Preoperative Biofeedback Assisted Behavioral Training to Decrease Post-Prostatectomy Incontinence: A Randomized, Controlled Trial

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Purpose: We tested the effectiveness of preoperative biofeedback assisted behavioral training for decreasing the duration and severity of incontinence, and improving quality of life in the 6 months following radical prostatectomy.

Materials and Methods: We performed a prospective, randomized, controlled trial comparing preoperative behavioral training to usual care. The volunteer sample included 125 men 53 to 68 years old who elected radical prostatectomy for prostate cancer. Patients were stratified according to age and tumor differentiation, and randomized to 1 preoperative session of biofeedback assisted behavioral training plus daily home exercise or a usual care control condition, consisting of simple postoperative instructions to interrupt the urinary stream. The main outcome measurements were duration of incontinence (time to continence), as derived from bladder diaries, incontinence severity (the proportion with severe/continual leakage), pad use, Incontinence Impact Questionnaire, psychological distress (Hopkins Symptom Checklist) and health related quality of life (Medical Outcomes Study Short Form Health Survey).

Results: Preoperative behavioral training significantly decreased time to continence ($p = 0.03$) and the proportion of patients with severe/continual leakage at the 6-month end point (5.9% vs 19.6%, $p = 0.04$). There were also significant differences between the groups for self-reported urine loss with coughing (22.0% vs 51.1%, $p = 0.003$), sneezing (26.0% vs 48.9%, $p = 0.02$) and getting up from lying down (14.0% vs 31.9%, $p = 0.04$). No differences were found on return to work and usual activities or quality of life measures.

Conclusions: Preoperative behavioral training can hasten the recovery of urine control and decrease the severity of incontinence following radical prostatectomy.

Key Words: bladder, urinary incontinence, biofeedback (psychology), prostatectomy, pelvic floor

Radical prostatectomy carries with it the common postoperative sequelae of urinary incontinence and impotence. Following radical prostatectomy most men are incontinent when the urinary catheter is removed. Patient survey research indicates that 8% to 56% of men report incontinence 1 year or more following surgery.[1–3] Rates vary widely due to survey methods, the definition of incontinence and surgical technique.

Regardless of its expected course involuntary urine loss can be a distressing condition for men. While it is tolerated well by some men, incontinence is deeply disturbing to others. Even transient incontinence can deter the return to employment and resumption of beneficial physical activity following surgery.[4] Because of the negative impact of incontinence on quality of life, intervention to decrease the duration or severity of urine loss should be considered an important aspect of care.

Among several treatment options available behavioral interventions have demonstrated 58% to 81% improvement in men with post-prostatectomy incontinence, persisting up to 12 years.[5,6] The current study was based on the hypothesis that, if behavioral interventions are effective for decreasing incontinence that persists following prostate surgery, perhaps these conservative measures would be effective if begun preoperatively. Because incontinence is so predictable postoperatively, it makes sense to initiate intervention preoperatively, so that patients can practice new motor skills before surgery and be more prepared to exercise and use the pelvic floor muscles immediately after catheter removal. We tested the effectiveness of preoperative biofeedback assisted behavioral training for hastening the recovery of urinary control, decreasing the severity of postoperative

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incontinence and improving quality of life in the 6 months following radical prostatectomy.

MATERIALS AND METHODS

Participants. Participants were men who elected radical prostatectomy between January 1996 and January 2001. Patients were recruited through a university based urology clinic, a VA Medical Center urology clinic and 7 private urology practices. To be eligible potential participants had to be ambulatory, continent and identified for the study at least 1 week prior to surgery. All participants provided informed consent. The study was approved by the University and VA Institutional Review Boards.

Evaluation. The clinical evaluation consisted of a history, dementia screening (Mini-Mental State Examination)[7] and brief physical examination (height, weight, vital signs and rectal examination). Urodynamic testing consisted of catheterization for post-void residual urine and 2-channel supine water cystometry.

Instruments completed at home. A 7-day bladder diary[8] and 2 quality of life instruments were completed before surgery. The bladder diary was used to document continence status prior to surgery. The Hopkins Symptom Checklist was used to measure psychological distress[9] and the Medical Outcomes Study Short Form Health Survey was used to assess health related quality of life.[10]

Exclusion criteria. Patients were excluded if they reported greater than 2 episodes of urinary incontinence in the previous 6 months, documented incontinence in the bladder diary, underwent prior prostatectomy, had impaired mental status (score less than 20 on the Mini-Mental State Examination) or there was less than 1 week before scheduled surgery.

Design. The study was a randomized, controlled trial to test the effects of preoperative behavioral training compared to a usual care control condition on the course of continence status following radical prostatectomy. Prior to randomization patients were stratified by age (younger than 65 vs 65 years or older) and tumor differentiation (Gleason score 5 or less vs greater than 5). In each stratum randomization was performed using computer generated random numbers and a block size of 4 to avoid inequity in the number of patients assigned to each group. The randomization schedule was implemented by the research nurse, so that interventionists would be blinded to the next group assignment. Patients were assigned to a single preoperative session of biofeedback assisted behavioral training plus daily home practice or to usual care, consisting of brief postoperative verbal instructions to practice interrupting the urinary stream during voiding.

Using the 2-sided log rank test this study had 80% power to detect a difference of 0.28 in the proportion of patients remaining incontinent at 6 months (0.32 intervention vs 0.60 in control), assuming a total sample size of 106 and a type I error rate of 0.05.

Preoperative behavioral training. Patients assigned to the intervention group received a single session of biofeedback assisted behavioral training, in which they learned pelvic floor muscle control and received instructions in daily pelvic floor muscle exercise. A rectal probe with 3 small balloons was used to measure and provide immediate visual feedback of rectal pressure (intra-abdominal) and external anal sphincter contraction.[5] Feedback plus verbal instruction and reinforcement was used to teach patients how to control the pelvic floor muscles, while keeping the abdominal muscles relaxed. Patients were taught to contract the sphincter muscles during 2 to 10-second periods separated by 2 to 10 seconds of relaxation depending on initial ability.

Written instructions for daily practice included 45 pelvic floor muscle exercises, divided into 3 sessions of 15 exercises. The initial duration of each contraction was based on ability and increased gradually to a maximum of 10 seconds. Patients were advised to practice in various positions and integrate the exercises into daily activities. Finally, they were instructed to practice interruption or slowing of the urinary stream during voiding once daily. Patients were encouraged to exercise daily until the surgery and then to resume after catheter removal.

Postoperative visit. When they returned to the surgeon for catheter removal, patients in the intervention group were reminded to resume the exercise regimen. Patients in the control condition were given usual care, that is brief verbal instructions to interrupt the urinary stream during voiding plus whatever instructions were provided by the surgeon as part of usual care.

All patients were taught how to document continual and episodic urine loss using bladder diaries and provided with a 7-day supply. Patients in each group were instructed to record the time of every void, and the time and circumstance of every incontinence episode. If incontinence was continual rather than episodic, they were instructed to draw a line through the time periods that they were leaking. Patients were also instructed to record the use of absorbent pads or other wetness management products. Patients were asked to complete and mail in a 1-day bladder diary weekly following surgery, eg every Wednesday. This allowed week-to-week tracking of continence status and yielded the primary outcome measure of duration, that is time to continence.

Followup. Patients were contacted again for followup 6 weeks, 3 months and 6 months following surgery. At each followup point they completed a patient questionnaire about bladder control and life-style issues, eg return to work or usual activities, a 7-day bladder diary and the 2 quality of life instruments. They also completed the Incontinence Impact Questionnaire, as modified for men.[11]

Data management and analysis. Equivalency of the treatment groups was evaluated on select variables that might influence continence status or quality of life in the recovery period. The chi-square statistic was used for categorical variables and the t test was used for continuous variables. For the few statistical tests that assumed a normal distribution of outcomes normal probability lots were used to assess the validity of the assumption.

Bladder diaries were scored by an individual blinded to group assignment. A patient was considered continent when he returned 3 consecutive weekly 1-day diaries that showed no leakage or when he completed a 7-day diary with no leakage. The duration of incontinence was examined using

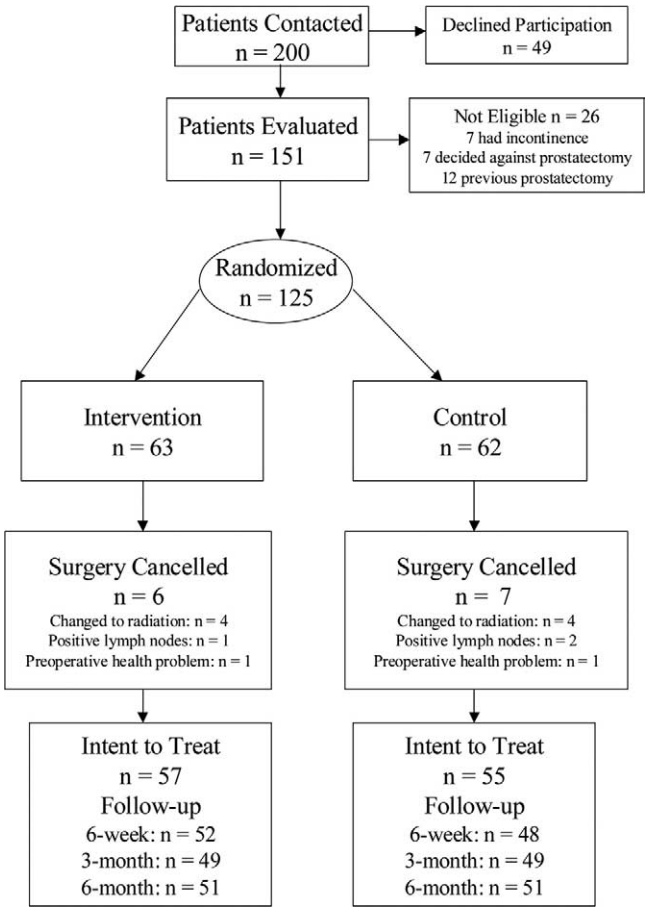

FIG. 1. Consolidated Standards of Reporting Trials flow diagram shows patient progress through trial, including withdrawals and followup.

the Kaplan-Meier procedure, in which all protocol eligible patients provided followup. The duration of incontinence was compared between the 2 groups using the log rank test. The severity of incontinence was based on the 7-day diaries completed at the 6-month followup. The proportion of patients with severe incontinence (continual leakage or leakages too numerous to record) was analyzed using the chi-square statistic. Data on pad use were derived from the patient questionnaire and the bladder diary, and analyzed using the chi-square statistic and t test for independent samples.

For the Medical Outcomes Study Short Form Health Survey and Hopkins Symptom Checklist multiple regression analysis was used to regress the 6-month score on treatment group, while controlling for baseline score. Multiple regression was also used for impact of incontinence questionnaire scores but without baseline scores because patients were continent before surgery. SPSS, version 10.0.5 (SPSS, Chicago, Illinois) was used for all statistical analyses.

RESULTS

A total of 151 men were evaluated for the study and 125 who were 53 to 68 years old were randomized (fig. 1). Table 1 lists treatment group characteristics. Before surgery the 2 groups were comparable in all clinical variables, including urodynamic parameters and pathology findings.

Table 2 lists the characteristics of the surgical procedures. No significant differences were found between the groups on key surgical variables except urethral length preservation. More patients in the control group had preserved urethral length, thus, favoring the control group ($p = 0.03$). In the intervention group 70.0% of men reported that they were still doing the exercises at the 6-month followup.

Duration of incontinence. Our primary hypothesis was that the behavioral intervention group would regain continence more rapidly than the control group in the 6 months following surgery. Kaplan-Meier curves for the 2 groups showed that the data supported this hypothesis and the log rank test indicated statistical significance ($p = 0.04$, fig. 2). Median time to continence in the intervention group was 3.5 months. In the study time frame fewer than 50% of the control group achieved continence. Therefore, median time to continence could not be estimated, but it was greater than 6 months. The difference between the groups in the proportion of men remaining incontinent at 6 months was 20.03% (95% CI 6.02% to 34.63%).

Severity, type and impact of incontinence. Figure 3 shows the proportion of patients who had severe/continual leakage at each followup point. Six months after surgery severe/continual leakage was still present in 19.6% of controls compared to 5.9% of those in intervention ($p = 0.04$). At 6 months patients in the intervention group also had a higher proportion of dry days ($p = 0.04$), a lower proportion using pads ($p < 0.05$) and a lower proportion reporting symptoms of stress incontinence (coughing, sneezing and getting up from a lying position) (table 3). No group differences were found in life-style variables, incontinence impact ($p = 0.36$), psychological distress ($p = 0.69$) or quality of life ($p = 0.31$ to 0.89).

DISCUSSION

The results of this study show that preoperative behavioral training can decrease the duration and severity of incontinence following radical prostatectomy. A previous study of pelvic floor muscle training with biofeedback prior to surgery compared outcomes at 6 weeks and 12 months.[12] Findings were promising on several measures but the small sample size (8 per group) precluded statistical comparisons of the outcomes. A study of preoperative pelvic floor muscle training initiated 2 to 4 weeks before surgery showed no benefit.[13]

Other groups examined the effects of pelvic floor muscle training soon after surgery with mixed results. In 1 trial patients who were incontinent on day 15 after radical prostatectomy received weekly pelvic floor re-education for up to a year or placebo therapy.[14] The treatment group showed advantages in the duration and degree of incontinence. Other studies have not shown a benefit for training initiated 3,[15] 6[16] or 8[17] weeks after surgery. In some cases there was evidence of a training effect but sample sizes suggest that the studies were underpowered. One study that combined preoperative training with 3 months of postoperative treatment showed benefit compared to no intervention.[18]

Although this study showed a shorter duration of incontinence in the intervention group, the finding was not accompanied by differences in the proportion of men who returned to work or usual activities by the 6-month followup.

TABLE 1. *Baseline characteristics of surgical patients*

Characteristic	Intervention	Control	Total
No. pts	57	55	112
Demographics:			
Mean age ± SD	60.7 ± 6.6	61.1 ± 7.2	60.9 ± 6.9
% High school graduate (No.)*	83.3 (35)	85.7 (36)	84.5 (71)
% Black (No.)	22.8 (13)	32.7 (18)	27.7 (31)
% Employed outside home (No.)	50.0 (28)	54.7 (29)	52.2 (57)
% Recruitment source (No.):			
University	38.6 (22)	47.3 (26)	42.9 (48)
VA Medical Center	10.5 (6)	5.5 (3)	8.0 (9)
Private practice	50.9 (29)	47.3 (26)	49.1 (55)
% History (No.):			
Bowel incontinence	5.3 (3)	3.6 (2)	4.5 (5)
Arthritis	49.1 (28)	52.7 (29)	50.9 (57)
Hypertension	45.6 (26)	56.4 (31)	50.9 (57)
Congestive heart failure	3.5 (2)	0.0	1.8 (2)
Parkinson's disease	0.0	0.0	0.0
Stroke	0.0	0.0	0.0
Diabetes mellitus	17.5 (10)	9.3 (5)	13.5 (15)
Current smoker	10.5 (6)	9.1 (5)	9.8 (11)
Prior transrethral prostate resection	3.5 (2)	1.8 (1)	2.7 (3)
Mean urodynamic findings ± SD (ml):			
Post-void residual volume	37.0 (45.8)	39.7 (54.2)	38.4 (49.9)
First desire to void	180.4 (123.1)	175.7 (107.5)	178.1 (114.8)
Strong desire to void	274.4 (121.6)	281.2 (131.1)	268.7 (125.5)
Cystometric capacity	346.2 (114.7)	337.7 (128.2)	340.8 (120.9)
% Pathology findings (No.):†			
T2a	28.3 (13)	30.8 (12)	29.4 (25)
T2b	71.7 (33)	69.2 (27)	70.6 (60)
Pos bladder or urethral margins	14.9 (7)	8.7 (4)	11.8 (11)
Well differentiated (Gleason score 5 or less)	14.0 (8)	16.4 (9)	15.2 (17)
Moderately poorly differentiated (Gleason score greater than 5)	86.0 (49)	83.6 (46)	84.8 (95)
% Ng/ml prostate specific antigen (No.):			
Less than 10	79.2 (38)	81.4 (35)	80.2 (73)
10 or Greater	20.8 (10)	18.6 (8)	19.8 (18)

* Not all patients reported education level on the patient questionnaire.
† Medical records were not accessible in some patients.

Consistent with this are minimal differences that the intervention made in the impact of incontinence on psychosocial function, as indicated by the quality of life instruments. These findings were not surprising in light of previous research on prostate cancer. A well controlled study of men treated for clinically localized prostate cancer and age matched controls showed that general health and well-being scores did not differ significantly between the groups.[19] The fact that the groups in our study were also not different on the condition specific Impact of Incontinence Questionnaire suggests that the effects of intervention may not have been strong enough to affect quality of life or the men found ways to circumvent the impact of incontinence on well-being. It is also possible that differences in incontinence were confounded or overshadowed by other quality of life issues, such as recovery from surgery, anxiety about cancer or sexual dysfunction.

A limitation of this study is that pad use served as a secondary measure of incontinence. We observed that many men recorded pad use in the absence of urine leakage and it has become clear that men do not necessarily stop wearing pads immediately after they regain continence. The discon-

TABLE 2. *Surgery characteristics*

Characteristic	Intervention	Control	Total	p Value
No. pts	57	55	112	
% Surgical approach (No.):				0.525
Retropubic	98.2 (53)	96.1 (49)	97.1 (102)	
Perineal	1.9 (1)	3.9 (2)	2.9 (3)	
% Neurovascular bundles preserved (No.):				
2	44.7 (21)	46.7 (21)	45.7 (42)	0.713
1	14.9 (7)	20.0 (9)	17.4 (16)	
% Urethral length preserved (No.)	85.2 (46)	98.0 (48)	91.3 (94)	0.033
% Anatomical dissection (No.)	59.6 (31)	57.1 (28)	58.4 (59)	0.842
% Mucosa everted neck closure (No.)	51.0 (25)	56.5 (26)	53.7 (51)	0.682
% Bladder neck closed (No.):	61.2 (30)	57.5 (27)	59.4 (57)	0.836
Tennis racket closure	53.1 (26)	45.8 (22)	49.5 (48)	0.545
Mucosa everted	47.9 (23)	47.8 (22)	47.9 (45)	0.999
Mean No. sutures ± SD	5.1 (1.4)	5.3 (1.2)	5.2 (1.3)	0.400
Mean No. posterior sutures ± SD	2.5 (.83)	2.6 (.61)	2.5 (.72)	0.618
Mean operative time ± SD (mins)	183.6 (47.9)	172.9 (51.0)	178.0 (49.5)	0.393
Mean estimated blood loss ± SD (ml)	1,067 (576)	1,080 (812)	1,073 (700)	0.931
Mean prostate wt ± SD (gm)	47.1 (19.1)	45.1 (14.2)	46.1 (16.8)	0.615

Not all operative records were accessible for chart abstraction.

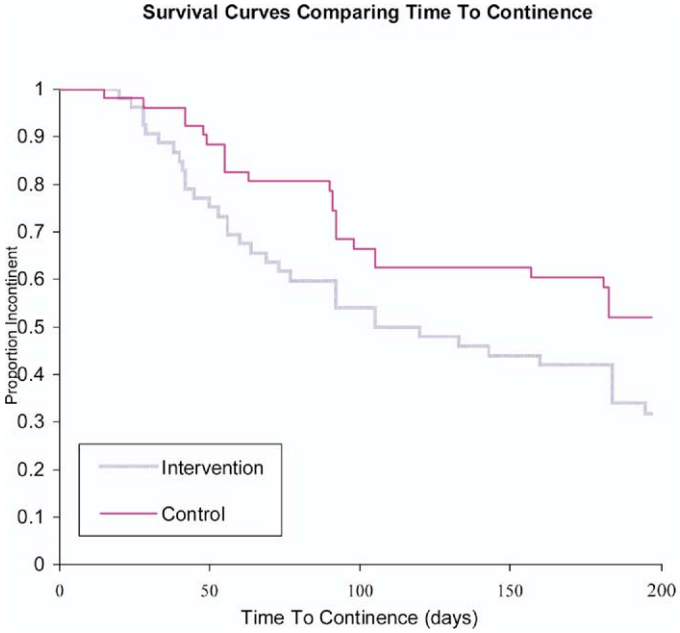

FIG. 2. Survival curves demonstrate shorter time to continence after surgery in intervention vs control group. Number of individuals at risk (known incontinent) at specified times was 49 in intervention and 51 in control groups 30 days after catheter removal, 37 in intervention and 42 in control groups at 60 days, 32 in intervention and 40 in control groups at 90 days, 25 in intervention and 31 in control groups at 120 days, and 22 in intervention and 30 in control groups at 150 days.

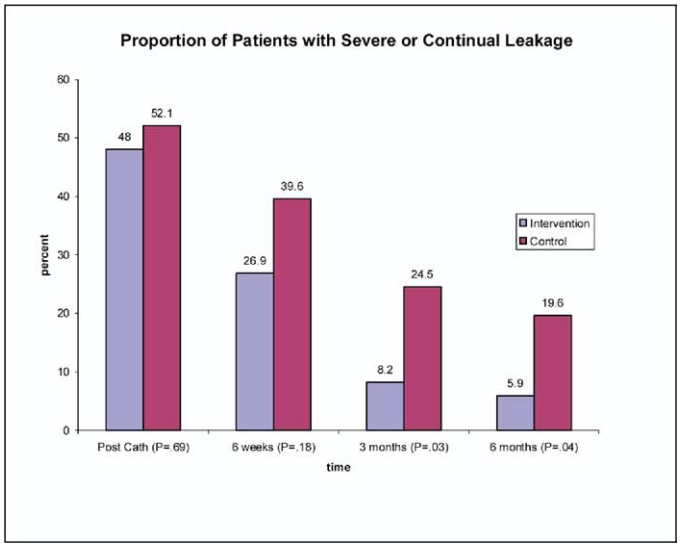

FIG. 3. Proportion of patients with severe/continual leakage by group following radical prostatectomy.

tinuation of pad use often comes much later, when they have regained confidence in continence. Therefore, we recommend caution in interpreting the results of this study and others in which pad use serves as a measure of incontinence.[13,15,16]

In this study preoperative training was done with biofeedback to ensure that patients learned proper muscle control. However, we do not know whether biofeedback is necessary to achieve these results. It is possible that training would have been successful even without biofeedback, which would be consistent with previous studies showing that biofeedback did not improve outcomes.[13,16]

Based on the spontaneous recovery that occurs during the postoperative period some groups have argued that intervention for incontinence should be delayed for at least 3 months following surgery.[20] Our data indicate that intervening before surgery has definite value. An advantage of training before surgery is that the men learn how to control their muscles when they are pain-free and sensation is normal. In addition, they are prepared in advance to begin using the muscles immediately after catheter removal. To our knowledge the optimal time frame in which to implement behavioral training remains to be determined. However, if it is possible to attenuate some effects of surgery by initiating preoperative training, this would decrease the burden that men bear as they recover from surgery.

The significant effect of intervention in this study was achieved with a single preoperative treatment session and a brief encounter at the postoperative visit when the catheter was removed. We suggest that the training effect might have been greater had we used more intensive preoperative training or resumed intervention after surgery with a more regular program of postoperative visits to further optimize outcomes.[14] Future research might explore whether the impact of such intervention would be greater if access to preoperative and postoperative training were enhanced by integrating the program into urology practices.

TABLE 3. *Outcomes at 6 months*

Outcome Measure	Intervention	Control	p Value
No. pts	50	47	
Mean days with no leakage ± SD	72.6 (0.39)	54.2 (0.47)	0.04
% Wearing pads (No./total No.)	32.0 (16/50)	52.2 (24/46)	<0.05
Mean No. pads/day ± SD	0.54 ± 1.44	0.92 ± 1.59	0.27
% Urine loss (No./total No.):			
Coughing	22.0 (11/50)	51.1 (24/47)	0.003
Sneezing	26.0 (13/50)	48.9 (23/47)	0.02
Getting up from lying position	14.0 (7/50)	31.9 (15/47)	0.04
Lifting	46.0 (23/50)	55.3 (26/47)	0.36
Walking	20.0 (10/50)	36.2 (17/47)	0.08
Urge to urinate on way to toilet	27.7 (13/47)	40.4 (19/47)	0.19
% Return to work (No./total No.)	78.6 (22/28)*	79.3 (23/29)	0.95
% Resume usual activities (No./total No.)	84.8 (28/33)	91.7 (33/36)	0.38

* Total of 16 patients were retired and did not work.

CONCLUSIONS

Preoperative behavioral training can hasten the recovery of urine control and decrease the severity of incontinence following radical prostatectomy. Urologists might consider referring their patients who elect prostatectomy for prostate cancer treatment to a continence center for preoperative pelvic floor muscle training or integrating such training into their office practice.

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APPENDIX

Urologists who referred participants to the study: Drs. L. Keith Lloyd, University of Alabama at Birmingham, Douglas Modling, Jr., Albert Tulley, Jr., A. Scott Tulley, Thomas E. Moody and William Leitner, Urology Centers of Alabama, W. Glen Wells, Rodney Dennis, Lee Hammontree and Andrew W. Daniel, Brookwood Medical Center and William C. Renneker, Princeton Urology, Birmingham, Maumon Pacha, Coosa Valley Urology, Sylacauga and James R. Monath, Maxwell-Gunter Air Force Base, Alabama; E. P. Rivas, New Orleans, Louisiana; and William J. Catalona, Urological Research Foundation, St. Louis, Missouri.

Abbreviations and Acronyms

VA = Veterans Affairs

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EDITORIAL COMMENT

Biobehavioral therapy, including pelvic floor muscle exercises and biofeedback training, is often used for post-prostatectomy urinary incontinence. However, most published studies are limited by small sample sizes and incomplete followup data. A recent meta-analysis including 5 clinical trials of pelvic floor muscle exercise combined with biofeedback yielded a relative risk for post-prostatectomy urinary incontinence of 0.74 (95% CI 0.60 to 0.93) compared to no treatment.[1] The current article presents a well designed, randomized, controlled clinical trial of this therapy. The investigators clearly report improved objective and subjective outcomes. However, several important questions remain to be answered. What is the optimal timing for the implementation of pelvic floor exercises in men undergoing radical prostatectomy? To what degree does the addition of biofeedback augment the observed improvements? How can this therapy be best incorporated into routine urological practice? Additional research on this topic will help clarify these issues.

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