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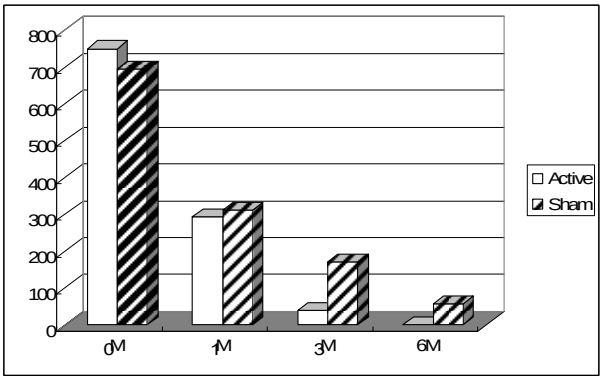
A RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF ELECTRICAL STIMULATION WITH PELVIC FLOOR MUSCLE TRAINING FOR THE TREATMENT OF URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY

Hypothesis / aims of study
Urinary incontinence (UI) after retropubic radical prostatectomy (RRP) is a common and potentially devastating problem affecting 6-63% of men. For prevention and treatment of this post-prostatectomy incontinence, pelvic floor muscle training (PFMT) has been reported to be effective, but it may take several months to recover continence and some patients may have persistent incontinence even if they were continuing PFMT. While PFMT represent ordinary muscle contraction, electrical stimulation (ES) artificially stimulates the pudendal nerve and its branches to cause direct and reflex responses of the urethral and pelvic floor striates muscles. ES may enhance the success of PFMT in patients with incontinence after RRP. However, the enhancement effect of ES and PFMT has not been verified by the placebo-controlled, randomized controlled trial using sham stimulation. The aim of the present study is to evaluate the usefulness of electrical stimulation with PFMT for UI after RRP in a randomized, double-blind manner.

Study design, materials and methods
Thirty two male patients with UI after RRP aged 65.7±7.0 years old were studied. Inclusion criteria included 1) amount of UI of >100g daily after the removal of the catheter, 2) no residual cancer after RRP by pathological diagnosis. All patients were instructed preoperative PFMT by nurses and continued after the removal of the urethral catheter. The stimulation was given for 15 minutes twice daily using an anal electrode. For the active stimulation, 50Hz square waves of 300 μs pulse duration, with a maximum output of 70mA were used, and the duty cycles of 5 seconds on and 5 seconds off periods were applied. Sham device consisted of the same system but was limited to a minimum output of 3mA with the duty cycles of 2 seconds on and13 seconds off periods. The efficacy was evaluated on the basis of 24hr pad test, ICIQ-SF and KHQ questionnaire before and 1, 3, 6 months after the treatment. Cure was defined as amount of leak less than 8g in 24hour pad test. Local ethical committee approval and written informed consent from each subject was obtained before entry into the study.

Results
Seventeen patients were assigned to the active group and 15 in the sham group. One patient in the active group stopped treatment because of pain. Mean daily amount of leak was 750.0±432.1ml before the treatment, 294.5±378.9 ml at 1 month, 38.1±71.6ml at 3month after the active stimulation. All patients in the active group were continent at 6months after the treatment. Mean daily amount of leak was 693.8±378.3ml before the treatment, 312.5±278.8ml at 1 month, 171.7±239.4ml at 3month and 56.22±98.8ml after the sham stimulation. At 6months after the treatment, seven patients in the sham group still had >50mg of leaks daily. The mean sum score of ICIQ-SF in the active group was 16.9±5.5, 8.18±8.1, 3.88±5.4 and 1.41±2.1, before, and at 1, 3 and 6 month after the treatment, respectively. The mean sum score of ICIQ-SF in the sham group was 18.3±3.7, 14.3±5.0, 7.60±4.1 and 4.88±2.9, before, and at 1, 3 and 6 month after the therapy, respectively. Duration until cure was 2.2±1.75 months in the active group and 7.0±3.6 in the sham group (p=0.0017).

Figure: Amount of leak after the treatment



Interpretation of results
PFMT resolved UI at 6month postoperatively in most of the patients. However, the active group (active electrical stimulation and PFMT) achieved continence earlier than the sham group did.

Concluding message
Electrical stimulation with PFMT produced early recovery of continence in patients with urinary incontinence after RRP.

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CLINICAL TRIAL REGISTRATION: **This clinical trial has not yet been registered in a public clinical trials registry.**

HUMAN SUBJECTS: **This study was approved by the Dokkyo University Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.**