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PRINCIPAL INVESTIGATOR: Hugh Mulligan
COL Gary Davis

CONTRACTING ORGANIZATION: Facilitators of Applied Clinical Trials
San Antonio, Texas 78216

Madigan Army Medical Center
Tacoma. Washington 98431-5000

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Hugh Mulligan and COL Gary Davis

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Facilitators of Applied Clinical Trials
San Antonio, TX 78216

Madigan Army Medical Center
Tacoma, Washington 98431-5000

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13. ABSTRACT *(Maximum 200*

Results of the incidence survey indicate that about one third of 450 female soldiers experience problematic urinary incontinence during exercise and field training activities. No studies have previously been performed to determine the effectiveness of behavioral treatments, such as Kegel (pelvic muscle) exercises or vaginal electromyographic biofeedback, for urinary incontinence within this population. Thirty-nine female soldiers reporting exercise induced urinary incontinence were recruited by means of questionnaires and referrals. All underwent an objective urodynamic assessment (UCMG) of bladder capacity, urethral closure pressure, and detrusor contraction pressures. They were also given a questionnaire before and after therapy. Subjects were then stratified according to diagnosis of genuine stress incontinence or mixed urge/stress incontinence and were then randomized into one of two groups. Group one's 23 participants received pelvic muscle exercises with biofeedback for eight weeks. Group two's 16 participants received only pelvic muscle exercises for eight weeks. Patient's reports as well as the post-treatment urodynamic and physical examinations indicated that all subjects improved.

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FOREWORD

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______________________ 9 July, 1996
Principal Investigator

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1. INTRODUCTION:

a. **Objectives**:

(1) To determine the incidence of exercise induced urinary incontinence among female soldiers

(2) To determine the effectiveness of urinary tract biofeedback and exercise training for stress and mixed stress/urge urinary incontinence.

b. **Hypotheses**:

(1) That about one third of female soldiers will have at least moderate exercise induced urinary incontinence with at least ten percent having the problem to such an extent that they have to drop out of training programs such as airborne.

(2) That urinary tract biofeedback combined with exercise training for stress and urge urinary incontinence will be sufficiently effective for about half of the female soldiers that they can take the PT test without dehydrating themselves and that a large minority will not require further treatment.

c. **Status**: The prevalence of urinary incontinence among elderly women is well documented. The National Institutes of Health (NIH) and U.S. Department of Health and Human Services stated that approximately 15-30% of women over the age of 60 and up to 50% of nursing home residents are affected by this condition (Clinical Practice Guideline; Urinary Incontinence In Adults). Burns, et al. (1990) cites several surveys that have found the incidence rate of urinary incontinence to be around 30% in the elderly.

Researchers have recently reported that a significant number of young, nulliparous females report urinary loss. Bo, et al. (1994) conducted a study on first-year physical education students and found that 13 out of the 37 subjects (38%) had some degree of stress urinary incontinence. In one of their previous studies, they reported 26% of young, nulliparous, physically fit women having stress urinary incontinence. Another researcher (Nygaard, 1995) stated that about one third of female exercisers develop this condition. Cutler (1992), in his study on the prevalence of stress urinary incontinence among healthy women, found that more that 50% of the 194 women that he surveyed acknowledged having problems with involuntary loss of urine. Because this condition is often embarrassing to the patient, many do not report their symptoms and urinary incontinence remains under diagnosed. It often causes women to stop exercising or to change the type of exercise in which they engage (Nygaard, 1995).

Women in the military have recently assumed more physically demanding roles. These demands have contributed to an increased risk for developing urinary incontinence. Pilot work performed by the senior author of the current study found that about one third of female soldiers have problems with urinary incontinence during exercises and field training. Twelve percent of female soldiers who dropped out of airborne training listed urinary incontinence as a major factor contributing to this decision. No large studies have been done to determine the impact urinary incontinence has upon female soldiers' abilities to perform their tasks and participate in field exercises.

The female soldier leads a physically demanding life, and must be in a constant state of readiness. Therefore, ideal treatment for urinary incontinence should not interfere with lifestyle or ability to function. Behavioral treatments of urinary incontinence have no side effects and do not require a prolonged absence from work (Burns et al, 1993), while surgical and pharmacological therapies have significant side effects or prolonged recovery periods. Many studies have shown pelvic muscle exercises and vaginal electromyographic (EMG) biofeedback to be an effective way to treat urinary incontinence in the elderly (Burns et al, 1993 & Hu, 1989). However, no studies have been performed to determine the effectiveness non-invasive treatments such as biofeedback or pelvic muscle exercises in the active duty female population.

2. BODY (METHODS):

Subjects
Participants include 39 female active duty soldiers from Fort Lewis, WA, Bremerton Naval Base, WA, and McChord Air Force Base, WA who all indicated that they had some degree of urinary incontinence. The urodynamic evaluations revealed that 77% had stress urinary incontinence, 23% had mixed urinary incontinence.

Materials
In order to evaluate the extent of this problem we developed a questionnaire asking about any problems with exercise related urinary incontinence. Urodynamic evaluations (UCMG's) were performed using the Life-Tech 1711 UROFLOW urodynamic system (P.O. Box 36221, Houston, TX, 77236) which has the capability to record abdominal, vesical, urethral, and detrusor pressures. The system is additionally able to perform uroflometry with post void residual urine volume measurement, retrograde provocuative water cystometry, resting and stressed urethral axis determination and direct visualization testing for fluid loss with stress. Biofeedback was accomplished using the I-410 J&J Biofeedback System (22797 Holgar Ct. N.E., Poulsbo, WA 98370) which was connected to a 486 IBM compatible computer containing the software designed for this system. Perry-vaginal sensors (MODEL #SRS-4509, 14770 N.E. 95th St. Redmond, WA 98052) picked up EMG (electromyographic) activity from the pelvic floor muscles while additional adhesive sensors were attached to the abdomen to measure abdominal EMG. Thought Technology's (MODEL #9500, 2180 Belgrave Avenue, Montreal, Quebec, Canada H4A-2L8) MyoTrac2 biofeedback home trainers were given to patients in the biofeedback group for the first week of their treatment.

Procedure
Questionnaires were distributed to all military units at Fort Lewis containing a significant number of female soldiers. Soldiers indicating that they desired treatment were contacted and were asked to be a part of the study.

Prior to treatment, all subjects underwent a standard evaluation of the lower urinary tract which included a detailed urogynecologic history, genitourinary physical and neurologic examination, and multi-channel urodynamic evaluation (UCMG). The genitourinary physical involved a pelvic examination to assess pelvic support and muscle tone. The subjects were then classified according to criteria specified by the International Continence Society as follows:

Stress incontinence: Patients were categorized as having stress incontinence if they experienced an involuntary loss of urine with increases in intra abdominal pressure. Patients with stress incontinence demonstrated a neurologically normal bladder upon urodynamic testing, but a paravaginal wall defect upon physical examination.

Urge incontinence: Urge incontinence is characterized as an uncontrollable loss of urine associated with a strong desire to void. Patients with urge incontinence demonstrated detrusor muscle instablity upon urodynamic testing, but a physiologically intact pelvic floor upon the physical examination. Detrusor muscle instability is the inability to voluntarily control the detrusor muscle that lies superior to the bladder. The normal function of the detrusor is to make a person aware that she has to urinate by slightly spasming and to contract upon urination.

Mixed incontinence: Those patients who were categorized as having mixed incontinence have symptoms of both stress and urge incontinence. They demonstrated both detrusor muscle activity upon urodynamic testing and a paravaginal wall defect upon physical examination.

No subjects were referred who had pure urge incontinence so the two classification groups in our study were (a) stress incontinence and (b) mixed urge/stress incontinence. Subjects were stratified by diagnosis and were then randomized into either Group 1 who received Kegel exercises with biofeedback, or Group 2 who performed Kegel exercises without biofeedback. All subjects received their respective treatments over a period of two months and all sessions were scheduled about two weeks apart. A therapist who was trained in biofeedback techniques coached all sessions. During the first session, all subjects were given a patient education booklet and were educated on the norms of voiding.

During all sessions, patients in the Group 1 practiced Kegel exercises with the assistance of the I-410 J&J Biofeedback system. The protocol consisted of a 10 second contraction/10 second relax, repeated 5 times within each trial, with a 30 second break in between each of the 5 trials. Patients were told to contract the pelvic floor muscle while trying to keep the abdominal, gluteal, and thigh muscles relaxed. The EMG signals of both their pelvic floor muscle (in blue) and their abdominal muscle (in red) were displayed on the computer screen. They were instructed to keep the red line at baseline by relaxing the abdominal muscle while raising the blue line by contracting the pelvic floor muscle. They were asked to maintain the contraction for the entire 10 seconds and then to relax all muscles so the both of the lines returned to baseline. During at least one of the sessions, the therapist would leave the room so that the patient could practice the Kegels without any performance anxiety. The patients were also asked to practice the Kegels while looking away from the computer screen to assure that they were practicing the exercises correctly at home. Subjects in this group were also given a MyoTrac2 (Thought Technology, Inc.) biofeedback home training device to take with them for the first week.

Patients in Group 2 performed Kegels using the biofeedback system only as a timer. The screen prompted them to contract and to relax but they were not attached to the system nor could they see any signals. Just like the subjects in Group 1, patients in this group were instructed to contract their pelvic floor muscle (vaginal muscle) "like they are squeezing a tampon" while keeping their abdominal, gluteal, and thigh muscles quiet. It was sometimes possible to tell if they were recruiting their abdominal muscles if they held their breath. Tension in their gluteal muscles and thigh muscles were evidenced by visually noticing movement in those areas.

For home practice, patients were instructed to practice the Kegel exercises (10 second contraction/10 second relaxation) for twenty minutes two times a day. Patients were put on bladder training schedules (voiding schedules starting at every one hour and working up to every two hours) and were taught urge control (three second Kegels designed to suppress the urgency) when applicable.

After two months of treatment, all subjects had another pelvic examination and urodynamic evaluation to assess their improvement. To determine whether the Kegel exercise with vaginal biofeedback group differed from the Kegel exercise only group and to assess change in the subjects before and after treatment, they were graded on several parameters:

(1) amount of urine per void (0=always a little w/ an urge, 1=a little as a preventative measure, 2=depends, 3=10oz-24oz of urine)
(2) time between voids (0=every ½ hour or less, 1=every ½ hour-1 hour, 2=every 1 hour-1.5 hours, 3=can wait longer than 1.5 hours)
(3) degree of urgency (0=leak on the way to the restroom, 1=can just make it to the bathroom without a leak, 2=can wait 10 min-1/2 hour after getting the urge, 3=can wait longer than ½ hour after getting the urge)
(4) ability to stop the stream of urine (0=no, 1=can slow the stream of urine, 2=can stop the stream if not too full, 3=can stop it completely always)
(5) activity level, (0= no exercise, 1=0-3.9 hours of exercise per week, 2= 4-6.9 hours of exercise per week, 3=more than 7 hours of exercise per week)
(6) subject's rating of severity of problem, (0=severe, 1=moderate, 2=mild, 3=non-existent)
(7) size of defect, (0=large, 1=medium, 2=small, 3=none)
(8) performed Kegels previous to treatment, (0=never, 1=a while ago, 2=occasionally, 3=for many years consistently)
(9) type of urinary incontinence, (0=overflow, 1=stress, 2=urge, 3=mixed)
(10) how much practice occurred during treatment (0= rarely, 1=occasionally, 2=frequently, 3=all the time)
(11) days of treatment (parametric)
(12) number of treatments (parametric)
(13) number of leaks per day (parametric)
(14) number of voids per night (parametric)
(15) fluid intake per day (oz.) (parametric)
(16) UCMG bladder capacity (parametric)
(17) UCMG Maximum Urethral Closure Pressure (parametric)
(18) UCMG detrusor contraction pressure (parametric).

3. RESULTS:

Out of the 450 questionnaires that were distributed, 123 of them indicated that they were currently experiencing urinary incontinence. As expected, 27% of female soldiers reported having some degree of urinary incontinence.

Table I summarizes the differences between the Kegels only group and the Kegels with vaginal EMG biofeedback group. Table II shows the pre to post therapy changes in all parameters measured for both groups. Mann-Whitney U tests (for ordinal measures) indicated that the Kegel exercise only group practiced the exercises significantly ($p=.01$) more often than the Kegel exercise with vaginal biofeedback group. The Mann-Whitney U tests (for ordinal measures) showed no other significant differences ($p>.05$) nor did t-tests or ANOVAs (for parametric measures) show any significant differences ($p>.05$) between the subjects in the Kegel exercise with biofeedback group and the Kegel exercise only group on any of the other variables analyzed either before or after treatment. Repeated measures t-tests (for parametric measures) and Wilcoxon Signed Ranks tests (for ordinal measures) indicated that subjects in the Kegel exercise with biofeedback group improved significantly ($p<.05$) on all variables except activity level, EMG vaginal resting level, and average EMG contraction. Subjects in the Kegel exercise only group improved significantly ($p<.05$) on all variables except activity level, and UCMG detrusor contraction pressures.

There were an additional four people in the Kegel exercise only group who received biofeedback (to treat PMS/Dysmenorrhea) from a concurrent study. They were not included in the analyses because there were too few subjects. Another additional subject in the study was diagnosed with overflow incontinence upon objective urodynamic testing. She was treated with Kegel exercises with biofeedback for eight weeks and showed no signs of improvement on any of the parameters. During the course of treatment, two additional subjects injured their pelvic floor muscles even more while engaging in job duties and both opted for surgery.

Table 1: Differences between group receiving Kegel exercises with vaginal biofeedback and group receiving Kegel exercises only

ORDINAL DATA (Mann-Whitney U test)		Number of subjects in Kegel exercises with vaginal biofeedback Group	Number of subject in Kegel exercises only group	p-value
Time between Voids	Before	23	16	0.2
	After	23	16	0.36
Degree of Urgency	Before	23	16	0.13
	After	23	16	0.18
Ability to stop stream of Urine	before	22	16	0.98
	after	22	16	0.31
Activity Level	before	22	14	0.89
	after	22	15	0.29
Amount of Urine per Void	before	23	16	0.19
	after	23	16	0.26
Severity of Problem	before	20	16	0.32
	after	20	16	0.95
Size of Defect		23	16	0.95
Performed Kegels Previously		23	16	0.46
Type of Urinary Incont.		23	16	0.60

How much practice		22		15		**0.01**
PARAMETRIC DATA						
(Unpaired t-test)		**Kegels with Vaginal Biofeedback**		**Kegels Only**		**p-value**
Days of Treatment	N	23		14		**0.35**
	Mean (x̄)	86.34		102.19		
	SD	30.30		72.80		
Number of Treatments	N	23		15		**0.28**
	Mean (x̄)	3.74		3.27		
	SD	1.29		1.28		
(2-way repeated measures ANOVA)		**Before**	**After**	**Before**	**After**	
Number of Leaks	N	22	22	16	16	0.06
	Mean (x̄)	7.27	2.90	15.72	5.25	
	SD	7.44	6.53	10.71	7.24	
Number of Voids per Night	N	23	23	16	16	0.07
	Mean (x̄)	0.65	0.26	1.19	0.25	
	SD	0.94	0.54	1.28	0.45	
Fluid Intake per Day (oz.)	N	22	22	16	16	0.96
	Mean (x̄)	50.58	58.82	46.13	54.63	
	SD	19.64	15.18	17.34	14.60	
UCMG Bladder Capacity	N	21	21	13	13	0.40
	Mean (x̄)	343.76	398.91	252.23	331.92	
	SD	105.98	104.63	115.79	101.68	
UCMG Maximum Urethral Closure Pressure	N	19	19	11	11	0.62
	Mean (x̄)	59.68	80.16	51.46	77.18	
	SD	16.50	27.50	23.73	38.41	
UCMG Detrusor Contractions	N	21	21	12	12	0.44
	Mean (x̄)	19.10	0.00	10.00	0.00	
	SD	35.63	0.00	23.36	0.00	

Table 2 Significance levels for variables before and after treatment.

	Kegels with Vaginal Biofeedback		Kegels Only	
ORDINAL DATA				
	N	**p value**	**N**	**p value**
Amount of Urine per Void	23	**0.004**	16	**0.03**
Time in between Voids	23	**0.02**	16	**0.02**
Degree of Urgency	23	**0.0009**	16	**0.01**
Ability to Stop the Stream of Urine	22	**0.003**	16	**0.01**
Activity Level	22	0.28	15	0.56
Subjects Rating of Severity	20	**0.002**	16	**0.0008**

PARAMETRIC DATA

		Kegels with Vaginal Biofeedback		Kegels Only		p value pre/post
		Before	**After**	**Before**	**After**	**(2-way ANOVA)**
Number of Leaks	N	22	22	16	16	**<0.0001**
	Mean ($\bar{x}$)	7.27	2.90	15.72	5.25	
	SD	7.44	6.53	10.71	7.24	
	"t" p-value	**0.01**		**0.003**		
Number of Voids per Night	N	23	23	16	16	**0.0002**
	Mean ($\bar{x}$)	0.65	0.26	1.19	0.25	
	SD	0.94	0.54	1.28	0.45	
	"t" p-value	**0.02**		**0.005**		
Fluid Intake per Day (oz.)	N	22	22	16	16	**0.005**
	Mean ($\bar{x}$)	50.58	58.82	46.13	54.63	
	SD	19.64	15.18	17.34	14.60	
	"t" p-value	**0.04**		**0.06**		
EMG Vaginal Resting Level	N	23	23	----	----	
	"t" p-value	0.32		----		---------

Average EMG Vaginal Contraction	N	23	23	----	----	--------
	"t" p-value	0.40		----		
UCMG Bladder Capacity	N	21	21	13	13	**<0.0001**
	Mean ($\bar{x}$)	343.76	398.91	252.23	331.92	
	SD	105.98	104.63	115.79	101.68	
	"t" p-value	**0.001**		**0.02**		
UCMG Maximum Urethral Closure Pressure	N	19	19	11	11	**<0.0001**
	Mean ($\bar{x}$)	59.68	80.16	51.46	77.18	
	SD	16.50	27.50	23.73	38.41	
	"t" p-value	**0.002**		**0.02**		
UCMG Detrusor Contraction Pressure	N	21	21	12	12	**0.01**
	Mean ($\bar{x}$)	19.10	0.00	10.00	0.00	
	SD	35.63	0.00	23.36	0.00	
	"t" p-value	**0.02**		0.17		

4. CONCLUSION

Our results clearly show that non-invasive behavioral treatments are effective in improving symptoms of urinary incontinence among this population. The fact that this population consisted of young, healthy, physically fit soldiers may have contributed to our findings that a successful treatment could be obtained using Kegel exercises in the absence of biofeedback.

Although the differences between the average EMG contraction level did not significantly change from the start to the end of the treatment, we do not feel that this is an indicator of whether they did or did not learn how to perform the Kegel exercises. Most biofeedback patients performed the Kegel exercises correctly from the beginning without recruiting accessory muscles (abdominal, gluteal, or thigh). The EMG signals that they generated had almost no lag time at the time of the contraction, and their endurance was, in general, fairly good. A difficulty in relaxing the pelvic floor muscles after each contraction was apparent in several women and tended to improve in later sessions. According to Joan Coxe, RN., (personal communication, 1996) elderly women tend to have a longer lag period when contracting and have difficulty discriminating between their pelvic floor muscles. It is therefore perhaps possible that elderly women would benefit from biofeedback because it would help them to learn the Kegel exercises, while young women may not need much assistance in learning these exercises and do just as well without the biofeedback.

Although we determined that such behavioral treatments were successful, we did find it difficult to get the treatment to the soldiers. Out of the 124 soldiers indicating on the survey that they had some problem with urinary incontinence, only 74 (59%) noted that they would like treatment for it. Out of those 74 women indicating that they desire treatment, only 10 women actually entered the program. Most of the women who entered the program were those who called us on their own accord or those who filled out a survey in one of the hospital clinics while waiting for a medical appointment. Also, we had a significant drop out rate due mainly to time conflicts. In most cases, it was necessary for the researcher to seek after the subjects in order to get them in for their appointments. Initially we had also planned to objectively test the subjects for leakage by having them wear a pad during a mock Army Physical Training test before and after treatment. However, this part of the study failed due to poor compliance. Perhaps if the soldiers were more educated on the prevalence of urinary incontinence and the possibilities for treatment, they would be more likely to seek help. Since our research found that adding biofeedback to Kegel exercises is not necessary to obtain a successful treatment, it may be advantageous to teach female soldiers how to perform Kegels in group sessions. More research would have to be conducted to determine if this would be effective.

5. PUBLICATION AND PRESENTATION

a. **Presentation:** Wong M, Sherman R, Davis G: Behavioral Treatment of Exercise Induced Urinary Incontinence Among Female Soldiers. Presented at the Association for Applied Psychophysiology's 26th Annual Meeting Albuquerque, New Mexico March 20-24, 1996

b. **Publication Submission:** Sherman R, Wong M, Davis G: Behavioral Treatment of Exercise Induced Urinary Incontinence Among Female Soldiers. Submitted to Biofeedback and Self-Regulation in July, 1996.

6. FUTURE PLANS:

a. **Incidence of training injuries vs. phase of the menstrual cycle**: The most important finding to date was totally unexpected. This is the relationship between incontinence and the luteal phase. If ligaments are actually being significantly stretched/weakened during this phase, a huge rate of training injuries would occur during this phase relative to the others. This must be investigated immediately as it has profound economic and health implications for military training. We are beginning a pilot study of this problem in the next few weeks and will apply for funding at the earliest opportunity for a full study (if the pilot results warrant it) relating all training injuries among female soldiers to the phase of their menstrual cycle.

b. **Ambulatory recording of urodynamic functioning during training:** This study has already confirmed the importance and prevalence of the problem but we do not understand how it develops. Until we understand the mechanisms causing the problem, we can't develop preventive measures. We have received funding to perform a longitudinal study of female Army trainees who will wear ambulatory urodynamic recorders during active periods of their training to determine what is happening to bring about incontinence.

c. **Test of the ability to utilize biofeedback for urinary incontinence among female soldiers in normal clinical troop treatment arenas:** This study has also already shown that biofeedback is very effective for treatment of urinary incontinence among female soldiers. We need to perform a larger study designed to bring this treatment from the clinical laboratory into general practice and to determine its effectiveness in the normal clinical / troop clinic environment. We will apply for funding for this study at the earliest opportunity.

d. **Determination of the incidence and treatment of fecal incontinence among female soldiers**: As word of this study has spread through a variety of clinical areas including troop medical clinics, Ob-Gyn, family practice, and Orthopedics, health care providers have begun asking their female soldiers about fecal incontinence as well as about urinary incontinence problems. Although it appears to be somewhat less frequent, it is a significant problem which has been unrecognized at this time. We have proposed a study virtually identical to the current study to investigate incidence and treatment of the problem.

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