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Extracorporeal magnetic innervation increases functional bladder capacity and quality of life in patients with urinary incontinence after robotic-assisted radical prostatectomy

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ABSTRACT

Objective: Postprostatectomy incontinence (PPI) is a major health problem that has substantial effects on health-related quality of life. In recent years, extracorporeal magnetic innervation (ExMI) has become a preferred treatment method for urinary incontinence. We evaluated the effects of ExMI on patients with PPI after robotic-assisted radical prostatectomy (RARP), specifically regarding health-related quality of life.

Materials and methods: From September to December 2014, patients with post-RARP PPI were enrolled in the study. A 20-minute ExMI treatment session was provided twice a week for two months. Number of voids, incontinence and urgency episodes, and mean and maximum voided volume per micturition (mL) were recorded in a 3-day bladder diary. Quality of life was assessed using the Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), and International Prostate Symptom Score quality-of-life questionnaire (IPSS-QoL). All assessments were conducted before and within 2 weeks after ExMI treatment. A favorable outcome was defined as an IPSS-QoL score <2 or a >2-point decrease in the pretreatment score.

Results: Thirteen patients with a mean age of 69.3 years were enrolled. After ExMI, the number of incontinence episodes/3 d decreased to 5.85 from 9.15 ($p = 0.004$). The mean number of voids/d also decreased to 9.17 from 10.45 ($p = 0.036$). Patients' functional bladder capacity increased from 243.46 to 289.23 ($p = 0.007$). Scores of both UDI-6 and IPSS-QoL improved from 7.15 to 5.31 ($p = 0.024$) and 4.00 to 2.77 ($p = 0.007$). Patients aged <70 years were more likely to have a favorable outcome [odds ratio (OR) 28.6, confidence interval (CI) 1.12–731.40].

Conclusion: ExMI decreases the number of incontinence episodes, increases functional bladder capacity and quality of life in patients with post-RARP PPI, and may be considered as an option for patients with PPI.

1. Introduction

Radical prostatectomy (RP) is the standard treatment for localized prostate cancer. Postprostatectomy incontinence (PPI) is a potential symptom experienced following radical prostatectomy. Persistent PPI can be incapacitating and result in decreased quality of life (QoL).[1] PPI incidence rates vary from 5% to >80%.[2] Conservative management techniques include pelvic-floor muscle training with or without biofeedback, electrical stimulation, extracorporeal magnetic innervation (ExMI), compression devices (penile clamps), lifestyle changes, or a combination of methods. The ability to perform robotic-assisted RP (RARP) was first described in 2000.[3] During the past decade, RARP has become widely accepted and is now the dominant RP approach in Taiwan.[4] While there are no randomized studies comparing QoL outcomes following open versus RARP, data from a recent meta-analysis showed a statistically significant advantage for RARP compared to both open and

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laparoscopic approaches in terms of 12-month urinary continence recovery.[5]

Electrical stimulation was first used to treat urinary incontinence in 1963[6] and is reportedly effective at treatments associated with female stress and urge incontinence.[7,8] Electrical stimulation performed better than control interventions for PPI patients in terms of less incontinence, continence reacquisition, and improved QoL during a 6-month period.[9,10] Unlike electrical stimulation, ExMI uses a magnetic chair to stimulate contraction of pelvic-floor muscles and sacral-nerve roots. ExMI is a relatively painless, noninvasive, and convenient form of electrical therapy that is more acceptable to patients suffering from urinary incontinence.[11] Data from individual trials suggest that ExMI alone or in combination with other treatments may be beneficial for PPI patients.

Here, we investigate the effect of ExMI on PPI patients, specifically regarding health-related QoL.

2. Materials and methods

From September to December 2014, patients with post-RARP urinary incontinence were enrolled in the study. The medical history, prostate cancer parameters, and surgical techniques were recorded. All surgeries were performed by the same surgeon (CT Wu). A 3-day bladder diary was completed at baseline and within 2 weeks of completing ExMI therapy to evaluate voiding patterns and any possible changes.

The BioCon-2000W system (Mcube Technology, Seoul, South Korea) was used for ExMI. During treatment, the patients were instructed to sit on the chair fully clothed in order to position the perineum at the center of the coil and were informed that they would feel anal-sphincter contraction during stimulation. Stimulation was provided by an electromagnetic generator underneath the seat controlled by an external unit. Treatment sessions were 20 minutes, twice weekly, for 2 months. Pulse-field frequency was 10 Hz applied intermittently for 10 minutes, followed by a 1-minute rest period, then a second treatment at 50 Hz applied intermittently for 10 minutes.

The primary end point represented changes in the number of urinary incontinence episodes recorded in the 3-day bladder diary. Secondary end points represented changes in the mean number of voids/24 h and urgency episodes, mean voided volume/micturition (mL), and maximum voided volume/mL (functional bladder capacity, mL) recorded in the 3-day bladder diary. Incontinence symptoms and QoL were evaluated by self-administered validated versions of the Urogenital Distress Inventory-short form (UDI-6), Incontinence Impact Questionnaire-short form (IIQ-7), and International Prostate Symptom Score-QoL questionnaire (IPSS-QoL), Chinese-language version.[12] Favorable outcomes were defined as an IPSS-QoL score <2 indicating that participants were mostly satisfied or pleased post-ExMI treatment or a >2-point decrease in the pretreatment score.

Mean ± standard deviation was calculated for each of the primary and secondary outcome variables. The Wilcoxon signed-rank test was used for pre- and post-treatment comparisons with a significance level of 0.05 (two-tailed). All statistical analyses were carried out using SPSS version 13 (SPSS, Inc., Chicago, IL, USA).

3. Results

A total of 13 patients with post-RARP urinary incontinence were enrolled in the study. Demographics and clinical characteristics are shown in Table 1. Nine patients within 1 year after RARP, and four patients experiencing persistent incontinence 4.0–7.5 years after RARP were enrolled. Most patients suffered from varying degrees of urinary incontinence, except for one experiencing pure-urge incontinence and another experiencing pure-stress incontinence. All patients reached 100% treatment intensity and completed the 2-month treatment session with no reported adverse symptoms.

Table 1
Patient demographic characteristics ($n = 13$).

	Total
Age (y)	69.3 ± 4.8
BMI (kg/m^2)	25.2 ± 3.0
PSA	17.3 ± 12.6
Prostate volume (mL)	40.5 ± 18.8
Anterior urethropexy	7 (53.8%)
Nerve sparing	
Unilateral	6 (46.2%)
Bilateral	3 (23.1%)
Bladder neck preservation	6 (46.2%)
Positive surgical margin	6 (46.2%)

BMI = body mass index; PSA = prostate specific antigen.

Following 2 months of ExMI therapy, the mean number of incontinence episodes recorded in the 3-day bladder diary decreased by 36% (9.15 ± 4.83 to 5.85 ± 4.53, $p = 0.004$; Table 2, Figure 1). The patients' mean functional bladder capacity increased by 19% (243.46 ± 87.22 to 289.23 ± 8 7.22, $p = 0.007$; Table 2, Figure 2), however, there was only a marginal increase in their mean voided volume (120.97 ± 29.26 to 132.85 ± 36.91, $p = 0.046$; Table 2) and a marginal decrease in the mean voiding frequency per day (10.45 ± 29.26 to 9.17 ± 2.27, $p = 0.036$) recorded in the 3-day bladder diary.

UDI-6 scores were significantly lower following ExMI (7.15 ± 2.79 to 5.31 ± 2.50, $p = 0.024$; Table 2). When each of the six questions was compared separately, scores on the fourth question showed the most significant decrease (1.69 to 1.07, $p = 0.02$). Notably, the mean score for the fifth question, regarding difficulty in emptying the bladder, was 0.15 before ExMI and decreased to zero following ExMI ($p = 0.165$). The mean score for the sixth question, regarding pain and discomfort, increased from 0.46 to 0.54 following ExMI, however, the change was not statistically significant ($p = 0.337$).

IIQ-7 scores decreased from 10.92 ± 6.08 to 8.69 ± 5.69 following ExMI ($p = 0.074$), however, the change was not statistically significant. When we examined each of the seven questions, a trend of decreasing scores following treatment was observed for all questions, however, none of the changes were statistically significant. The mean IPSS-QoL score significantly decreased from 4.0 ± 1.29 to 2.77 ± 1.31 ($p = 0.007$).

Eight of the 13 patients had a favorable outcome following ExMI. Compared to older patients, those <70 years of age were significantly more likely to have a favorable outcome [Odds ratio (OR)

Table 2
Urinary symptoms and quality of life scores at baseline and after extracorporeal magnetic stimulation (ExMI) in patients experiencing postprostatectomy incontinence ($n = 13$).

	Pre-ExMI	Post-ExMI	p
Incontinence episodes/3 d	9.15 ± 4.83	5.85 ± 4.53	0.004
Urgency episodes/3 d	4.77 ± 2.24	3.64 ± 2.19	0.167
Mean void times/d	10.45 ± 2.47	9.17 ± 2.27	0.036
Mean voided volume (mL)	120.97 ± 29.26	132.85 ± 36.91	0.046
Functional bladder capacity (mL)	243.46 ± 80.37	289.23 ± 87.22	0.007
UDI-6	7.15 ± 2.79	5.31 ± 2.50	0.024
IIQ-7	10.92 ± 6.08	8.69 ± 5.69	0.074
IPSS-QoL	4.0 ± 1.29	2.77 ± 1.30	0.007

Pre- and post-ExMI scores calculated using Wilcoxon signed-rank test, two-tailed p values.
IIQ-7 = Incontinence Impact Questionnaire; IPSS-QoL = International Prostate Symptom Score quality-of-life questionnaire; UDI-6 = Urogenital Distress Inventory.