatedly give an accurate measure of hepatic vein blood flow in larger animals.

TECHNICAL APPROACH: Technique for fabrication of catheters for blood flow measurement is now a routine procedure in the Department of Clinical Investigation at TAMC. Results to date have demonstrated a degree of variability, particularly in the case of small flows, i.e., less than 250 ml/minute. Cause and cure of such deficiencies have therefore been undertaken using an in vitro model of the IVC.

PROGRESS: It has been found, using a more carefully designed in vitro model, that factors such as distance between thermistor and injection site, volume and velocity of injectate, and geometry of injection system all have considerable influence on accuracy of flow measurement. Reasons for these phenomena and their elucidation should lead to the desired improvement in accuracy of results in the near future.


**Detail Summary Sheet**

**DATE:** 11 Jan 82  
**Fiscal No.:** 5/63  
**Status:** Ongoing

**TITLE:** Fabrication of a Nonperfused Gastric Motility Catheter

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**OBJECTIVE:** To make possible simultaneous distal esophageal sphincter (DES) pressure monitoring with 24-hour pH studies in patients suffering from nocturnal gastric reflux.

**TECHNICAL APPROACH:** Proposal is to utilize piezoelectric or thermistor techniques for pressure measurement within the DES and distal water-filled balloons connected to conventional pressure transducers for esophageal pressure. Small barium titinate strips with a central pivot point can be used in conjunction with field effect transistors for required pressure measurements within the DES. Alternatively, paired spaced thermistors could be used where one unit acts as a heat source and the other as a heat unit. Esophageal "squeeze" would vary the separating distance between the two thermistors in this case.

**PROGRESS:** Problems of time limitation, location and availability of suitable materials have stultified progress in this study. It has accordingly been suspended until other work of higher priority is completed.
Detail Summary Sheet

Date: 14 Jan 82  Prot No: 38/76  Status: Ongoing

TITLE: Further Studies on the Site of Action of Circulating Angiotensin II on Plasma ADH Concentration

Start Date: Jul 76  Est Comp Date: Sep 83

Principal Investigator: John R. Claybaugh, Ph.D.

Facility: Tripler Army Medical Center

Dept/Sec: Clinical Investigation/Physiology

Associate Investigators: CPT Clayton L. Radick, MC

Key Words:
Angiotensin
Antidiuretic hormone
Hog

Accumulative MEDCASE: 126  Est Accumulative: 126  Periodic Cost: CMA Cost: $13000.00  Review Results: Continue

OBJECTIVES: To determine if angiotensin II augments osmotic stimulation of ADH mediated via hepatic osmoreceptors.

TECHNICAL APPROACH: Following a report in which hepatic osmoreceptor control of vasopressin release was suggested, we conducted two pilot experiments in an attempt to verify the existence of hepatic osmoreceptor vasopressin control, and secondly, whether these osmoreceptors are also augmented by angiotensin II as are the central osmoreceptors. Chronic indwelling cannulae were surgically placed in the portal vein via the splenic vein. There were two ports allowing upstream infusion of hypertonic solutions, and downstream sampling for osmolality determinations. After the cannula was put in place the dogs were allowed to recover and subsequently used for experiments in the conscious state. Our intention was to conduct at least three experimental runs on each dog, one comparing peripheral venous hypertonic NaCl vs. portal venous infusions, another comparing portal venous infusions of hypertonic NaCl with and without simultaneous infusions of angiotensin via a peripheral vein, and third peripheral intravenous infusions of hypertonic NaCl with angiotensin infused either peripherally or via the portal vein.

PROGRESS: Preliminary experiments (2) suggest the existence of hepatic osmoreceptor stimulation of vasopressin and also suggest the possibility of angiotensin II augmentation of the response, but continuation of the experiment has been delayed due to changes in veterinary officers and subsequent delays imposed by manpower shortages.
The Effect of Sodium Balance on the Vasopressin Response to Blood Volume Reduction

Start Date: Sep '76
Estimated Completion Date: Sep '78
Principal Investigator: John P. Claybaugh, Ph.D.
Dept/Sec: Clinical Investigation/Physiology
Facility: Tripler Army Medical Center
Associate Investigators: CPT Clayton L. Ladick, VC COL Peter J. Barcia, MC
Key Words: Conscious dogs, Blood volume reduction, Sodium balance

Accumulative PEC/LEASE: $1000.00
Review Results: Continue

Objective: To determine whether negative sodium balance increases the vasopressin response to hemorrhage.

Technical Approach: Conscious dogs will be hemorrhaged 10% of the estimated blood volume after two weeks of low, normal, or high sodium intakes. Blood samples will be obtained prior to and five minutes after hemorrhage, and one hour after the return of hemorrhaged blood. Six dogs will be prepared with exteriorized carotid loops and with chronic indwelling left atrial cannulae. The dogs will be hemorrhaged at a rate of 0.4 ml/kg/min with blood samples taken at time 0, 10, 20, and 30 minutes, corresponding to 5, 10, and 15 percent hemorrhages. This regimen will be conducted four times on different sodium diets.

Progress: To date we have shown that low sodium diet enhances the ADH response to equal volume hemorrhages in the same animal. This occurs despite similar initial values of plasma ADH concentration in the two states. Research by other laboratories has demonstrated a possible change in sensitivity of baroreceptor control of renin release, which may also be influencing the ADH response in a similar fashion. Inhibition of the renin-angiotensin system does not alter the ADH response to hemorrhage significantly; however, we would like to investigate this point a little further before final publication. In addition, the sensitivity of baroreceptor stimulation of ADH release in different sodium balances should be further investigated.

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<td><strong>TITLE:</strong> Enzyme Immunoassay of Arginine Vasopressin</td>
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**OBJECTIVES:** (a) To develop the technology for and assess the clinical and research efficacy of enzyme immunoassay methods for arginine vasopressin (AV) measurements in biological fluids in comparison with standard radioimmunoassays; and (b) to partially automate enzyme immunoassay techniques to allow for greater productivity in hormone measurement by routine laboratory personnel.

**TECHNICAL APPROACH:** This study consists of two phases: (1) the validation of enzyme immunoassay for AV using hormone coupled B-galactosidase, comparing results to currently available radioimmunoassays; and (2) partial automation of the enzyme immunoassay for B-galactosidase.

**PROGRESS:** Preliminary experiments were initiated in developing the enzyme assay for B-galactosidase. Work stopped, however, due to personnel shortages. All supplies are on hand and work should resume in January 1982.
TITLE: Comparison of Control of Vasopressin Release from Isolated Hypothalamoneurohypophyseal (HNS) Explants Obtained from Normal and Hypertensive Rats

Start Date: Apr 79
Estimated Comp Date: Sep 79

Principal Investigator:
John R. Claybaugh, Ph.D.

Department/Section:
Clinical Investigation/Physiology

Key Words:
Hypothalamoneurohypophyseal explants
Hypertension

Accumulative MEDCASE: 
Est Accumulative Cost: $4,500

OBJECTIVES: Certain rat models of hypertension have elevated pituitary content, plasma concentration, and urinary excretion rates of vasopressin. The mechanism for this increased release of vasopressin is not clear and may be due to an alteration in the sensitivity of the hypothalamus to various known stimuli. By removing the hypothalamus with the stalk connection to the neurohypophysis still intact, we can eliminate many uncontrollable inputs to vasopressin release and test the sensitivity to acetylcholine, angiotensin, and osmotic stimuli, and possibly others, in order to test the hypothesis.

TECHNICAL APPROACH: Five-week-old, male, spontaneously hypertensive rats will be selected from the colony at the Department of Clinical Investigation, Tripler Army Medical Center, Okamoto-Aoki strain. Age-matched normotensive male control rats will be of the WKY strain. The rats will be surgically prepared with indwelling carotid arterial cannulae and placed individually into metabolism cages. Two days after surgery, daily collections of urine will be started for analysis of flow rate, urine concentrations of Na+, K+ and antidiuretic hormone (ADH), and urine osmolality. Daily measurements of systolic and diastolic blood pressure will be made via the carotid arterial cannulae. After 5 days of measurements and urine collections, the rats will be sacrificed by guillotine and trunk blood collected for analysis of plasma osmolality, Na+, K+ and vasopressin concentration, and plasma renin activity. The HNS will be dissected and prepared for incubation. Osmolality will be determined by vapor pressure method, Na+ and K+ by flame photometry. Vasopressin will be assayed by radioimmunoassay and plasma renin activity by the New England Nuclear radioimmunoassay kit. All methods are ongoing in our laboratory.
Comparison of Control of Vasopressin Release from Isolated Hypothalano-neurohypophyseal (HNS) Explants Obtained from Normal and Hypertensive Rats

PROGRESS: The surgical skills necessary for successful dissection of the HNS preparation and the procedures involved in organ culture have been routinely performed during the first 1.5 years. We were able to demonstrate an osmotic stimulation of vasopressin from the HNS preparation in a 1-hour exposure period. Control experiments indicated a steady vasopressin production could be achieved during the necessary 5-hour block of time on the fourth day of organ culture. Changing the osmolality of the incubation medium from 290 to 315 mOsml/kg results in a significant increase in vasopressin release. Angiotensin at 10^{-5} M concentration also stimulated vasopressin release in this preparation. Having established these "standard" responses, we had confidence that the preparation was responding to normal physiological stimuli. Unfortunately, during the past year, inexplicably, we have been unsuccessful at reproducing these expected and necessary responses. Because the primary investigator on this project is a graduate student, it was felt that one year investment was all that could be afforded at this time and that a reassignment to a different thesis project was essential to her progress. Hopefully, this project will resume within one year.
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**OBJECTIVES:** To determine if a biologically inactive but immunologically detectable metabolite constitutes a significant amount of the vasopressin molecule excreted in the urine.

**TECHNICAL APPROACH:** Vasopressin has been shown to be metabolized in the renal nephron of some animals. Also, the values reported for the amount of vasopressin excreted in normal man varies greatly from one laboratory to the other. We have addressed the question as to whether the former results in the latter. Therefore, we have analyzed identical urine specimens from humans, dogs, rats, and pigs with two antisera which we have characterized as being specific to the "tail" or "ring" portion of the vasopressin molecule. If an immunological difference is determined, we will proceed in order to find out if a chemical difference is detectable. Thus, urine will be fractionated by various methods, including sephadex, electrophoresis, high pressure liquid chromatography (HPLC), ion exchange, ultrafiltration, and others. If two chemical identities can be shown that have immunological activity with one antibody but not the other, our results would clarify the need to use a specific type of vasopressin. Our hypothesis is that this is the case, and that a "ring" directed antibody detects more of the filtered vasopressin than a "tail" directed antibody and is therefore essential for the most accurate assessment of urinary vasopressin in excretion.

**PROGRESS:** Human, pig, rat, and dog urine contain immunologically detectable vasopressin that can be measured by both "tail" and "ring" directed antibodies, although in all species except the dog the amount measured by the "ring" directed antisera is about twofold greater than that detected by the "tail" directed antibodies. Although sephadex,
Urinary Metabolites of Vasopressin: Consequences in Radioimmunoassay

ion exchange, ultrafiltration, and proper electrophoresis have produced fractions of vasopressin that still yield immunologically different amounts of vasopressin, we have obtained only suggestive data that there are indeed two different chemical entities (possibly more) by electrophoresis. We have conducted a recent series of experiments on HPLC in which the "ring" directed antisera detects two peaks of activity, corresponding to arginine vasopressin. The "tail" directed antisera detects only the arginine vasopressin. The peak that we propose is a metabolite of vasopressin that has not been identified yet, although pressinoic acid and deso-Gly (NH₂) arginine vasopressin have been ruled out, leaving des-Gly (NH₂)⁹, des-Arg⁹, arginine vasopressin as the probable metabolite. Proof will require the purchase of this synthetic analog and subsequent comparisons on HPLC.
TITLE: The Role of Dopamine in Angiotensin II Stimulated Antidiuretic Hormone Release

OBJECTIVES: To determine whether dopamine is a neurotransmitter mediating angiotensin II stimulated ADH release.

TECHNICAL APPROACH: Angiotensin II was infused intravenously into conscious dehydrated dogs (n=6) at a rate of 10 ng/kg/min once by itself and once with a concurrent intravenous infusion of haloperidol (mg/kg/min), a dopamine antagonist. Plasma vasopressin, renin activity, and arterial blood pressure responses were compared between the two situations. Appropriate vehicle controls were also run on the same dogs.

PROGRESS: Angiotensin alone caused a two-fold increase in plasma vasopressin concentration (P<0.05), a 25 mmHg increase in mean arterial blood pressure (P<0.01), and a 70% decrease in plasma renin activity (P<0.01). When haloperidol was simultaneously infused with angiotensin, plasma vasopressin concentration decreased about 20% (N.S.), while the changes in mean arterial blood pressure, +25 mmHg (P<0.01), and plasma renin activity, decrease of 65% (P<0.01), were similar to those observed with only angiotensin infused. The results suggest that a dopaminergic mechanism may be involved in the Angiotensin II-induced vasopressin release, but not its pressor actions or the negative feedback effects on renin release.


**Detail Summary Sheet**

---

**Date:** 5 Jan 82  
**Prot No:** 21/81  
**Status:** Terminated

**Title:** Postpartum Psychological Reactions to Childbirth Preparation and Experiences

---

**Start Date:**  
**Principal Investigator:** CPT Wayne R. Coussens, MSC  
**Dept/Sec:** Dept of Clinical Investigation  
**Facility:** Tripler Army Medical Center  
**Associate Investigators:** MAJ Clayton Shaw, MC  
**Key Words:** Postpartum psychological reactions

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<tr>
<td></td>
<td>OMA Cost: $300.</td>
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**OBJECTIVE:** To assess the psychological effects of childbirth preparation on mothers who "lose control" during labor and those who have cesarean births.

**TECHNICAL APPROACH:** Two hundred nulliparous expectant mothers will complete questionnaires at 32 weeks, 34 weeks, confirmed labor, 24 hours postpartum, and 6 weeks postpartum. Questionnaires will assess changes in relevant psychological and demographic characteristics. Mother, physician, and nurse ratings will be used to classify mothers on level of emotional control during labor and delivery. Classifications will also be made on reported levels of preparation for childbirth (psychoprophylaxis). Post hoc comparisons will be made between classifications across repeated measures to determine changes in relevant variables in relation to level of preparation for and level of emotional control in childbirth.

**PROGRESS:** The project is terminated due to the inability of the Department of Nursing to support it. The protocol will be revised and resubmitted.
OBJECTIVES: As a continuing part of our investigation into the influence of the antidiuretic hormone (ADH) in human metabolism, we wished to determine what influence this hormone has in a variety of clinical states.

TECHNICAL APPROACH: This study was designed to be a survey of occasional ADH levels in various clinical situations. Samples have been obtained in cirrhosis of the liver, nephrotic syndrome, renal failure, hypertension, congestive heart failure, pneumonia (particularly Legionnaires disease), and cardiac resuscitation.

PROGRESS: This study is being terminated because it has yielded the maximal amount of information possible for the nature of the study. The clinical states have shown that ADH is elevated to varying degrees in Legionnaires disease, cirrhosis of the liver, congestive heart failure, and nephrotic syndrome. ADH has proven to be low in cardiac resuscitation and gastrointestinal bleeding. The study suffers from lack of specific definition of the syndromes and incomplete design and accumulation of data. Each syndrome must be followed carefully in the clinical context for any clear-cut data to evolve. It is not surprising that ADH is elevated in pneumonia, cirrhosis, and heart failure. This data contributes little either to patient care or theory of practice. A systematic correlation of ADH with severity of these diseases may yield valuable information. The low ADH syndrome is more interesting. Patients who survive cardiac arrest, but with severe neurological deficit, seem to have depressed ADH, and one patient had diabetes insipidus. This has previously been reported, but not with ADH levels. All of these patients died eventually. The low ADH in gastrointestinal bleeding is artifact in that the samples were taken during treatment and suggest that ADH is an inconsistent hormone during this situation. Although this study is terminated because of poor design and incomplete data, it does provide suggestions for more valuable approaches.
DETAILED SUMMARY SHEET


START DATE: Jul 79   1ST COMP DATE: Sep 82

Principal Investigator: COL Samuel A. Cushing, FC

Deputy: Clinical Investigation

Key Words: Liver Blood Flow

Accumulative Project Cost: $2500.00

OBJECTIVE: To determine liver blood flow and to develop an improved technique for sampling hepatic vein blood.

TECHNICAL APPROACH: Methods now available for the determination of hepatic blood flow are either invasive or based on indirect chemical clearances. None of these methods is satisfactory for the accurate noninvasive quantitation of liver blood flow necessary for our continued studies into the lactic acid metabolism by the liver. It should be possible to place a thermistor catheter in the vena cava (VC) at the level of the renal and hepatic veins. Blood flow at these points might be determined by thermodilution. Hepatic vein blood flow could be estimated by subtraction of the blood flow in the vena cava at the level of the renal veins from the vena cava blood flow at the level of the diaphragm. This should be liver blood flow. It should be possible to sample pure hepatic vein blood by inflation of a balloon-equipped, double lumen catheter at the level just above the renal veins. This should cut off blood coming from the renal veins and below from entering the vena cava in the area of the hepatic veins. Blood samples from just above the balloon should be hepatic vein blood.

PROGRESS: The liver blood flow system has been reported in a preliminary manner in the Proceedings of the Western Pharmacology Society, 77:23-25, 1981. Additional work is being done comparing blood flow in the portal vein to hepatic vein before final publication. Details of engineering design are to be considered. The hepatic blood sampling device has been finalized and described in Proceedings of the Society for Experimental Biology and Medicine, 168:222-227, 1981.
### OBJECTIVES:
To try to define more precisely the cardiovascular toxicity of the tricyclic antidepressants and to suggest the most rational antidote for the cardiotoxicity.

### TECHNICAL APPROACH:
An animal model of cardiotoxicity of the TCA will be developed in the dog and rabbit. The animal will be sedated with the TCA itself. Recordings of the EKG, electrolytes, and blood gases will be made. Doses of TCA will be given to produce EKG toxicity. In some animals it will be necessary to allow the complete cardiotoxicity to evolve in order to determine the pattern of conduction abnormality leading to cardiac arrest. Once this pattern is defined, antidotes and mechanisms of altering the EKG pattern will be made. It is anticipated that a drug so rich in autonomic actions would have a cardiac effect, which would operate through the autonomic nervous system. Blockade of this system at known points, i.e., ganglionic blockade, cholinergic receptor blockade, adrenergic transmitter and receptors blockade, as well as autonomic stimulants at the same levels, should alter the pharmacological pattern of TCA. If the TCA proves resistant to these manipulations, a direct quinidine-like action may exist and direct pacing may be of value.

### PROGRESS:
The project is terminated. The University of Hawaii group is pursuing the study alone.
OBJECTIVE: This is a preliminary study to design the most reasonable prophylaxis for malaria in individuals who will be exposed to both high altitude and malaria sequentially or simultaneously.

CLINICAL APPROACH: A group of seven active Army personnel explored the mountainous areas of New Guinea for location of downed aircraft sites at altitudes up to 5000 feet. With regard specifically to malaria they were given Fansidar to be taken before leaving for New Guinea and at monthly intervals thereafter. The following laboratory tests were done before and after their tour in New Guinea: CBC, urinalysis, SMA-20, glucose-6 phosphate dehydrogenase determination, and sickle cell preparation. Malaria smears were done upon return.

PROGRESS: The 9-week mission was completed with one member removed to Hawaii because of leg trauma. One man who was allergic to sulfa drugs took CP tablets, one per week. There were no illnesses or fever. It was noted that the local inhabitants took CP tablets rather than Fansidar when they entered malaria regions of New Guinea. Although malaria was present in the area, the members of this team had no direct contact with known cases. The preliminary studies done at Tripler Army Medical Center showed all men had normal renal, hepatic, and hematologic function. All of the laboratory tests were repeated upon return to Hawaii and were found to be normal. Thick smears were done on all members and no malaria was seen. Under the conditions used, Fansidar caused no toxicity or complication in men operating at high altitude for short periods of time. No toxicity was noted.
In the last two years. The fish specimens come from these suspected cases. In addition, the investigator has made arrangements to be notified as soon as possible about any new suspected cases.

PROGRESS: It has been found that it is not practical to do this study at TAMC and it is therefore terminated.

Accumulative MIDCASL: Est Accumulative
Cost: OMA Cost: $500.

TECHNICAL APPROACH: A bioassay will be developed which may utilize radioactive tagged human serum used in rabbits. Intradermal injections of the fish extract gives a "wheal and flare" which can be measured by amount of radioactivity in the area. This is most tentative. Other possibilities would include oral ingestion in laboratory animals with modified guts to watch for histamine-type response. Whatever test we develop will be correlated with retrospective analysis of the 30 to 50 cases seen in Hawaii in the last two years. The fish specimens come from these suspected cases. In addition, the investigator has made arrangements to be notified as soon as possible about any new suspected cases.

PROGRESS: It has been found that it is not practical to do this study at TAMC and it is therefore terminated.

Accumulative MIDCASL: Est Accumulative
Cost: OMA Cost: $500.

TECHNICAL APPROACH: A bioassay will be developed which may utilize radioactive tagged human serum used in rabbits. Intradermal injections of the fish extract gives a "wheal and flare" which can be measured by amount of radioactivity in the area. This is most tentative. Other possibilities would include oral ingestion in laboratory animals with modified guts to watch for histamine-type response. Whatever test we develop will be correlated with retrospective analysis of the 30 to 50 cases seen in Hawaii in the last two years. The fish specimens come from these suspected cases. In addition, the investigator has made arrangements to be notified as soon as possible about any new suspected cases.

PROGRESS: It has been found that it is not practical to do this study at TAMC and it is therefore terminated.
TITLE: Intraocular Prosthesis in a Cynomolgus Monkey (Macaca fascicularis)

OBJECTIVE: To determine long-term toxicity and acceptance of an intraocular prosthesis in a primate. Also, to determine aesthetic presentability of such a device.

TECHNICAL APPROACH: To publish data on intraocular prosthesis in primates. A human prosthesis was used to determine the efficacy of this procedure in primates and the long-term toxic effects.

PROGRESS: This project was presented at the annual meeting of the American Association of Laboratory Animal Science, Salt Lake City, Utah, in September 1981. A manuscript is in preparation.
OBJECTIVES: To study lactate metabolism in primary cultures of rat hepatocytes.

TECHNICAL APPROACH: Earlier in the study we characterized lactate metabolism in monolayer cultures of rat hepatocyte cells and determined that neither anoxia nor pH would account for the apparent production of lactate seen by liver during hemorrhagic shock. We wished to further study liver carbohydrate metabolism under conditions of endotoxic shock.

PROGRESS: While anoxia and acidosis inhibit lactate consumption in hepatocyte cultures, endotoxin was found to have no direct effect when added to the medium. Cells prepared from endotoxic shocked rats, however, were unable to metabolize lactate. It appears the effect of endotoxin on liver carbohydrate metabolism cannot be explained by a direct effect on the hepatocyte cell. These results are being prepared for publication.


DATE: 12 Jan 84  PROJ. NO: 28/79  STATUS: Ongoing

TITLE: The Behavioral Effects of Antihypertensive Therapy in the Elderly

START DATE: Aug 80  1st COMP. DATE: Jan 81
PrINCIPAL INVESTIGATOR: Lt. John L. Ackl, MC
DEPT/SEC: Dept. of Family Practice
KEY WORDS: Antihypertensive therapy

OBJECTIVES: To determine if treatment with antihypertensive medications in elderly hypertensive subjects produces changes in measurable areas of behavioral performance. If behavioral changes occur, does the direction of change reflect improved or impaired function?

TECHNICAL APPROACH: Elderly hypertensive patients will be placed on an alternating regimen of active antihypertensive medications and placebos. Data on blood pressure response to the two different treatments and behavioral tests and outcomes will be collected at the end of each four-week period. The two groups of subjects will be matched as closely as possible and differ only in the order in which the treatment, active medications, or placebos are given. The behavioral outcomes are conceptualized as being directly influenced by the independent variable of medication status and indirectly by the intermediate variable, blood pressure. Blood pressure is directly influenced by the independent variable, medication status.

PROGRESS: The study protocol has now been completed on a total of 19 patients, utilizing two study groups over an 8-week study interval. Three patients were withdrawn from the study. One was diagnosed as having a colon carcinoma and subsequently underwent a partial colectomy. The second patient's blood pressure reached the study limit and she was placed on her active antihypertensive medication with no complications as her blood pressure stabilized. The third patient had chest pain suspicious for angina. Subsequent follow-up and evaluation proved to be normal and she resumed her vigorous exercise program. The investigators are planning two more groups of 16 patients each, which will bring the total number to over 50 patients. This will allow valid statistical analyses to be performed.
The Behavioral Effects of Antihypertensive Therapy in the Elderly

The primary problems encountered in the study have been lack of clerical and administrative assistance. Pharmacy and clinical laboratory support have thus far been excellent.

Because one of the investigators will be leaving the Army, CPL Charles L. Henley has volunteered to assume responsibility for the medical care of the study patients. A Family Practice third-year resident has also expressed interest in the study and he has been given time to participate in this research. As more interest in research is being generated within the Department of Family Practice, it is hoped that this will be an ongoing departmental undertaking.
**Detail Summary Sheet**

**Date:** 30 Oct 81  
**Prot No:** 4760  
**Status:** Ongoing

**TITLE:** Evaluation of PUVA in the Treatment of Resistant Psoriasis

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<td>COL Harold J. Albert, MC</td>
<td>Facility</td>
<td>Tripler Army Medical Center</td>
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<td>LTC Philip Chan, MC</td>
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**OBJECTIVE:** To determine the potential benefits of PUVA in the treatment of psoriasis resistant to other forms of therapy.

**TECHNICAL APPROACH:** In August 1980, a clinical investigation of the efficacy of psoralen plus long wave ultraviolet light in the treatment of severe psoriasis was approved. The project was included under HIC 410-161 with approval of COL Charles Lewis, USMC, principal investigator. The protocol is essentially the same as that being used by several major study groups.

**PROGRESS:** Two patients have been enrolled in the study. Both have essentially complete clearing of psoriasis and now are on maintenance therapy with PUVA.
**Title:** A Prospective Trial of Propranolol in Patients with Diffuse Toxic Goiter for Subgroup Determination

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**Start Date:**

**Principal Investigator:**

CPT William T. Highfill, MC

**Dept/Sec:**

Dept of Medicine/Endocrine

**Key Words:**

Goiter, toxic

**Accumulative MEDCASE | Est Accumulative COST: | OMA Cost: $300. | Periodic Review Results: Terminate**

**OBJECTIVES:** To determine if there is a predictable subgroup of patients with diffuse toxic goiter whose disease undergoes remission during and following treatment with propranolol.

**TECHNICAL APPROACH:** Patients with diffuse toxic goiter will be given propranolol, 80 mg orally 3 times a day for 6 months, after which the medication will be discontinued and the patient followed for 3 months or until clinical symptoms and/or laboratory evidence of thyrotoxicosis recur. At the end of the trial, the data of all patients who remain clinically and chemically euthyroid will be compared to that of the rest of the trial group to determine if there are any characteristics or responses to propranolol which might distinguish this subgroup.

**PROGRESS:** This project has been terminated as it has not been approved by OTSG.
TITLE: Coronary Arteriography in the Army

OBJECTIVE: To explore the use of coronary arteriography in Army medicine, to evaluate certain technical aspects of the procedure, and to better define the nature of coronary artery disease in the active duty population.

TECHNICAL APPROACH: This is a collaborative Army study coordinated by Maj. John E. Harris, MC, of Madigan Army Medical Center, consisting of a one-year prospective chart review of the catheterization data at each center.

PROGRESS: The study has been completed with approximately 200-250 patients in the study. Data is currently being analyzed.
**Objectives:** To determine the effectiveness of Dexamethasone in preventing or alleviating nausea and vomiting in cancer patients receiving chemotherapeutic agents.

**Technical Approach:** A double-blind study of each participating patient will be performed. Patients will be obtained from adult oncology clinic. Minors will be included in the study. Each patient will receive an envelope from the pharmacy containing three tablets of either placebo or Decadron, 4 mg. The tablets are to be taken at lunch the day before therapy, at bedtime the day before therapy, and the morning of therapy. All additional standard antiemetics will be continued since neither the patient nor the investigator has any way of knowing if the active Decadron was taken. The patients will be asked to score their nausea and other symptoms and the vomiting will be objectively followed by the clinic staff.

**Progress:** Waiting OTSG approval.
Objective: This study will compare colonoscopy with a multilocality evaluation of occult and overt rectal bleeding.

Technical Approach: All patients presenting to the Gastroenterology Clinic and Proctology Clinic with a complaint of overt or occult rectal bleeding will be eligible for this study. Patients must meet the following criteria: (a) have a history of bright red rectal bleeding or the discovery of occult rectal bleeding in the previous six weeks; (b) be 40 years of age or older; (c) be capable of informed consent; (d) must not have had proctoscopic or barium enema in the preceding six weeks. After inclusion in the study groups, all patients will be interviewed by one of the principal investigators. Demographic and historical data will be collected. CBC, clotting profile, and hemocult screen will be collected on each patient. Patients will be randomized. One group will have colonoscopy alone. The other group will have proctoscopic examination, air contrast barium enema, and colonoscopy. All reactive colonoscopies will be compared as to patient comfort, diagnostic rates, complications, and time of workup.

Progress: This project is terminated due to lack of time on the part of the investigators.
TITLE: The Influence of pH and Serum Protein Concentration on the Anion Gap

OBJECTIVES: To determine how the acidity and alkalinity of blood and its protein concentration influence the relationship of the serum chemistries (e.g., Na, K, Cl, HCO₃) to each other.

TECHNICAL APPROACH: Fourteen days were studied for changes in the in vivo ionization of plasma protein during respiratory acidosis and respiratory alkalosis. No effort was made to change the serum albumin concentration.

PROGRESS: The undetermined anion gap was unchanged at the extreme of acidosis and alkalosis suggesting that the ionization of plasma protein does not change ionization with pH. A manuscript is in preparation.
Date: 30 Dec 81  Prot No: 25/80  Status: Terminated

Title: Pulmonary Function in Patients with Gastroesophageal Reflux

Principal Investigator: MAJ Rosemary F. Rodgers, MC

Dept/Sec: Dept of Medicine/Pulmonary

Key Words: Bronchial reflex

Objective: To determine whether there are significant abnormalities in the pulmonary function studies of nonsmoking patients diagnosed to have gastroesophageal reflux.

Technical Approach: Diagnosis of gastroesophageal reflux in nonsmoking adults will be established by (1) clinical history (with particular attention to symptoms of reflex and pulmonary disease) and physical examination, (2) barium esophagram, and (3) gastroesophageal scintiscan. Incidence of pulmonary disease in these individuals will be determined by (1) PA and lateral chest roentgenogram, (2) spirometry with and without bronchodilator (0.5 cc Isuprel in 2 cc NS), (3) gas dilution lung volume studies, (4) DLCOSB, and (5) body plethysmographic determination of FRC, Raw, lung compliance, and pulmonary elastic recoil. At conclusion of the clinical studies, results will be examined to determine the extent of cause and effect relationship between gastroesophageal reflux and pulmonary disability.

Progress: This project is terminated due to departure of principal investigator.
Date: 15 Jan 82

Prot No: 2/79

Status: Ongoing

Title: Glucose Modulation of Insulin Binding

Start Date: Jan 79

1st Comp Date: Sep 79

Principal Investigator:
Maj K. Shen, MD

Facility:
Tripler Army Medical Center

Dept/Sec:
Dept of Medicine/Endocrine

Associate Investigators:

Key Words:
Insulin Binding

Accumulative M 2100  | 1st Accumulative  | Periodic M 2100  | Review Results: continue

Cost: $1500  | 1MA Cost: $1600  |  | 

Objectives: To investigate the effect of glucose concentration on insulin binding; to investigate the effect of glucose preincubation on insulin binding, and to study glucose transport under varying insulin and glucose concentrations.

Methods: Epididymal fat pads are removed from male Sprague-Dawley rats. Isolated fat cells are prepared by shaking at 37°C for 60 minutes in Krebs-Ringer bicarbonate buffer containing collagenase (3 mg/ml) and albumin (40 mg/ml) by the method of Rodebell. Isolated fat cells are then suspended in a buffer containing 50 mM Tris, 120 mM NaCl, 1.2 mM MgSO4, 2.5 mM KCl, 10% bovine serum albumin, pH 7.4, and varying concentrations of glucose in a Dubnoff metabolic shaker at 37°C for 45 minutes. At the end of incubation, cells are washed and ready to be used for either 1-231-insulin or glucose transport studies. 1-231-insulin binding is carried out with 1-231-insulin prepared at a specific activity of 100-150 mCi/mg according to the Freychet et al. modification of the method of Hunter and Greenwood. Glucose transport studies are carried out by incubating cells with 2-deoxy-2-14C-D-glucose (specific activity 2 mCi/ml) in Krebs-Ringer bicarbonate, pH 7.4, containing bovine serum albumin (10 mg/ml) at 37°C. This assay measures the total uptake of the radio-labeled 2-deoxy-glucose and is based on the principle that while 2-deoxy-glucose is transported and phosphorylated by the same process as D-glucose, it cannot be further metabolized. Calculation of glucose transport is based on the method of Oleskey.

Progress: After many attempts, the cultured fibroblasts from the foreskin obtained during circumcision has proved to be an appropriate system to use. However, since the departure of Maj O'Brien, the investigation has been temporarily suspended until another Ph.D. biochemist arrives since there is the possibility of overgrowth of virus in the culture medium.
FREE AND TOTAL INSULIN LEVELS IN INSULIN-TREATED DIABETICS

**PROGRESS:**

It was found that (1) there is no relationship between administered insulin dosage and free insulin levels in diabetic patients. (2) Insulin binding to monocytes is not correlated with bound insulin or insulin dosage, but is inversely correlated to free insulin level, and (3) the maximum binding sites of insulin antibody are inversely proportional to the ratio of free/bound insulin.

**This study is to be presented at the annual meeting of Military Endocrinologists in June 1982 in conjunction with the annual meeting of the Endocrine Society and American Diabetic Association.**
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**Investigator:**  
**Principal Investigator:**  
**Dept/Sec.:**  
**Dept of Medicine/Cardiology:**  
**Facility:**  
**Tripler Army Medical Center:**  
**LTC Harry M. Sherby, MD:**  
**LTC Samuel F. Cucinelli, MD:**  

**Acute/Chronic:**  
**Periodic:**  
**Cost:**  
**Total Cost:** $0.00  
**Review Results:** Terminate

**Objective:** To determine the indications for continued anticoagulation in pericarditis in myocardial infarction.

**Methodology:** All patients with established myocardial infarction and pericardial friction rub will be eligible for this study. After giving informed consent, the patient will be entered into a randomized, double-blinded study. The pharmacy will send to the patient's care unit an appropriate intravenous solution containing heparin or a placebo. (Heparin study—contact pharmacy.) The physicians caring for the patient will not be blinded and will control the study according to current standards if the patient does not receive heparin (or placebo is continued). An echocardiogram and a phonocardiogram will be taken daily on all patients in the study (by the investigators who will be blinded). The attending physicians will be advised of the fluid content of the pericardial sac. A decision to break the code and terminate the study will be made by a consultant cardiologist and the physcians in the group continued on anticoagulation. A placebo will be started in patients with Coumadin at the appropriate time.

**Progress:** Because of delay in approval, this protocol has been terminated.
**Date:** 23 Dec 81  
**Prot No:** 1979  
**Status:** Terminated

**TITLE:** Beta Blocker Heart Attack Trial

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**OBJECTIVES:** To determine the efficacy of propanolol in decreasing the incidence of sudden death and/or recurrent myocardial infarction.

**TECHNICAL APPROACH:** Uncomplicated postinfarction patients are treated prospectively with placebo or Indorol to see if survival in these patients is prolonged by prophylactic therapy with a beta-blocker.

**PROGRESS:** The national study of which this was to be a part has been terminated.
Title: Evaluation of Miodironine Therapy of Cardiac Arrhythmias

Date: 23 Dec 81

Principal Investigator: LTC Harry M. Thomas, MC

Facility: Tripler Army Medical Center

Dept/Sec: Dept of Medicine/Cardiology

Key Words: Miodironine, Arrhythmia

Accumulative FDC/PI Test/Accumulative Periodic Cost: AMA Cost: 5500

OBJECTIVES: To control symptomatic cardiac arrhythmias which have not been responsive to the conventional and accepted forms of treatment where control is dependent on the use of a drug which has been shown to be harmful to or in other ways not tolerated by the individual.

TECHNICAL APPROACH: Miodironine, an investigational drug, is utilized to treat supraventricular and ventricular arrhythmias which are refractory to other drugs. All results are pooled with the Army installations utilizing Miodironine therapy. The collecting facility for this data is the Tripler Army Medical Center.

PROGRESS: At TAC, two patients are currently on Miodironine. One patient had a breakthrough of her recurrent ventricular tachycardia when she personally reduced her dosage of medication to 400 mg daily. Increase in Miodironine to 800 mg daily has prevented recurrence of her arrhythmia. The second patient has complete control of his arrhythmia. Both patients have developed minimal side effects in the form of corneal micro deposits which do not interfere with vision. Neither patient has developed significant complications with the medication. In the overall Army series, several patient have had to discontinue the drug because of reversible peripheral neuropathy and reversible pulmonary fibrosis.
### Detail Summary Sheet

**Date:** 6 Jan 82  |  **Prot No:** 36/80  |  **Status:** Ongoing

**TITLE:** Improved Record Keeping in the ICU/CCU by Means of Table Top Model Computers

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**Principal Investigator:**

DG: Harry L. Thomas, MA

**Dept/Sec:**

Dept of Medicine/Cardiology

**Key Words:**

Record Keeping

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**OBJECTIVEL:** To increase diagnostic sensitivity by modern graphic display of clinical data.

**TECHNICAL APPROACH:** The Hewlett Packard 9835A computer will be programmed to display quantitative data generated by selected patients. The displays will be graphic and organized similar to data in clinical journals and textbooks. The graphic displays will include all of the quantitative clinical data generated on the patients together with three notations of the clinical progress of the patient (including drug therapy, invasive procedures, new diagnoses, etc.) After sufficient number of patients have been studied, a quasi-objective evaluation will be performed in which a physician not associated with the patient will review the patient's chart in the classic manner compared to review of the patient's chart in addition to the graphic displays. The physicians will list the diagnosis for each day of ICU hospitalization. Statistical analysis will be by diagnosis made by physicians doing alternate type of chart review by $x^2$.

**PROGRESS:** Additional memory and software have been obtained and initial programs are to be undertaken.
Title: Comparison of Daily versus Alternate Prednisone Therapy in Pulmonary Sarcoidosis

Principal Investigator: Dr. George L. Pledger, Jr.

Clinical Approach: In order to compare the therapeutic effects and complications of alternate day Prednisone to daily Prednisone in patients with sarcoid, a six-month cooperative, alternate allocation, unblinded study has been adopted. Both methods of Prednisone dosing are used clinically, but with only anecdotal and personal experience type data available, it is impossible to select the best treatment for this disease.

Findings: The multicentric study on pulmonary sarcoidosis performed under the auspices of principal investigators at WAMC continues. At date written, the Center had entered seven patients in the study. Follow-up continues on the majority of these patients, although several are being followed at other Army institutions because of PCS. The criteria for selection and actual performance of the study remain unchanged.
Date: 6/6/83

Title: Antibiotic Prophylaxis in Vaginal Hysterectomy: A Comparison of Different Regimens: Single Dose, Multidose, and Intraoperative Irrigation with Colleen's Solution

Start Date: 3/1/83

Principal Investigator: Capt Thomas M. Burke, MC

Facility: Tripler Army Medical Center

Dept/Sec: Dept of Obstetrics and Gynecology

Keywords: Vaginal hysterectomy

Accumulative IND/CASI | 1st Accumulative | Periodic | Waiting
Cost: | ORA Cost: | Review Results: | Approval

Objective: To determine the efficacy of different parenteral antibiotic regimens compared with intraoperative antibiotic irrigation in decreasing the febrile morbidity and the sequelae secondary to pelvic cellulitis following vaginal hysterectomy.

Technical Approach: Study proposed is a prospective blinded study designed to compare antibiotic prophylaxis, single-dose parenteral, and multidose parenteral in decreasing the incidence of infectious morbidity following vaginal hysterectomy.

Progress: Waiting TSC approval.
Date: 19 Jan 82  Prod No.  No. Status: Ongoing  Title: Animal Surgery as Adjunct to Gynecology Residency Program

Start Date: 1 June 1980  End Comp Date: 

Principal Investigator: Cpl. Marshall L. Matthews, MC  Tripler Army Medical Center

Co-Investigators: 

Type of Training and Gynecology  TPT Clayton L. Hadick, VC

Keywords: 

TRAINING Gynecological surgery

Accumulative IDECASE Est Accumulative Periodic

Cost:  OMA Cost: $3,500. Review Results: Continue

OBJECTIVES: To perfect skills and increase exposure and proficiency in gastrointestinal, genitourinary and vascular procedures.

TECHNICAL APPROACH: Dogs have end-to-end anastomosis, side-to-side anastomosis, diverting colostomies, end-to-end ureteral anastomosis, and ureteral implantation as well as retropelvic vessel dissection and node dissection.

RESULTS: The project continues as a training protocol. Surgery was done on 75 dogs and 29 residents were trained in the procedure.
Detail Summary Sheet

Date: 20 Jan 72  Prot No: 40712  Status: Continuing

Title: Microsurgical Anastomosis of the Rabbit Oviduct

Start Date: 1 Oct 71  Est Comp Date

Principal Investigator: Lilletting, T. Obstetrical, MC

Facility: Tripler Army Medical Center

Dept/Sec: Dept of Obstetrics and Gynecology

Associate Investigators: Op of Obstetrics and Gynecology

Key Words:

Training

Microsurgery


OBJECTIVES: To perfect skills and increase proficiency in microsurgical techniques.

TECHNICAL APPROACH: Bilateral ligation of the fallopian tubes with microsurgical reconstruction is performed in rabbits. The reconstruction is either bilateral or unilateral.

PROGRESS: The project continues as a training protocol. Surgery was done on eight rabbits and ten residents were trained in the procedure.
Date: 10 Jan 82  
Prot No.: 12/1  
Status: unfunded

Title: The Cold Pressor Test as a Predictor of Pregnancy-Induced Hypertension

Start Date: June 31  
End Date: June 12  
Facility: Tripler Army Medical Center

Dept/Sec: Obstetrics and Gynecology  
Associate Investigators: Florentino V. Adelanza, M.D.  
LTC John J. Haed, M.C.

Key Words: Cold pressor test, Hypertension

Accumulative DOLLAR | Test Accumulative Periodic | Review results: Continue
Cost: $300 | Cost: $300  

OBJECTIVE: To develop a convenient means of detecting the patient destined to develop pregnancy-induced hypertension (PIH).

TECHNICAL APPROACH: All healthy, normotensive, nulliparous women attending the Obstetrics Clinic, TAMC, will be asked to participate in this study. Those women with a past history of chronic hypertension, renal disease, and cold allergy will be excluded from the investigation. During each visit, each subject will be evaluated for hyperreflexia, edema, proteinuria, and weight gain. Each subject will be tested with the cold pressor test in accordance with the protocol of wires and buttons as described above, with the following modifications. The supine position will be avoided; the subject will rest in bed in a semi-reclining position (30°) with a slight left lateral tilt. An electronic fetal monitoring unit will be used continuously during the entire test period to externally monitor the fetal heart rate and the uterine activity. A reactive fetal heart rate pattern and absence of uterine contractions will be a prerequisite for proceeding to the cold pressor test. The subject's pulse rate will also be continuously monitored. Urinalysis for proteinuria will be done before and after the cold pressor test. Each subject will initially be tested at 28 to 30 weeks' gestation and again at 34 weeks' gestation. The subjects will then be followed again routinely in the Obstetrics Clinic and eventually in Labor and Delivery, and the presence or absence of PIH will be noted. Hyperreactors will be retested 3 months after delivery.

PROGRESS: Only one patient has been entered in the study thus far. Problems have been encountered with recruiting of volunteers due to lack of support by residents. The principal investigator plans to personally recruit volunteers in the future.
**Objective:** To compare the efficacy of ambulation vs oxytocin in cases of dysfunctional labor, so-called dystocia.

**Technical Approach:** 100 patients will be studied. All patients with demonstrated failure to progress in labor for one hour, are at least 4 cm dilated, and who are felt to require augmentation of labor are eligible for the study. Patients will be randomized into two groups, one utilizing ambulation and the other utilizing oxytocin. Examinations will be conducted at the end of one and two hours and uterine activity will be quantified. If after two hours no progress has occurred, patients on ambulation will be returned to bed and oxytocin utilized; patients on oxytocin will be given the option to ambulate. Length of labor, time from study entry to delivery, type of delivery, 1 and 5 minute Apgar scores, cord blood gases, maternal pain perception, newborn weight and neonatal problems will be noted.

**Progress:** No subjects have been entered into this protocol as yet due to lack of time. Study will be started as soon as time permits.
A Comparison Study of Different Concentrations of Ofloxacin
Neatate During Cesarean Section

Principal Investigator: Dr. Eugene G. Fudd, MC
Dept/Sec: Dept. of Obstetrics and Gynecology
Key Words: Cefamandole neatate

OBJECTIVE: To compare the efficacy of intrauterine irrigation with cefamandole neatate versus parenterally administered cefamandole neatate before, during and after cesarean section in reducing the febrile morbidity and the incidence of endometritis and its resulting complications following cesarean section.

TECHNICAL APPROACH: This study was designed to compare intravenous antibiotics to intrauterine irrigation with antibiotic post-cesarean section.

PROGRESS: Terminated due to departure of principal investigator.
Title: Retrospective Study of Conization Followed by Hysterectomy for Various Stages of Dysplasia

Date: 13 Jan 82           Prot no.: 16/41           Status: Completed

Principal Investigator: Maj Clayton L. Shaw, MC, USAF
Facility: Tripler Army Medical Center

Associate Investigators: LTC Heinz U. Osterholzer, MC
CGL Kenio Miyazawa, MC

Key Words: Dysplasia

Accumulative MEDCASE Test Accumulative Cost: $500. Periodic Review Results:

Objective: (1) To clarify the need for reporting margin involvement in conization specimens and for follow-up histological examinations at the time of hysterectomy; and (2) to determine the incidence of persistent dysplasia in cones with negative and cones with positive margins.

Methodical Approach: A review was made of the patients who underwent conization for dysplasia and C15 from January 1974 to July 1980, followed with a hysterectomy. This group of patients were studied by the following criteria:

<table>
<thead>
<tr>
<th>CONE</th>
<th>HYSTERECTOMY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of surgery</td>
<td>Date of surgery</td>
</tr>
<tr>
<td>Depth of cone</td>
<td>Type of hysterectomy</td>
</tr>
<tr>
<td>Indication for cone</td>
<td>If BSO done</td>
</tr>
<tr>
<td>Pathology of cone</td>
<td>Cuff comments</td>
</tr>
<tr>
<td>Number of slides</td>
<td>Preoperative indications</td>
</tr>
<tr>
<td>ICC at surgery</td>
<td>Specimen gross description</td>
</tr>
<tr>
<td>Margins</td>
<td>Specimen pathology (residual tumor)</td>
</tr>
</tbody>
</table>

Depending on the size of the specimen, a minimum of 10 slides per specimen were reviewed.

PROGRESS: Charts and slides of 77 patients have been reviewed. A paper is in preparation.
**Date**: 4/4/72

**Prot No**: 1102

**Status**: Phase I

**Title**: Development of Clinical Assays

<table>
<thead>
<tr>
<th>Test Date: 7/27/72</th>
<th>Last Test Date:</th>
</tr>
</thead>
</table>

**Principal Investigator**: Peter Ambratt, M.D.

**Dept/Sec**: Pathology

**Dept of Pathology**: Tripler Army Medical Center

**Associate Investigators**:
- PT Willie Frazier, M.C.
- John L. Cieslaugh, M.C.
- CL Samuel A. Cucinella, M.C.
- Col James L. Lester, M.C.

**Accumulative Test**: PTC/SL

**Accumulative Test**: PTC/SL

**Cost**: $150.00

**Periodic Test**: Continue

**Comments**: This study is designed to (a) familiarize the clinical pathology resident with the field of new and developing assay kits; (b) give him an opportunity to evaluate the various assay kits for cost, effectiveness, and technique; and (c) determine which of the kits would be of greatest service in the future.

**Technical Approach**: All new laboratory tests which become available commercially will be evaluated by sending for information from the manufacturer. A number of kits will be purchased from various manufacturers. Clinical specimens will be obtained from patients with established diagnoses as well as from appropriate controls. Each kit will be compared for accuracy, sensitivity, cost of performance, time, shelf life, etc. The investigator will estimate, based on current and future hospital requirements, which test (if any) is best.

**SUCCESS**: The Abbott Laboratories' HBcAg kit will be evaluated next. As soon as evaluation is completed, a comprehensive serodiagnostic panel will be tested and compared to the current process to diagnose hepatitis B, hepatitis C, and posttransfusion hepatitis (non-A, non-B). This panel will test for HBsAg, Anti-HBc, Anti-HAV, HBeAg, Anti-HBc, and Anti-HBs. A group of patients will be used to compare both methods of diagnosis and to establish which one is (a) faster, (b) more cost-effective (full panel vs. sequential ordering), and (c) more informative for follow-up purposes.
**Objective:** To evaluate and determine the physiologic response of antidiuretic hormone (ADH) secretion in cerebrospinal fluid (CSF) and plasma in the newborn infant who has experienced central nervous system (CNS) injury, hypoxemia and asphyxia, i.e., is there evidence for independent control of release of ADH into the CSF and plasma. Also, to test the hypothesis that hypoxemia will increase the release of ADH into the CSF and consequently lead to increased pressure in the CSF or other evidence of cerebral edema.

**Technical Approach:** Subjects used for this study will be neonates admitted to the Special Care Nursery for evaluation of sepsis or possible sepsis. In addition, all newborn infants with intracranial hemorrhage, CNS injuries from birth trauma, and neonates experiencing severe asphyxia with hypoxemia, increased intracranial pressure, and cerebral edema. Asphyxia will be defined as follows: A 5-min APGAR score ≤6 and/or arterial blood pH ≤7.25 on admission to Special Care Nursery. On admission, each patient's APGAR scores, temperature, heart rate, blood pressure, and weight are recorded. Arterial blood gases are required for evaluation of acidosis, hypoxemia, and oxygen requirement. From each neonate, when possible, CSF opening pressure will be recorded, then 2 ml of spinal fluid will be collected and mixed with 5.4 ml of 1.0 N HCl or 0.8 ml of 1.0 N NaCl and immediately frozen for ADH assay. In addition, 1 ml of blood will be placed in a heparinized tube and plasma preserved with 0.1 ml of 1.0 N HCl/ml and frozen for ADH assay. Plasma and CSF will also be evaluated for K+ and Na+ concentration and osmolality. The data collected will be assessed to determine the correlation of CSF ADH.
and the correlations between factors of the type: heart rate, other stimulators of ADH release, e.g., plasma osmolality, plasma level of AVP, body temperature, and arterial blood pressure and plasma ADH. These data will be analyzed by multiple regression analysis to determine which factors most influence the independent release patterns of ADH into either the plasma or CSF. If computerized axial tomography scans are performed, an attempt will be made to correlate central edema with high CSF ADH levels. It is anticipated that about 100 patients would provide sufficient information regarding the above-mentioned correlations.

Progress: Project is ongoing and still active; initial data continues to be collected. Data to the present time is now being analyzed. To date, 22 neonates have been assessed for CSF ADH concentration. Of these, 20 have had sufficient blood gas analysis for preliminary statistical work-ups. None of the following results are as yet statistically significant, although expected tendencies are evident.

<table>
<thead>
<tr>
<th>Slope</th>
<th>r</th>
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<tbody>
<tr>
<td>Increased i[H+] - CSF [ADH]</td>
<td>-0.93</td>
</tr>
<tr>
<td>Increased Al [H+] - 3 min - CSF [ADH]</td>
<td>-0.62</td>
</tr>
<tr>
<td>Increased Al [H+] - 10 min - CSF [ADH]</td>
<td>-0.63</td>
</tr>
<tr>
<td>Increased Fe-OCS - CSF [ADH]</td>
<td>-0.62</td>
</tr>
<tr>
<td>Increased Fe-OCS - CSF [ADH]</td>
<td>-0.05</td>
</tr>
</tbody>
</table>

Additionally, 13 neonates have been assessed for six 4-hour sequential urine samples postpartum, some of whom also had CSF ADH determinations. Correlations between CSF and/or urinary ADH with maternal Fe-OCS, pH, body excess, body temperature, systolic blood pressure, and Al [H+] scores, are presently underway. We have had difficulty getting the enthusiastic support that we need from the Department of Pediatrics in order to continue this project. We would like to emphasize the measurement of plasma [ADH] along with CSF [ADH] in future observations. It is expected that 100 to 120 more patients would be sufficient to complete this study.
Date: 14 Jan 82

PROJ NO: 70/75

Title: Intubation and Chest Tube Placement in Small Laboratory Animals

Status: Active

Staff: F. V. (p. h., D. V. M.)

Principal Investigator: (p. h., D. V. M.)

Unit: Dept. of Pediatrics, Anatomy

Objectives:

1. To provide a teaching model for medical trainees in the proper techniques of endotracheal intubation and chest tube insertion.

2. To establish an animal facility and provide instruction in proper technique.

3. To use the animal models to refine his own abilities.

Technical Approach:

Young kittens and rabbits housed at the Tripler Army Medical Center Animal Facility will serve as animal models. The anatomy of the thorax and airway closely approximates that of the premature human infant. Standard intubation and thoracotomy equipment will be set up on a weekly basis at a time prearranged with Clinical Investigation Service and the Newborn Medicine Service. One of the above-named investigators will accompany 1-2 junior house staff officers to the facility and provide instruction in proper technique. Each house staff officer will then use the animal models to refine his own abilities.

Progress:

Training program continues unchanged. The above program was used in instructing all pediatric interns and some obstetrical interns during June and July 1981.
**DATE:** 15 Jan 82  
**Protocol No:** WJ062  
**Status:** (copying)  

**TITLE:** Comparison of Involved Field (IF) Radiotherapy and MPFP + Low Dose Bleomycin with IF Radiotherapy and 7-COPP in Stage III Hodgkin's Disease  

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>Aug 81</th>
<th>1st Comp Date:</th>
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</tr>
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<tbody>
<tr>
<td>Principal Investigator:</td>
<td>COL David A. Maybee, FC</td>
<td>Facility:</td>
<td>Tripler Army Medical Center</td>
</tr>
<tr>
<td>Dept/Sec:</td>
<td>Pediatrics/Hematology-Oncology</td>
<td>Associate Investigators:</td>
<td>COL Constance P. Hastings, MD</td>
</tr>
</tbody>
</table>

**Key Words:** Hodgkin’s disease, stage III  

<table>
<thead>
<tr>
<th>Accumulative PElDCase</th>
<th>1st Accumulative PElDCase</th>
<th>Periodic Cost:</th>
<th>QTR Cost:</th>
<th>$300.</th>
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</table>

**Objectives:** To determine the effectiveness of a five chemotherapy drug and radiation therapy treatment on stage III Hodgkin’s disease and to determine which of the five chemotherapy drug combinations gives the best results with the least side effects.  

**Clinical Eligibility:** Children diagnosed as having stage III Hodgkin’s disease are eligible.  

**Treatment will be as outlined in the study protocol.**  

**Progress:** No patients have been entered into this protocol as yet.
TITLE: Combination Chemotherapy with Vinblastine Sulfate and Lomustine Infusion in Children with Metastatic Solid Tumors (Phase II)

Start Date: Aug 01
Principal Investigator:
Col. David A. Maybee, MC
Dept/Sec:
Pediatrics/Hematology/Oncology
Key Words:
Lymphoma's Disease
Neuroblastoma
Histiocytosis

Est. Cumulative Cost: $300,000

OBJECTIVE: To determine the effects of this combination of chemotherapy on recurrent or metastatic solid tumors.

TREATMENT: Patient eligibility will be limited to patients with lymphoma, neuroblastoma, and histiocytosis.

STATUS: This protocol is now closed to new registrations.
Detail Summary Sheet

Date: 15 Jan 82     Prot No: SWOG 7621     Status: terminated

III: MOPP versus NOPP in the Treatment of Children with Recurrent
      Brain Tumors (Phase III)

Start Date: Aug 71

Principa Investigator:
COL David A. Maybee, MC

Facility:
Tripler Army Medical Center

Dept/Sec:
Pediatrics/Hematology-Oncology

Associate Investigators:
COL Constance J. Hastings, MC

Key Words:
Brain tumor, recurrent

Accumulative MEDCASE: 15  Est Accumulative Cost: $3000

Periodic Review Results: Jan 1982

OBJECTIVE: To determine the effect of the combination chemotherapy on
      brain tumor and to determine whether eliminating the MOPP from the
      NOPP combination will be as effective as the MOPP combination but with
      possibly less side effects.

TECHNICAL APPROACH: Children with brain tumor not responding to standard
      treatment will be eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. Protocol was closed to
      patient entry on 21 Oct 81.
Title: Evaluation of Systemic Regimens in the Treatment of Acute Leukemia of Childhood, Phase III

Start Date: Aug 61
End Comp Date: 

Principal Investigator: COL David A. Maybee, MC
Facility: Tripler Army Medical Center

Dept/Sec: Pediatrics/Hematology-Oncology
Associate Investigators: COL Constance F. Hastings, MC

Key Words:
Leukemia, acute, childhood

Accumulative PBCAST | Est Accumulative Periodic Cost: $900
OMA Cost: $300

OBJECTIVES: To determine the effect of intensive, multiagent chemotherapy of acute lymphocytic leukemia and to determine the role of treating with an antibiotic, called trimethoprim-sulfamethoxazole, to prevent infection during treatment for acute lymphocytic leukemia.

TECHNICAL APPROACH: Patients under 21 years of age at time of diagnosis of ALL, AML, or APL, with no previous therapy except for one week or less of corticosteroids prior to admission, falling into a good or poor prognosis category and having either no markers or T-cell markers, are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: Nine patients have been registered. This protocol is now closed to new entrants due to sufficient patient accrual.
**Objective:** To compare two forms of treatment for stage I and stage II Hodgkin's disease.

**Clinical Approach:** Children 18 and under with untreated stage I and II Hodgkin's disease are eligible. Patients with massive mediastinal disease requiring local radiotherapy on an urgent basis for tumor shrinkage prior to lymphography and administration of anesthesia for staging mediastinoscopy are eligible.

Treatment will be as outlined in the study protocol.

**Progress:** Two patients have been registered in this protocol. The protocol is now closed to new entrants due to sufficient patient accrual.
OBJECTIVE: To determine whether, after a course of six treatments of three chemotherapy drugs given into the spinal fluid, radiation to the head and spinal column followed by no further treatment is better than radiation to the head alone followed by continuing courses of the three drugs into the spinal fluid.

TECHNICAL APPROACH: Children with acute lymphoblastic leukemia who have recurred in the central nervous system are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into this protocol as yet.
Date: 19 Jan B2  Project No: SKOC 77/2  Status: Completed

Title: Evaluation of Induction, Maintenance with and without Periodic Reinforcement, and CNS Prophylaxis in Acute Non-lymphocytic Leukemia

Start Date: Aug 81
End Date: 1st Comp Date: 19 Jan B2

Principal Investigator:
Col. David A. Mayhew, M.D.

Co-Investigators:
Tripler Army Medical Center
Col. Constance F. Festing, M.C.

Facility:
Tripler Army Medical Center

Key Words:
Leukemia, nonlymphocytic, acute

Objective:
To try to cause a remission, to try to prevent metastases to the central nervous system, and to try to prolong the remission as long as possible.

Technical Approach:
Patients under 61 years of age with diagnosis of acute myelocytic leukemia or acute myelomonocytic leukemia are eligible. Patients with a diagnosis of chronic granulocytic leukemia in blast crisis, erythroleukemia, or other rare forms of myelocytic leukemia are eligible, but will not be randomized. Patients must have had no previous therapy except one week or less of corticosteroids prior to admission. Patients must be available for periodic follow-up.

Treatment will be as outlined in the study protocol.

Progress:
Three patients have been registered. The protocol is now closed to patient entry due to sufficient patient accrual.
TITLE: Evaluation of Anguidine in Children with Acute Leukemia in Relapse, Phase II

Project No: SWOG 7810
Status: Enrolled

Start Date: Aug 78
End Date: 1st Comp Date:

Principal Investigator: COL David F. Mayle, FL
Dept/Sec: Pediatrics/Hematology-Oncology

Facility: Tripler Army Medical Center
Associate Investigators: COL Constance F. Easton, IC

Key Words:
Lymphoid malignancy

Accumulative MEDICAL
Cost: $300.00

PERIODIC

OBJECTIVE: To determine the effect of anguidine on lymphoid malignancy.

CLINICAL APPROACH: Children having lymphoid malignancy, diagnosed in relapse, previously diagnosed as acute leukemia or lymphoma, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been registered. This study is now closed due to slow accrual of patients.
**Date:** 15 Jan 82  
**Proj No:** SWOG 711  
**Status:** Moving

**TITLE:** Evaluation of Anguidine in the Treatment of Central Nervous System Tumors (Phase II)

<table>
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<tr>
<th>Start Date</th>
<th>Aug 81</th>
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</thead>
</table>

**Principal Investigator:**  
COL David A. Maybee, MC

**Dept/Sec:** Pediatrics/Hematology-Oncology

**Key Words:** Central nervous system tumors

<table>
<thead>
<tr>
<th>Periodic Cost</th>
<th>Total Cost: $400</th>
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**OBJECTIVE:** To determine the effect of anguidine on brain or spinal cord tumor.

**TECHNICAL APPROACH:** Children with malignant tumor of the brain or spinal cord that has not responded to therapy or for which there is no standard therapy are eligible.

Treatment will be as outlined in the study protocol.

**PROGRESS:** No patients registered as yet.
Detail Summary Sheet

Date: 15 Jan 82  Prot No: SWOG 701  Status: Enrolling

TITLE: Evaluation of Rubidazole in Children with Acute Leukemia in Remission: Phase II

Start Date: Apr 61  Est Comp Date:  
Principal Investigator: COL David A. Maybee, MC  Facility: Tripler Army Medical Center
Dept/Sec: Pediatrics/Hematology-Oncology  Associate Investigators: COL Constance F. Hastings, MC

Key Words: Leukemia

Accumulative MEDCASE Est Accumulative Cost:  
OMA Cost: $300.  Periodic Review Result: Continue

OBJECTIVE: To determine the effect of rubidazole on leukemia.

TECHNICAL APPROACH: Children with acute leukemia not responding to standard forms of therapy are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients have been entered into trial as yet.
DEEPLY I. H. 

DATE: May 12, 1980 A.M. Reconsidered
TITLE: Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II

Start Date: Apr 1, 1980
End Comp. Date: 
Principal Investigator: COL David M. Hayter, MC
Co-PI: COL Constance L. Hastings, MC
Dept/Sec: Pediatrics/Hematology-Oncology
Charles: CNS

Accumulative PREDICT [Est. Accumulative Periodic
Cost: [CPA Cost: $2000, Review Results: Ter, Date:

OBJECTIVE: To determine whether a lower dose of methotrexate given into the spinal fluid is more effective than the larger standard dose in treating central nervous system leukemia.

TECHNICAL APPROACH: Children with leukemia in the central nervous system that recur in spite of previous treatment are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: No patients recruited. Protocol closed to new entries as of 21 Oct 81.
**Detail Summary Sheet**

**Title:** Second Induction and Maintenance in Acute Lymphocytic Leukemia (Phase III)

**Date:** 15 Jan 82 | **Prot No:** SKOG 7712 | **Status:** Ongoing

| Start Date: | Aug 81 | 1st Comp Date: |
| Principal Investigator: | |
| (Incl. Incl. N. Hayhoe, MD) | Facility: |
| (Incl. Sec) | Triage: Any Medical Center |
| Pediatrics/Hematology-Oncology | Associate Investigators: |
| Key Words: | (Incl. Constantine A. Sauter, MD) |
| Intensive, lymphocytic leukemia |

<table>
<thead>
<tr>
<th>Periodic</th>
<th>1st Accumulative Periodic Cost:</th>
<th>OMIC Cost: $3,000.</th>
<th>Review Results: Continue</th>
</tr>
</thead>
</table>

**Objective:** To try to cause a remission, to try to prevent the spread of the leukemia to the central nervous system and to try to prolong the remission as long as possible.

**Inclusion Criteria:** Patients must be under 11 years of age. Patients having received prior treatment with adriamycin, daunorubicin, 6-MP, or systemic cytosine arabinoside are ineligible. Patients having had a previously treated relapse (CRS, IMI) are ineligible. For patients in their first CRS relapse, concurrent registration to SKOG 7712 is required. Patients with IMI are eligible; concurrent registration to the IMI protocol is required if patient qualifies. Patients with a combination of initial CRS and/or IMI relapse are eligible. Patients with IMI and/or IMI at initial diagnosis and previously treated are eligible.

Treatment will be as outlined in the study protocol.

**Status:** Two patients have been registered.
Date: 15 Jan 84

Title: Evaluation of Systemic Therapy for Children with T-cell Acute Lymphatic Leukemia, Phase II

Start Date: Aug 88
Principal Investigator: Dr. Dave D. Haynes, II
Lept/Sec: Pediatrics/Hematology-Oncology

Key Words: Leukemia, T-cell

Cumulative No/Case List: Cumulative Summary
Periodic Periodic
Cost: UMA Cost: $300.

Objectives:
1. To determine the effectiveness of aggressive treatment of T-cell acute lymphatic leukemia and to determine which of two protocols is most effective with the least amount of side effects.
2. Eligibility Criteria: Children with T-cell leukemia are eligible.
3. Treatment will be as outlined in the study protocol.
4. Progress: To patients have been entered into the protocol as yet.
**Objectives**

- To determine the effectiveness of radiation therapy in controlling acute lymphoblastic leukemia outside of the bone marrow and outside of the central nervous system.

**Technical Approach**: Children with acute lymphoblastic leukemia receiving outside of the bone marrow and outside the central nervous system are eligible.

**Radiation Therapy**

- Treatment will be as outlined in the study protocol.
Objective: To determine the effect of the combination of chemotherapy and radiation therapy on non-Hodgkin's lymphoma and to determine which of the protocols is more effective with the least side effects.

Technical Approach: Children with non-Hodgkin's lymphoma are eligible. Treatment will be as outlined in the study protocol.

Progress: One patient has been registered.
**Title:** Multidrug Paediatric Chemotherapy in Osteosarcoma (comparison of CONPADRI-I with CONPADRI-V (Phase III))

**Cart Date:** Aug 61 | **Est Imp Date:**
---|---
**Principal Investigator:** COL David H. Maybee, MD | **Facility:** Tripler Army Medical Center
**Dept/Sec:** Pediatrics/Hematology-Oncology | **Associate Investigators:** COL Constance L. Hastings, MD

**Key Words:**
- Osteosarcoma, nonmetastatic

**AccumulativePEDCASE** | **Est Accumulative UMA Cost:** $300 | **Periodic Review Results:**
---|---|---

**OBJECTIVE:** To determine the effect of a combination of chemotherapy on osteosarcoma, to determine the effect of adding high-dose methotrexate to the combination of chemotherapy drugs in CONPADRI-I, and to determine which combination, CONPADRI-I or CONPADRI-V, is more effective in treating osteosarcoma.

**RATIONALE:** Children with osteosarcoma.

**Inclusion:** Patients will be as outlined in the study protocol.

**PROGRESS:** No patients have been registered. Protocol is now closer to patient entry.
Title: Evaluation of m-AMSA in Children with Acute Leukemia and Non-Hodgkin's Lymphoma in Eclipse, Phase II

Start Date: Aug. 82

Principal Investigator:
COL David A. Fayhee, MC

Dept/Sec:
Pediatrics/Hematology-oncology

Key Words:
Leukemia
Lymphoma, treatment

Objective: To determine the effect of m-AMSA on acute leukemia or non-Hodgkin's lymphoma.

METHOD: Children with acute lymphoblastic leukemia, acute non-lymphoblastic leukemia, or non-Hodgkin's lymphoma are eligible.

Treatment will be as outlined in the study protocol.

Comment: The protocol has been entered into this protocol as of yet.
TITL: Therapy for Extraocular Retinoblastoma with Cyclophosphamide, Vincristine, Adriamycin, and Irradiation

Start Date: Aug 41
Principal Investigator: COL David A. Maybee, MC
Dept/Sec: Pediatrics/Hematology-Oncology
Key Words: Retinoblastoma

OBJECTIVE: To determine the effectiveness of chemotherapy drugs in treating retinoblastoma and the effectiveness of combining radiation therapy and chemotherapy.

TECHNICAL APPROVAL: Children with histologically proven extraocular retinoblastoma are eligible.

Treatment will be as outlined in the study protocol.

PROGRESS: This study was closed due to lack of patient accrual.
**Date:** 15 Jan 82  
**Prot. No.:** SWOG E2CO  
**Status:** Enrolling

**TITLE:** The National Wilms' Tumor Study II

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>Aug 81</th>
<th>1st Corp Date:</th>
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<tbody>
<tr>
<td>Principal Investigator:</td>
<td>Dr. David A. Maybee, MD</td>
<td>Facility: Tripler Army Medical Center</td>
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<tr>
<td>Dept/Sec:</td>
<td>Pediatrics/Hematology-Oncology</td>
<td>Associate Investigators: Dr Constance L. Hastings, MD</td>
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<td>Key Investigators:</td>
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</table>

**Accumulative Malignant Lymphoma:** 1st Accumulative Therapeutic

| Date: | IOM (pt): 329.0 | Review: Results: Continue |

**Objective:** To determine the effect of chemotherapy on Wilms' tumor and to determine which chemotherapy schedule is best. This study is also designed to determine if radiation therapy is necessary when the tumor has been completely removed and in what dosage.

**THERAPEUTIC APPROACH:** Children diagnosed as having Wilms' tumor are included.

Treatment will be as outlined in the study protocol.

**PROGRESS:** Two patients have been registered.
**Investigator:** Col. David A. Maybee, MC  
**Dept./Sec.:** Pediatrics/Hematology-Oncology  
**Facility:** Tripler Army Medical Center  
**Associate Investigators:** COL Constance F. Hastings, MC

**Objective:** To determine the effectiveness of the chemotherapy drug ICV on medulloblastoma and ependymoma recurring after previous therapy.

**Technical Approach:** Children with medulloblastoma or ependymoma recurring following therapy are eligible.

**Treatment will be as outlined in the study protocol.**

**Progress:** No patients have been entered into this protocol as yet.
TREATMENT OBJECTIVE: To determine the effectiveness of the investigational drug m-AMS in solid tumors recurring after previous treatment.

TREATMENT APPROACH: All patients with solid tumors in relapse who are 18 years of age or younger at the time of diagnosis, who are not eligible for protocols of higher priority, and who are resistant to conventional forms of therapy, will be eligible. Patients must have measurable tumor and a life expectancy of at least 4 weeks. Patients must have an albumin >2.5 g/dl and platelet count >100,000/mm$^3$, unless patient has evidence of tumor invasion of the bone marrow. Normal renal [BUN <20 and creatinine <1.2 mg/dl] and liver function tests pretherapy (bilirubin <1.0 mg/dl) and normal serum potassium are required for all patients. Patients may have received no prior therapy with m-AMS.

Treatment will be as outlined in the study protocol.

STATUS: No patients have been entered into this protocol as yet.
**Summary Sheet**

**Title:** Evaluation of Vindesine Twice Weekly Plus Prednisone and a Cross-over Study of Vindesine-Prednisone vs Vincristine-Prednisone to Children with Acute Lymphoblastic Leukemia, Hodgkin's Disease, and Non-Hodgkin's Lymphoma, Phase III

**Principal Investigator:** W. David A. Faybee, MD

**Facility:** Tripler Army Medical Center

**Associate Investigators:** Constance E. Hastings, et al.

**Keywords:** Leukemia, acute lymphoblastic Hodgkin's disease Lymphoma, non-Hodgkin's

**Cost:** Research Cost: $300

**Periodic Results:** Continue

**Objective:** To compare the effectiveness of vindesine plus prednisone to the standard therapy of vincristine plus prednisone for the treatment of acute lymphoblastic leukemia, Hodgkin's disease, and non-Hodgkin's lymphoma.

**Technique:** Children with acute lymphoblastic leukemia, Hodgkin's disease, and non-Hodgkin's lymphoma recurring on therapy and not shown to be resistant to vincristine and prednisone are eligible.

**Treatment:** Treatment will be as outlined in the study protocol.

**Progress:** Ten patients have been entered into this protocol as of now.
**Primary Goal:**
To look at how cancer might be passed on in the genes.

**Technical Approach:** All newly diagnosed patients with ALL (black only) or central nervous system (white only) 18 years of age and under are eligible. Treatment will be as outlined in the study protocol.

**Pilot:**
No patients have been entered into the study as yet.
**Date:** 12 Jan 82
**Protocol:** $460-7203
**Status:** Ongoing

**TITLE:** Multimodal Therapy of Metastatic Ewing's Sarcoma With Chemotherapy Plus Irradiation and Surgery (if feasible), Intergroup Phase III

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<td>Aug 81</td>
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</tbody>
</table>

**Principal Investigator:** Dr. David A. Payton, MD
**Dept/Sec:** Pediatrics/Hematology-Oncology

**Key Words:** Ewing's sarcoma

- **Accumulative T/CDCAST:**
- **Test Accumulative Test:**
- **UPA Cost:** $300
- **Periodic Review Results:** Continue

**OBJECTIVE:** To determine the effectiveness of an intensive 5-drug chemotherapy plan using Adriamycin, vincristine, cyclophosphamide, ifosfamide, and actinomycin-D plus radiation therapy and surgery in metastatic Ewing's sarcoma.

**METHOD/APPRAISAL:** Children with metastatic Ewing's sarcoma are eligible.

Treatment will be as outlined in the study protocol.

**PROGRESS:** To date, no patients have been entered into this protocol as yet.
As part of a larger program of research, it is proposed to use a retrospective chart study method to compare the decrement in cognition associated with depression in two age groups. Patients with a diagnosis of depression who are over 60 will be compared to patients with a similar diagnosis who are under 30. It is specifically hypothesized a greater right hemisphere decrement in cognition as a function of depression occur in the older group of patients.

TECHNICAL APPROACH: We plan to select all cases of patients with a diagnosis of depression in the last three years for whom intelligence testing was done, and who are either over 60 or under 30. Using the charts and psychological evaluations of these patients, we will construct an index to rate the severity of each patient's depression. Using this index, patients within each age group will be subdivided into severe and moderate depression groups. The subtest scores of each group will then be compared to the age-related norms that are published for each subtest. We will also form comparable groups made up of age-matched nondemented patients as comparison samples. The scores of each age group will also be compared to each other. Standard statistical techniques will be used to analyze the data.

NOTE: This project currently awaits a list of funds requested from the Federal Administration Division.
THE MILITARY CHILD PSYCHIATRY OUTPATIENT POPULATION: A STUDY OF DEMOGRAPHICS, ETHEL LETTERS, AND MANUSCRIPT


Abstract:

The purpose of this study is to assess demographic variables, referral patterns, and diagnostic categories of the clinic population.

Method:

A retrospective review of cases from 1960 to 1965. Information was obtained from standardized intake forms completed by the patients' parents at the time of evaluation. Relevant data included variables such as sex, family composition, ethnic background, educational status, previous psychiatric treatment, referral source, presenting symptoms, and final DSM III diagnosis. The clinic patient's marital status, socioeconomic level, religion, and military status were also recorded. The statistics compiled were compared to the statistics available on the military population of Hawaii.

Results:

The data of this report indicate that the incidence of child psychiatry referrals among Hawaii's military population differs little from the incidence reported by similar civilian clinics. The parental situation was similar to that of the civilian community and was somewhat more stable than that reported by civilian clinics. The incidence of referrals for each branch of service was quite similar, suggesting that interservice differences in military stresses do not play a role in child psychiatry referrals. The similarity between CHANEL and military clinic cases indicated that neither facility was servicing a sector of the military population distinct from the other. One must question whether the perpetuation of the duplication of services is the most cost-effective way of providing optimum child psychiatry services for the military. The economic and therapeutic issues are of such magnitude that this matter clearly warrants further investigation. A manuscript is in preparation.
SHORT title: Pedi: 1/1

Title: Adolescent Obesity: A Behavioral Treatment Program Evaluation

Principal Investigator:
Matthew J. Weiss, Ph.D.
M.D.

Co-Investigator:
Richard L. Ostrander, M.D.

Principal Investigator:
Matthew J. Weiss, Ph.D.

Facility:
Drexel University

Division of Adolescent Psychiatry

Summary:
Participants have not yet begun treatment or received any of the necessary equipment.
RADIUM: Since there is currently a moratorium on the use of radioactive substances in cisternography, it is our purpose to substitute Indium-111 labeled albumin in this procedure. Indium-111 labeled albumin is presently being used in the spinal fluid in the diagnosis and treatment of spinal fluid leakage. The results will be correlated with the results obtained with older methods of spinal fluid diagnosis. The availability of labeled albumin is expected to offer a significant improvement in the clinical diagnosis of spinal fluid leakage. The results of this procedure are expected to improve the accuracy and reliability of the diagnostic testing of spinal fluid leakage.

METHODS: Radiological cisternography will be performed utilizing Indium-111 labeled albumin in those patients with the above described clinical problem. Results obtained from these procedures will be compared with results obtained with earlier methods of spinal fluid diagnosis. The results of clinical findings by radiological cisternography will be correlated with the results of clinical findings by other methods of spinal fluid diagnosis. The limitations of this procedure in each of the clinical investigations of spinal fluid leakage will be evaluated. The results of this procedure will be evaluated for both clinical and radiological fluid pathways to determine the value of this method in the diagnosis and treatment of spinal fluid leakage. The patients who will benefit from this procedure are those who have been diagnosed with spinal fluid leakage and who have been treated with other methods of spinal fluid diagnosis. The results of this procedure will be evaluated for both clinical and radiological fluid pathways to determine the value of this method in the diagnosis and treatment of spinal fluid leakage.

RADIUM: Cisternography was performed on 18 patients during 1971. The study has proved to be a useful adjunct in exploring the cisternographic fluid dynamics of all patients.
TITLE: CLINICAL EVALUATION OF FLUORESCENT SCANNING OF THE THYROID WITH A SERIES 111

Principal Investigator: Reba H. Hade, M.D.
Facility: Medical Group, Nuclear Medicine Dept.
Associate Investigators:

Objectives:

1. To determine the value of fluorescent thyroid imaging as a means of visualizing focal abnormalities of the thyroid gland in the diagnosis of a variety of thyroid abnormalities.

2. To correlate dual studies involving both conventional thyroid scanning and fluorescent technique scanning in order to test the efficacy of the latter method.

Methodology:

Fluorescent scans were performed during the week of a thyroid scan. When personnel shortages are resolved, the project will again be resumed.
**Title:** Study of the Internal Mammary Lymph Nodes in Patients with Upper Quadrant Breast Cancer

**Facility:**
- University Hospital Center
- Associate Investigators: Medical and Nuclear Medicine

**Objectives:**
- To determine if the presence or absence of lymphatic metastasis in mammary lymph nodes will make any difference in the morbidity or mortality of patients with breast cancer.

**Rationale:**
- Patients studied will be women who have proven or highly suspected breast carcinoma. No pregnant or lactating women or those under 18 years of age will be admitted to the study. The benefits to be gained by the study outweigh any risk to the patient or the physician.

The anthracnoma sulcide colloid will be obtained from the Research Corporation. Tagging will be performed locally with I-131.

An anthracnoma sulcide colloid 500 µl will be injected into the posterior rectus sheath on the ipsilateral side. For the other half, three hours later a camera will be utilized with a suitable collimator to image the internal mammary lymph nodes on the ipsilateral side.

**Highlights:**
- To date, approval for performing this study has not been granted by the Surgeon General's Human Subjects Research Committee. Therefore, no progress on this study has been made.
Title:

**In Vivo Evaluation of Hepatobiliary Scans**

**Principal Investigator:** 

**Facility:**

**Department/Section/Division:**

**Speciality:**

**Protocol Number:** 70/00

**Date:** February 10, 1975

**Committee:**

**Document Type:**

**Summary:** To demonstrate the safety and efficacy of a new hepatobiliary scintillation agent for the in vivo evaluation of hepatobiliary system in patients suspected of having hepatobiliary disease.

**Protocol Summary:**

The study will include patients suspected of having hepatobiliary disease, which can include jaundice or any clinical or pathologic evidence of disease of the liver or bile ducts. The drug, unless the benefits gained outweigh the risks, is administered orally. The BHA will be obtained in the form of a labeled technetium-99m complex. The suggested dose range employs an average of 30 to 50 mg of technetium-99m depending on the level of a recent serum bilirubin determination or clinical estimate of the degree of jaundice, if no serum bilirubin level is available.

**Findings:** Hepatobiliary scans were performed on 14 patients during 12/12/15. The studies proved to be useful adjuncts in assessing hepatobiliary disease.
Study of the density of the seminal fluid in men with varicocele.

The study of the density of the seminal fluid in men with varicocele showed a significant increase compared to control subjects. This finding is consistent with previous reports indicating a correlation between varicocele and semen quality. Further studies are needed to explore the mechanisms underlying this association.
Intravenous Pyelogram (IVP) Study

**Objective:** To study the effects of premedication on the incidence of contrast media reactions.

**Methodology:** This is a randomized, double-blind study involving participating medical centers across the U.S.A. As many as 400 patients receiving IVPs may eventually be enrolled in this study. Patients will be assigned to one of four groups: (1) 32 mg of Atropine in the evening preceding urography and 32 mg of Atropine again in the morning at least 2 hours before the IVP is given. (2) 32 mg of Atropine in the morning at least 2 hours before the IVP is given. (3) Placebo in the evening preceding urography and again in the morning at least 2 hours before the IVP is given. (4) Placebo in the morning at least 2 hours before the IVP is given. The intravenous pyelogram will be carried out with the usual technique employed in each institution. Appropriate medications to treat reactions, if they occur, will be readily available.

**Reasons:** Because of the long delay in obtaining approval and the problems with communication between San Diego and Indianapolis, this study was terminated prior to starting. No patients were studied.
<table>
<thead>
<tr>
<th>Date of Report</th>
<th>Principal Investigator</th>
<th>Facility</th>
<th>Associate Investigators</th>
<th>Project Title</th>
<th>List Report</th>
<th>Report Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 Aug 78</td>
<td>Dr. Charles J. Anderson</td>
<td>Tripler Army Medical Center</td>
<td>Dr. John L. Treadway, Lt. Col.</td>
<td>The Value of Gallium Scans in Determining Prostatic Graft Infections in Canines</td>
<td>Dr. John L. Treadway, Lt. Col.</td>
<td>Gallium scan is used to detect graft infections. After surgery, both animals are sacrificed and gallium scans are performed to detect infections. The gallium scan accurately predicts the presence of a graft infection. After surgery, the animals are sacrificed and gallium scans are performed to detect infections. The gallium scan accurately predicts the presence of a graft infection.</td>
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There was no progress made in the project since the last report. It was previously determined that more control studies were needed, and this is planned for the next fiscal year.
Detail Summary Sheet

Date: [Missing]  Prec Int: [Missing]  Status: Completed

Initials: [Missing]  Facility: [Missing]

Initial Investigator: David J. Anderson  Tripler Army Medical Center

Type of Surgery: [Missing]

Cumulative Review

ACRUST | 1st Acummulative | Periodic
---|---|---
(Rev. Cost. | Sou. | Review Results)

OBJECTIVE: To evaluate the effectiveness of an audiovisual tape, togerher with a written transcript of the audio portion of the tape, in preparing patients for an operation.

METHODOLOGY: All patients undergoing elective cholecystectomy will be counseled by the operating surgeon utilizing the format that they have previously used. In addition to the routine counseling, 10 percent of these surgeon's (randomly selected) patients will be selected to receive an audiovisual tape on gallbladder surgery by a nurse who is not involved in their care. These patients will then be given a printed transcript of the tape. The nurse will have all cholecystectomy patients complete a questionnaire in regard to attitudes. After each patient in the study and ten minutes, the nurse will review the chart and record pertinent data. All patients will be asked to complete a retrospective questionnaire.

The study is to be conducted as a joint project with the support from the participating hospitals. The data will be collected, compiled, and coded for 12 months. At the conclusion of the study, the data analysis will be conducted in two phases: initial descriptive level-by-level analysis of the data with an interpretive summary.

SUCCESS: The clinical work has been completed at Tripler Army Medical Center, Kaiser Clinic, Queen's Medical Center, and Kaiser Hospital. The data is currently being analyzed by physicians and statisticians, and appropriate papers will be prepared.

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Surgical Training Protocol

<table>
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<tr>
<th>Contract No.:</th>
<th>Page:</th>
<th>Principal Investigator:</th>
<th>Facility:</th>
</tr>
</thead>
<tbody>
<tr>
<td>130-77-15</td>
<td>2</td>
<td>W.S. Sherlock, Jr., M.D.</td>
<td>Tripler Army Medical Center</td>
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</tbody>
</table>

Field of Surgery / Plastic Surgery:

- Plastic
- Vascular

Surgical Training: The surgical training for vascular surgery involves practice on cadaveric specimens and the use of animal models. Initial efforts have been focused on developing techniques for vascular reconstruction.

Preplanned: In June 1977, the second plastic surgeon arrived. The initial efforts included vascular repair in rats, the repair of vessels in vivo with various graft materials. An evaluation of patency is planned. Efforts towards developing techniques for use in the rabbit ear and dog intestine and vas deferens is possible.

Update: Until the arrival of a second plastic surgeon in June of 1977, the Clinic workload precluded weekly laboratory sessions. Since then, the workload has lessened and the project will soon be continued on a regular basis.
This study comprises a review of 500 patients admitted to hospital for injuries sustained in motorcycle accidents over a 6-month period. All patients were cared for by the surgical house staff of a large metropolitan hospital. All operative procedures were performed by the house staff with attending staff supervision. Most of the patients were under 30 years old and lower extremity fractures occurred most frequently. Patients were hospitalized for an average of 6 weeks. An effort is being made to relate length of motorcycle ownership and riding experience to the potential for significant injury.

An abstract has been accepted for presentation at the Residents' Session, American Orthopaedic Association, Washington, D.C., April 1962.
Project Title: Radiotrace Scanning, in the Diagnosis of Joint Infections

Principal Investigator: [Name]

Facility: [Facility Name]

Brief: It is necessary to evaluate the accuracy of radionuclear scanning in the diagnosis of infections in joints. The data obtained in this project will be compared with other diagnostic methods already used to determine the accuracy of radionuclear scanning in the diagnosis of infections.

Method: The radionuclear scanning studies will be done on a patient with a history of arthritis of the knee. The patient will be scanned at an early stage of the infection using technetium-99m. Other diagnostic methods will be used for comparison.

Conclusion: This project is terminated due to the departure of the principal investigator.
result to the Type B-1 test. The following results were found:

<table>
<thead>
<tr>
<th>Type B-1 Test</th>
<th>Type C-2 Test</th>
<th>Type D-3 Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Negative</td>
<td>Positive</td>
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<tr>
<td>Negative</td>
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<tr>
<td>Positive</td>
<td>Positive</td>
<td>Negative</td>
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The results indicate the presence of specific antibodies in Type B-1 and Type D-3 tests, while the Type C-2 test remains negative.

Further tests are recommended to confirm the diagnosis.
Partial Cystectomy Followed by Cholecystectomy and Anastomotic Ureteroplasty with the Gallbladder in Rats

Start Date: Jun 10

Principal Investigator: Dr. George C. Regatti, M.D.

Facility: Tripler Army Medical Center

Dept of Surgery/Therio: Associate Investigators

Objectives: To determine the feasibility of using the gallbladder as a substitute for the ureter in rats.

INITIAL PROGRESS: Gallbladders have been used to correct renal defects in the dogs of urinary leakage in rats.

RIGHT NOW: This project is terminated due to the departure of the principal investigator.
To review compartment syndromes related to the clinical, pathological, tissue pressure, dermatological, surgical, treatment, and the clinical approach to the syndrome.

The following established a comprehensive review of typical syndromes, the dynamics of circulation, infection, and compartment syndrome, reviewed the anatomy of the fascia and its constituents, the physiology involved within the compartment syndrome. Various ways of determining tissue pressure measurements. Utilizing the pathological factors involved in compartment syndromes, trends and early recommended for compartment syndromes, case reports, and a clinical approach.

The possibility of closed compartment syndrome causing or relieving a neurulocutaneous or an extensile fascial pressure are signs of a disturbance in circulation with increase tissue pressure. Tight bandaging is a common cause, and pressure toward the closed compartment may be present even when tissue tension does not occur. Delay in diagnosis and decompression may lead to a permanent defect, loss of function, and amputation. Fascial cut is required because tissue pressure that cannot be relieved.

The treatment of compartment syndrome is further detailed.
Finally, gathering of clinical data has been completed. We are now in the process of collating the data to permit final conclusions. It appears that while radionuclide scanning is a sensitive indicator of patellar subluxation, it is not specific enough to be of great value in the routine diagnosis of patellar disorders. However, some subcategories seem to have specific appearance on bone scan and we therefore can consider its use in specific applications. We plan to prepare this data in final form and submit it for publication in the near future.

Initial findings were presented at the Society of Military Orthopedic Surgeons meeting in November 1979.
International Day of the Rights of the Child

...
Lithotripsy: Preliminary study of staghorn calculi with direct extrapolation fractures in children.

Table 1: Preliminary study of staghorn calculi with direct extrapolation fractures in children.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Principal Investigator</th>
<th>Type of Injury/Extrapolation Fracture</th>
</tr>
</thead>
<tbody>
<tr>
<td>L. E. A. Beinker, M.D.</td>
<td>L. E. A. Beinker, M.D.</td>
<td>Direct Extrapolation Fracture</td>
</tr>
</tbody>
</table>

Results: To date, the results of treatment of direct extrapolation fractures in children with staghorn calculi have been evaluated, focusing on the specific injury, complications, and treatment. The injuries will be divided into those of the phalanges, metacarpals, carpals, clavicle, lower, and upper arm, shoulder, and clavicle. For each fracture site, the average age, type of follow-up, complications, and treatment will be summarized. Due to the large number of items involved, a statistical analysis with the use of computer programming is necessary for full realization of the information available. Attempts will be made to clarify which fractures have the greatest potential for relative motion, delayed healing, or other complications.

Preliminary: Preliminary contact has been made with the Computer Center and arrangements have been made for data to be collated. Further arrangements have been harpered by ISS of GM Landry who accompanied the preliminary contacts. Progress on the project is expected to follow soon.
<table>
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<tr>
<th>Article: A470</th>
<th>Facility:</th>
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<tbody>
<tr>
<td>Principal Investigator:</td>
<td>Facility Location:</td>
</tr>
<tr>
<td>Dr. Brown</td>
<td>Medical Research Center</td>
</tr>
<tr>
<td>Year: 2021</td>
<td>Associate Investigator:</td>
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<tr>
<td>Budget: $100,000</td>
<td>Lead Investigator:</td>
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</table>

The study aims to investigate the effects of certain substances. Each substance will be tested on skin specimens. The skin specimens will be cultured in vitro and exposed to each substance. The responses of the cultured skin specimens will be judged as to their comparison to controls. The treated skin specimen will serve as controls. The effect of response to each substance will be measured and compared to skin controls.

**Status:** This project is terminated due to lack of funds on the part of the investigators.
Objective: To develop a clinically useful hemodynamic monitor for continuous non-invasive monitoring of subendocardial ischemia.

Methods: An externally applied sensor will be placed in the abdominal aorta to measure cardiac output. An arterial camera with an electronic image intensifier indicates ischemic areas. Hemodynamic variables, such as cardiac index, central venous pressure, and left ventricular stroke work will be correlated with ratio of diastolic coronary blood flow over the mean arterial pressure to index stress to assess the reliability of the hemodynamic factors as markers of ischemia.

Results: Production of monitor has been discontinued. The project is therefore terminated.
Date: 18 Jan 82
Protocol: 122/77
Title: Tcil Clem Injections

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<thead>
<tr>
<th>Start Date</th>
<th>Aug 72</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>Dr. Thomas L. Van Scoy, M.D.</td>
</tr>
<tr>
<td>Site</td>
<td>Bronson Hospital/Fowler Clinic</td>
</tr>
<tr>
<td>Site Type</td>
<td>Outpatient</td>
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**Cumulative DURABLE**: 1st Accumulative Periodic

**DURABLE**: To participate in expanded clinical trials of Tcil Clem Injection for the following clinical indications: The selected treatment of patients with velopharyngeal insufficiency and/or externally patent eustachian tubes.

**METHODOLOGY**: The protocol will follow the clinical study group proposals. Patients will originate in the UIU Clinic. Only patients who have not responded to conventional treatment modalities will be considered. The procedure with its possible risks will be explained to the patient, as well as its investigative nature. If the patient agrees to participate, the case history will be forwarded for consideration to the study group who will furnish the necessary materials (injection).

Patients will require hospitalization for approximately 1-2 days for the surgical procedure which will be done under appropriate anesthesia. Recovery time will be 30 minutes to one hour. The patient's will continue to be followed on an outpatient basis for a minimum of 15 days as required by the protocol.

**RESULTS**: The project is terminated as of 12/31/82. It is longer necessary to collect data for this use.
The technique has been used in selective cases for approximately 1 year by the investigators. A course of instruction on the procedure illustrated by double slide projection and 3/4 video tape has been developed and presented by invitation on several occasions. A pilot study with the Neurosurgery service is underway comparing the endonasal approach for transseptal transbullal keyhole surgery. A teaching video tape is in development. A invitation has been received to continue presenting the instruction course at the spring meeting of the American Academy of Otolaryngology—Head Neck Surgery, Annual Meeting, Las Vegas, Nevada, Sep 1981.
### Objective
To investigate the feasibility of using cadaveric urachal and bladder-colic flaps for urinary diversion and as an alternative to the urinary bladder. To compare the advantages/disadvantages of these methods to the current methods of urinary diversion.

### Technical Approach
The technical approach of this procedure includes a laparotomy, a suprapubic catheter, and a colonic incision. The greater curvature of the stomach is vascularized by the left gastroepiploic artery. The ureter is then diverted into the abdominal cavity and the urethra reconnected to the skin in a standard fashion. Postoperative and postoperative renal function is assessed.

### Results
The group with cadaveric urachal and bladder-colic flaps showed better results in terms of renal function and urine output compared to the group with ileal conduit. However, complications such as anastomotic leak were more common in the cadaveric flaps group. Further studies are needed to compare these results with those obtained in other centers.
To examine the feasibility of determining strain differences of typhoidcoccus aureus by analysis of gas liquid chromatography (GLC) fatty acid profiles. If strain differences can be demonstrated, chromatographic analysis can be simplified, and rapid laboratory analysis can be made without resorting to time-consuming phage typing.

Step 1: Strains of S. aureus will be collected and identified by the Microbiology Section, Department of Pathology. Organisms will be prepared for gas chromatographic analysis according to the method of the method of the laboratory. Briefly, whole cell walls will be prepared for GLC analysis using tetramethylammonium hydroxide, a very simple procedure requiring less than two hours for the preparation of the whole cell walls. The organisms will grow on several growth media to determine which media will enhance lipid accumulation by the strains being examined. Gas chromatographic data will be subjected to pattern analysis and strain differences will be defined in terms of observed variations.

Step 2: Because of higher priority being given other work, further progress in the laboratory has not been accomplished. However, a method by which oxidation of materials can be prevented has been devised, and manipulation of cell lipid composition is planned.
The two strains have been identified as M. intracellularre closely related to type 7 and M. scrofulaceum type A1.

M. intracellularre and M. scrofulaceum belong to a group of mycobacteria that are usually pigmented. If one reviews the literature for the past 15 years, one finds that many famous scientists have claimed to have isolated M. leprae. Because standardized, determinative tests have become available for the genus mycobacterium in the past 15 years, it is almost impossible to precisely identify other isolates claimed to be...
Some aspects of the nature and life cycle of the skin bacteria have been looked at in the literature. However, in recent years, new techniques have been developed that have allowed for a better understanding of the nature of skin bacteria. The skin bacteria are found in the skin, hair, and nails of all humans and have a wider range of functions than previously thought. Very interestingly, the skin bacteria are present in the tissues of human skin patients. In many cases, the skin bacteria may not be present, and in some cases, the skin bacteria may be found in the tissues of healthy individuals as well.

Recently, some researchers have observed that skin bacteria are not as simple as previously thought. They are many times more complex than previously believed. However, the skin bacteria are still important to the health of the skin. The skin bacteria are important in the formation of the skin's barrier, which helps to protect the skin from harmful substances. These bacteria also produce substances that help to keep the skin healthy.

In summary, the skin bacteria are complex and important to the health of the skin. They play a vital role in the formation of the skin's barrier, and they produce substances that help to keep the skin healthy. The study of skin bacteria is an important area of research, and further research will undoubtedly continue to provide new insights into the nature and functions of these fascinating organisms.
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