Randomized, Placebo Controlled Study of Electrical Stimulation With Pelvic Floor Muscle Training for Severe Urinary Incontinence After Radical Prostatectomy

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Purpose: We evaluated electrical stimulation combined with pelvic floor muscle training for urinary incontinence after radical prostatectomy in a randomized controlled study.

Materials and Methods: A total of 56 men with severe urinary incontinence (more than 200 gm daily), mean ± SD age 66.6 ± 6.2 years, were randomized to an active treatment group (26) or a sham group (30). All patients performed pelvic floor muscle training preoperatively and continued throughout the study. For active stimulation 50 Hz square waves of 300 μs pulse duration and a 5 seconds on, 5 seconds off duty cycle were applied for 15 minutes twice daily with an anal electrode. Sham stimulation was limited to 3 mA with a 2 seconds on, 13 seconds off duty cycle.

Results: In the active group 8 (36%), 14 (63%), 18 (81%) and 19 (86%) patients were continent (22) vs 1 (4%), 4 (16%), 11 (44%) and 17 (86%) in the sham group (25) (leakage less than 8 gm daily) after 1, 3, 6 and 12 months, respectively. There was a significant difference in the number of continent patients between the groups at 1, 3 and 6 months ($p = 0.0161$, $p = 0.0021$ and $p = 0.0156$, respectively). The time to achieve continence was significantly shorter in the active group (2.71 ± 2.6 months) than in the sham group (6.82 ± 3.9 months, $p = 0.0006$). Changes in the amount of leakage, the International Consultation on Incontinence Questionnaire-Short Form score and the King's Health Questionnaire score were significantly larger in the active group at 1 month but there was no difference at 12 months.

Conclusions: Electrical stimulation resulted in earlier recovery of continence in patients with urinary incontinence after radical prostatectomy.

Key Words: prostatectomy, urinary incontinence, electric stimulation, placebos, randomized controlled trials

Abbreviations and Acronyms

ES = electrical stimulation

ICIQ-SF = International Consultation on Incontinence Questionnaire-Short Form

KHQ = King's Health Questionnaire

PFMT = pelvic floor muscle training

QOL = quality of life

RCT = randomized controlled trial

RRP = radical retropubic prostatectomy

UI = urinary incontinence

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URINARY incontinence after RRP is a common and potentially devastating problem.[1] Despite various improvements of the surgical technique and a better understanding of pelvic anatomy, studies indicate that 8% to 56% of men have UI at 1 year after RRP.[2] The primary cause of UI after RRP has been reported to be sphincter insufficiency, but detrusor overactivity, reduced bladder compliance and decreased contractility may also be relevant factors.[1,3–5] For the prevention and treatment of UI PFMT is the most widely recommended noninvasive method of increasing pelvic floor muscle strength.[2,6,7] However, it can take several months to restore conti-

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nence and some patients may have persistent incontinence despite continuing PFMT.

While PFMT relies on ordinary muscle contraction, ES of the pudendal nerve and its branches can produce direct and reflex responses of the urethral and pelvic floor striated muscles.[8,9] ES is believed to be more effective in patients who are initially unable to identify and contract the correct pelvic floor muscles, and its use may enhance the success of PFMT for incontinence.[9–12] ES combined with PFMT has been reported to be effective for the treatment of women with stress incontinence who were unable to spontaneously generate adequate pelvic floor muscle contraction.[13] However, the beneficial effect of ES plus PFMT on urinary incontinence after RRP needs to be verified by a randomized controlled trial. Accordingly in this study we evaluate the effectiveness of ES combined with PFMT for UI after RRP in a prospective, randomized, sham controlled, double-blind trial.

MATERIALS AND METHODS

Of 187 male patients who underwent open RRP from June 2003 to December 2008, 56 with severe postoperative UI, mean age 66.6 ± 6.2 years (range 50 to 76), were included in this study. Standard PFMT was taught by nurses (verbal and written instructions) and patients continued PFMT throughout the study with coaching at followup visits.[14] The urethral catheter was removed at 2 weeks postoperatively, and a 3-day pad test, ICIQ-SF and KHQ were assessed at 1 week after catheter removal. Inclusion criteria were UI of more than 200 gm daily and no residual cancer after RRP on pathological examination. Exclusion criteria were treatment with anticholinergics or tricyclic antidepressants, neurological disorders and urethral stricture. Pretreatment urinalysis showed no abnormalities in any patients. The institutional review board of Dokkyo Medical University approved this study and written informed consent was obtained from each subject before enrollment.

Electrical stimulation was performed for 15 minutes twice daily with an anal electrode. Improving the contractility of the pelvic floor muscle was thought to be most beneficial for the treatment of UI after RRP. Therefore, 50 Hz square waves with a 300 μs pulse duration and a maximum output of 70 mA (5 seconds on, 5 seconds off duty cycle) were used for active stimulation.[8,9] Sham stimulation was performed with the same system but was limited to an output of 3 mA and a 2 seconds on, 13 seconds off duty cycle. Randomization was done by computer. After registering the patients in the computer system and connecting the stimulation device, the computer randomly assigned each subject to active or sham ES.[8] None of the patients, doctors or medical staff knew which type of stimulation had been assigned until the key code was opened. Patients continued ES until incontinence was resolved or until the end of the study after 12 months.

The primary efficacy end points were continence rates after 1, 3, 6 and 12 months of treatment. Continence was defined as the loss of 8 gm or less of urine during a 24-hour pad test.[14,15] The secondary efficacy end points were time until continence, urine loss (gm) during a 24-hour pad test, and changes in ICIQ-SF and KHQ scores. The ICIQ-SF included the frequency of leakage score (0 to 5 points), the amount of leakage score (0 to 6 points) and QOL score using a visual analog scale (0 to 10 points).[11,16,17] The KHQ score was assessed before treatment, at 1 month and at the end of treatment (usually 12 months).[18]

In terms of statistical analysis results are expressed as mean ± SD. The Wilcoxon signed ranks test was used for assessment of intragroup differences. Student's t test, Fisher's exact probability test and the Mann-Whitney U test were used to evaluate intergroup differences as well as the effect of therapy, with p less than 0.05 considered statistically significant. Based on our previous data for stress incontinence (45% and 9% continent rates for active ES and sham ES, respectively), power analysis demonstrated that 22 patients per group were required for 80% power to be achieved by a 2-group study.[8]

RESULTS

There were 26 patients assigned to the active ES group and 30 placed in the sham group. The baseline characteristics of the patients are summarized in table 1. The 2 groups were well matched with regard to baseline daily urine leak, baseline daily percent leakage (daily leakage/[daily voided volume + daily leakage] × 100 [%]), total ICIQ-SF score, individual ICIQ-SF scores (frequency of leak score, leak volume score and QOL score) and all domains of the KHQ score. In the active ES group 2 patients and in the sham group 4 discontinued the study due to discomfort or anal pain during ES. In the active ES group 2 patients discontinued after 2 and 3 months, respectively, due to urethral stricture at the bladder neck. In the sham group 1 patient discontinued treatment at 7 months because of an increase in prostate specific antigen and he then underwent radiation therapy. Also in the sham group 5 patients complained that ES was not working well enough,

Table 1. *Baseline patient characteristics*

	Mean ± SD Active Group	Mean ± SD Sham Group	p Value (Mann-Whitney U test)
Age	65.4 ± 5.6	68.0 ± 5.6	0.0888
KHQ score domain:			
General health perceptions	55.3 ± 25.8	59.7 ± 27.3	0.5195
Impact on life	77.2 ± 25.0	77.8 ± 25.6	0.9658
Role limitations	59.7 ± 18.7	66.7 ± 25.0	0.4548
Physical limitations	70.2 ± 22.6	75.0 ± 21.6	0.3757
Social limitations	58.5 ± 32.7	51.9 ± 28.8	0.3591
Personal relationships	34.2 ± 41.7	33.3 ± 39.1	0.8311
Emotional problems	53.2 ± 36.0	58.6 ± 30.5	0.9097
Sleep/energy	36.0 ± 29.0	49.1 ± 25.9	0.1748
Severity measures	54.0 ± 22.2	61.5 ± 18.7	0.3396

but they continued the study up to 12 months of treatment. Finally 47 patients (22 in the active ES group and 25 in the sham group) completed the study.

In the active ES group 8 (36%), 14 (63%), 18 (81%) and 19 patients (86%) were continent after 1, 3, 6 and 12 months of treatment, respectively. In the sham group 1 (4%), 4 (16%), 11 (44%) and 17 patients (86%) were continent after 1, 3, 6 and 12 months of treatment, respectively. There were significant differences in the number of continent patients between the groups at 1, 3 and 6 months, respectively ($p = 0.0161$, $p = 0.0021$ and $p = 0.0156$, respectively), but a significant difference was not found at 12 months ($p = 0.1878$). For the patients who became continent (19 in the active ES group and 17 in the sham group) the time until continence was significantly shorter in the active group (2.71 ± 2.6 months, range 1 to 12) than in the sham group (6.82 ± 3.9 months, range 1 to 12) ($p = 0.0006$).

Results of the 24-hour pad test before, and after 1, 3, 6 and 12 months of treatment are summarized in table 2. The change in the amount of leakage from baseline was significantly greater in the active group than in the sham group after 1 month of treatment ($p = 0.0014$), and it tended to differ after 3 months ($p = 0.0504$). The change in percent leakage compared with baseline was significantly greater in the active group than in the sham group at 1, 3 and 6 months but not at 12 months.

Results of the ICIQ-SF before, and after 1, 3, 6 and 12 months of treatment are summarized in table 3. There was a significant difference between the groups with respect to changes in total ICIQ-SF score after 1 and 3 months of treatment ($p = 0.0016$ and $p = 0.0075$, respectively), but no difference was noted at 6 or 12 months ($p = 0.0674$ and $p = 0.6851$, respectively). There were significant intergroup differences in change in frequency of leak score at 1, 3 and 6 months ($p = 0.0358$, $p = 0.0145$ and $p = 0.0006$, respectively). There were also significant intergroup differences with regard to change in the leak volume score and QOL score at 1 month ($p = 0.0057$ and $p = 0.0038$, respectively), but no differences were found after 3, 6 or 12 months.

After 1 month of treatment a significant decrease was noted in every domain of the KHQ score except for personal relationships in the active ES group, while significant decreases were only noted for the physical limitations and severity measures domains in the sham group. At the end of treatment (usually at 12 months) a significant decrease was noted in every domain of the KHQ score except for personal relationships in both groups (see figure).

DISCUSSION

Several RCTs have investigated the conservative treatment of urinary incontinence after RRP. Most of these studies have compared PFMT with no therapy, intensive instructions or biofeedback by trained therapists, with the primary end point generally the number of continent patients or early recovery.[6,19,20] A RCT comparing PFMT with no therapy demonstrated that PFMT significantly improved the restoration of continence at 1 and 6 months.[19] A pooled analysis of 5 RCTs revealed that significantly more men in the biofeedback assisted PFMT group achieved continence or were without continual leakage than in the no training group at 1 to 2 months after RRP (57% vs 37%), while the benefit was no longer significant after 3 to 4 months with 87% and 69% of the men in the PFMT and no training groups achieving continence, respectively.[2,21] In contrast,

Table 2. *Results of 24-hour pad test*

	0 Mos (baseline)	1 Mo	3 Mos	6 Mos	12 Mos
Mean ± SD gm daily leakage:					
Active	738.5 ± 380.6	210.4 ± 261.2	80.6 ± 139.6	20.1 ± 49.2	18.0 ± 49.3
Sham	679.9 ± 370.5	422.6 ± 356.5	232.3 ± 339.0	132.4 ± 293.0	97.8 ± 276.6
Mean ± SD % daily leakage:					
Active	51.4 ± 29.3	14.4 ± 18.7	8.4 ± 15.6	1.2 ± 3.0	1.0 ± 2.6
Sham	48.4 ± 30.7	33.7 ± 28.0	15.3 ± 19.4	8.8 ± 17.8	5.3 ± 11.7
Mean ± SD gm changes in daily leakage vs baseline:					
Active		−528.1 ± 387.2*	−668.6 ± 360.5	−723.9 ± 391.5	−726.6 ± 392.5
Sham		−257.2 ± 279.0	−459.1 ± 385.6	−556.2 ± 421.7	−586.1 ± 442.7
Mean ± SD changes in daily % leakage vs baseline:					
Active		−72.8 ± 30.8†	−90.5 ± 14.0*	−97.6 ± 5.9‡	−97.9 ± 5.5
Sham		−32.6 ± 42.5	−66.7 ± 42.5	−84.4 ± 27.1	−86.6 ± 35.8
No. pts:					
Active	26	26	24	23	22
Sham	30	30	29	26	25

* Mann-Whitney U test $p < 0.01$.
† Mann-Whitney U test $p < 0.001$.
‡ Mann-Whitney U test $p < 0.05$.

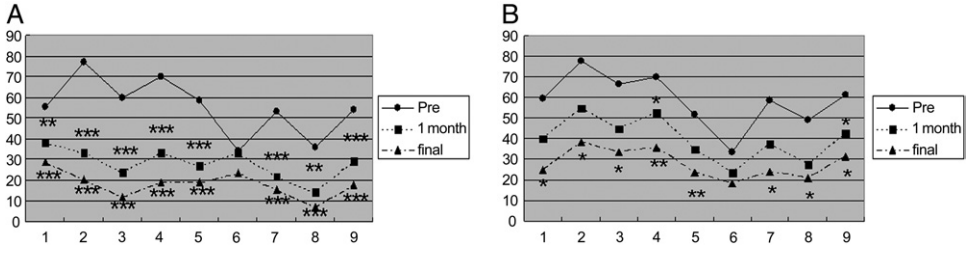
Table 3. *Results of ICIQ-SF*

	Mean ± SD				
	0 Mos (baseline)	1 Mo	3 Mos	6 Mos	12 Mos
Total ICIQ-SF score:					
Active	17.8 ± 4.0	10.6 ± 6.0	5.8 ± 5.7	4.3 ± 6.2	4.2 ± 6.2
Sham	17.5 ± 4.0	14.9 ± 4.9	11.2 ± 5.69	8.2 ± 5.3	5.6 ± 6.5
Frequency of leak score:					
Active	4.8 ± 0.4	3.6 ± 1.4	2.5 ± 1.6	1.4 ± 1.4	1.2 ± 1.5
Sham	4.7 ± 0.5	4.2 ± 1.0	3.4 ± 1.3	2.9 ± 1.5	2.0 ± 1.9
Leak vol score:					
Active	5.0 ± 1.3	3.2 ± 1.6	1.7 ± 1.7	1.3 ± 1.9	1.2 ± 1.9
Sham	5.3 ± 1.1	4.6 ± 1.6	3.2 ± 1.6	2.4 ± 1.4	1.6 ± 1.8
QOL score:					
Active	8.0 ± 2.6	4.2 ± 3.5	2.2 ± 2.3	1.6 ± 3.1	1.5 ± 3.1
Sham	7.4 ± 3.0	6.0 ± 3.0	3.7 ± 2.9	2.5 ± 2.2	1.9 ± 2.5
Changes in total ICIQ-SF score vs baseline:					
Active		−7.0 ± 5.4*	−11.4 ± 4.6†	−12.7 ± 5.9	−12.9 ± 6.1
Sham		−2.6 ± 3.6	−6.5 ± 6.6	−9.4 ± 6.5	−11.7 ± 7.5
Changes in frequency of leak score vs baseline:					
Active		−1.2 ± 1.2†	−2.4 ± 1.7†	−3.4 ± 1.4*	−3.6 ± 1.5
Sham		−0.5 ± 0.7	−1.3 ± 1.2	−1.8 ± 1.4	−2.7 ± 1.8
Changes in leak vol score vs baseline:					
Active		−1.8 ± 1.5*	−3.1 ± 1.5	−3.5 ± 1.9	−3.6 ± 2.0
Sham		−0.6 ± 1.5	−2.0 ± 2.1	−2.8 ± 1.9	−3.5 ± 2.2
Changes in QOL score vs baseline:					
Active		−3.7 ± 3.2*	−5.5 ± 2.1	−5.9 ± 3.1	−6.0 ± 3.2
Sham		−1.4 ± 2.2	−3.5 ± 3.7	−4.7 ± 3.4	−5.2 ± 3.8

* Mann-Whitney U test $p < 0.01$.
† Mann-Whitney U test $p < 0.05$.

Manassero et al reported that the percentage of incontinent men was significantly higher in the control group than in the PFMT group after 1 (97.5% vs 83.3%, $p = 0.04$) and 12 months (52.5% vs 16.6%, $p < 0.01$).[20] RCTs comparing biofeedback enhanced PFMT with written/verbal instruction have demonstrated no significant difference between these methods.[2,6,15,22] However, the studies included patients with differing severities of UI, including minimal or mild UI that can resolve spontaneously, and the natural rate of resolution is often not considered.[7]

Electrical stimulation combined with PFMT may have a stronger effect on UI after radical retropubic prostatectomy. However, most studies on the effects of ES have been nonrandomized or uncontrolled with placebo, with small heterogeneous patient populations, and no objective outcome measures or long-term followup.[9] Moore et al compared standard PFMT (verbal and written instructions), intensive PFMT and intensive PFMT plus rectal ES in 63 men with UI after radical retropubic prostatectomy.[23] Incontinence improved in all 3 groups, and no differences were noted among the groups in terms of urine loss at 16 and 24 weeks. Wille et al randomized 139 patients to 3 groups of PFMT alone (47), PFMT plus ES (46) and PFMT plus ES plus biofeedback (46).[22] The overall objective continence rate



KHQ scores for active ES group (*A*) and sham group (*B*). Single asterisk indicates $p < 0.05$, double asterisk indicates $p < 0.01$, triple asterisk indicates $p < 0.001$ compared with baseline (Wilcoxon matched pairs signed ranks test). 1, general health perceptions domain. 2, incontinence impact domain. 3, role limitations domain. 4, physical limitations domain. 5, social limitations domain. 6, personal relationships domain. 7, emotional problems domain. 8, sleep and energy domain. 9, severity (coping) measures domain.

(pad test) was 32.9% immediately after catheter removal, 65% after 3 months and 83% after 12 months without any significant differences among the groups. However, their study may include minimal or mild cases in which PFMT is enough to cure incontinence.[9]

Recently Mariotti et al randomized 60 patients with UI after radical retropubic prostatectomy to a treatment group (ES plus biofeedback) and a control group (PFMT only), and they reported earlier recovery of continence in the treatment group.[1] Thus, a significant additive effect of ES on PFMT compared with PFMT alone has only been shown in this study, although it was not placebo controlled and the subjects were consecutive patients undergoing RRP in whom leakage ranged widely from 20 to 1,500 gm daily.

Our patients all had severe UI with a mean leak of more than 650 gm. The active ES group (ES plus PFMT) achieved continence significantly faster than the sham group, suggesting that ES may promote early recovery of continence even in patients with severe urinary incontinence after RRP. In the sham group UI resolved in 44% of patients at 6 months and in 86% at 12 months. As shown in table 2 mean daily leakage and percent daily leakage were smaller in the active group than in the sham group up to 12 months of treatment. However, the difference in the changes in daily leakage and percent daily leakage between the groups did not reach statistical significance after 3 and 12 months, respectively. These results may be due to high variability of leakage volume resulting in a large standard deviation. There was no difference in ICIQ-SF score after 6 months and QOL score after 3 months. Therefore, PFMT alone may be effective after more than 6 months or UI may resolve spontaneously within approximately 12 months.

Yokoyama et al compared the effects of ES, magnetic stimulation and PFMT in 36 men with severe UI after RRP.[24] They found that magnetic stimulation and ES achieved higher continence rates at 1 and 3 months than PFMT, but the average 24-hour leakage was less than 10 gm in all groups after 6 months. Although they did not use placebo stimulation, their results appear similar to ours. All patients underwent open RRP so our results may not be applicable to other techniques such as laparoscopic RRP.

Regarding adverse events 6 patients (2 in the active ES group and 4 in the sham group) discontinued the study due to discomfort or anal pain, but there were no serious side effects or adverse events as a result of ES. Thus, ES seems to be safe if patients do not feel discomfort during insertion of the electrode.

CONCLUSIONS

The continence rate was significantly higher in the active ES group than in the sham group after 1, 3 and 6 months of treatment. However, there was no difference between the groups at 12 months and the effect of ES after more than 6 months of treatment was slight. Accordingly we recommend a combination of ES and PFMT for at least 3 to 6 months in patients with severe incontinence after RRP. Electrical stimulation with PFMT led to earlier restoration of continence in patients with urinary incontinence after RRP.

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