

PRELIMINARY RESULTS OF THE EFFECT OF SACRAL SURFACE THERAPEUTIC ELECTRICAL STIMULATION ON URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY: A PILOT STUDY.

Hypothesis / aims of study

Radical prostatectomy is a common procedure for the treatment of clinically localized prostate cancer. However, urinary incontinence is a significant potential source of morbidity following surgery. From our investigations, incontinence is severe during the early period after surgery. We investigated a new electrical stimulating system, which utilizes sacral surface therapeutic electrical stimulation (SS-TES), to prevent urinary incontinence for patients immediately after radical prostatectomy.

Study design, materials and methods

This investigation was a historical control study. A single surgeon performed radical prostatectomy. Twenty patients were enrolled in this study; the 9 early patients performed pelvic floor exercises four times a day before and after surgery (PFE group), whereas the 11 later patients received SS-TES from postoperative day (POD) 1 to POD 7. SS-TES was performed twice daily with a portable electrical stimulator (SS-TES group): for a 15-minute duration (10 seconds on, 5 seconds off) at a frequency of 30Hz, biphasic rectangular pulses, 200 μs width and sub-maximum tolerable intensity to the patient. The surface electrodes (10cm X 6cm) were placed bilaterally at the level of the sacral root from S2 to S4. Objective measurements included voiding diaries and incontinence volume. We compared the maximum bladder capacity and incontinence rate (incontinence volume/total urine volume/24hrs). SS-TES was continued from 7 to 10 days after surgery. UCLA-Prostate Cancer Index (UCLA-PCI) was measured one month after surgery.

Results

Maximum bladder capacity on the first day after removal of the urethral catheter, POD 5, was larger in the SS-TES group compared with the PFE group (250±60.8 vs. 327±65.6, respectively; p<0.01) (Fig.1). Incontinence rate was better in the SS-TES group (2.15±4.0% vs. 0.22±0.32%, p<0.05) (Fig.2). One patient exhibited sinus tachycardia on SS-TES under high-grade fever on the first postoperative day and was excluded from the study. Urinary function and urinary bother one month after surgery were not significant in either group .

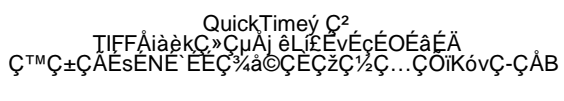
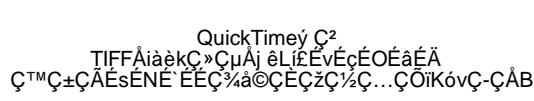


Fig.1: Maximum capacity of bladder measured on the first day after removal of catheter. Significant increase in the capacity of bladder was confirmed in the SS-TES group.

Fig.2: Urinary incontinence rate on the preceding day of hospital discharge. Significant decrease in urinary incontinence rate was confirmed in the SITES group.

Interpretation of results

The SS-TES group was significantly better in the incontinence rate and bladder capacity during the short term after radical prostatectomy. There were no differences in urinary function after one-month; we consider that the carry-over effect of electrical stimulation does not continue beyond one month. We have initiated a large scale randomized controlled trial for SS-TES after radical prostatectomy.

Concluding message

SS-TES offers a new option for the treatment of urinary incontinence after radical prostatectomy. Further studies are required to determine how long the benefits of treatment last and whether maintenance therapy is necessary.

References

- 1) Int J Urol. 2006 Sep; 13(9): 1191-6.
- 2) Urology. 2006 Jul; 68(1): 142-7.
- 3) Clin Rehabil. 2004 Dec; 18(8): 899-907.

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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 Ethics Committee Tohoku University School of Medicine and followed the Declaration of Helsinki Informed consent was obtained from the patients.