

## EFFICACY OF HIGH-FREQUENCY MAGNETIC STIMULATION OF THE SACRAL ROOT IN PATIENTS WITH STRESS URINARY INCONTINENCE FOLLOWING A RADICAL PROSTATECTOMY

### Hypothesis / aims of study

To elucidate the efficacy of magnetic stimulation on the sacral roots for the intractable post-radical prostatectomy (RP) stress urinary incontinence (SUI) in a prospective study.

### Study design, materials and methods

Fourteen males who had been suffering from SUI which had lasted for more than one year after a RP were consecutively enrolled in the treatment protocol. Patients with anastomotic urethral stenosis and recurrence of prostatic cancer were all excluded. Preoperatively, all patients were neurologically intact and free of urinary incontinence without detrusor overactivity. Present studies were performed according to the Declaration of Helsinki and the procedures were approved by the local ethics committee. All patients were properly counseled, and gave their informed consent before treatment.

Treatment was performed using a 90mm. circular coil (Magstim*Rapid*, United Kingdom). Each treatment session consisted of the repetitive magnetic stimulation (15Hz) at 50% maximum output for 5 seconds per minute. The stimulation was carried out without anesthesia for 30 minutes resulting in total 2,250 stimuli were given in each session. Treatment was repeated once in two weeks for 40 weeks, resulting in totally 20 sessions were performed.

All the patients were assessed before starting the first session, at the 1 week after the first session and 1 week after the final session, with the filling cystometry, urethral pressure profile, pad-test during 60 minutes, completion of a 3-day voiding diary and disease specific QOL by using King's Health Questionnaire (KHQ). Voiding diary was checked again at 2 months after the final session. Treatment was considered to be successful if an amount of urinary leakage by 1hr pad-test assessed at the 1 week after the final session decreased to less than 50% of the value before treatment in order to estimate factors which associated with the treatment success. Analysis of variance (ANOVA) was used for repeated measures to assess treatment effects with post hoc least significant difference tests where appropriate, with  $p < 0.05$  considered significant.

### Results

The mean age at treatment was 65.4 years (47 - 75). The mean duration from the surgery to the onset of magnetic stimulation was 432 days (382 - 625). Overall results of treatment are summarized in Table 1. The amount of urinary leakage assessing by one-hour pad test and the number of leaks during a day improved significantly after the first treatment session. Efficacy of the treatment was consistently observed after the final treatment session. The number of leaks during a day remained to be improved at 2 months after the final treatment session without any additional treatment (3.2 times/day in average at 12 months after the onset of the treatment). Urodynamic parameters including bladder capacity at the first desire to void (FDV), the capacity at the strong desire to void (SDV) and maximum urethral closing pressure (MUCP) all increased significantly after magnetic stimulation.

The successful treatment efficacy according to our definition was observed in 6 of the 14 patients (42.8%). In the patients with successful treatment, 2 cases gained complete continence without requiring the pads on their daily life. Pretreatment variables including patient age, duration from the surgery to the onset of the treatment and baseline conditions of urinary incontinence (amount of urinary leakage and baseline frequency of leak episodes), as well as baseline urodynamic parameter representing bladder and urethral function, did not differ significantly between patients with treatment success and patients without treatment success (Table 2). QOL assessed by KHQ significantly improved only in patients with successful treatment efficacy. No obvious complication was observed in all patients during

and after the treatment.

#### Interpretation of results

The effectiveness of magnetic stimulation of the sacral root on male obstinate SUI after a RP was potentially elucidated. Both an increase of bladder capacity and an elevation of urethral resistance may account for the improvement of SUI following magnetic stimulation. While we could not elucidate any predictive variables regarding outcomes following long-term magnetic treatment, the initial treatment was almost as effective as that obtained after the final treatment, indicating the possibility that the long-term efficacy of the treatment can be speculated from the efficacy observed during the initial treatment. The result that frequency of leak episodes remained to be improved at least for 2 months after the final treatment without additional stimulation, suggesting that magnetic stimulation of the sacral root may have a carry-over effect on this type of SUI.

#### Concluding message

High-frequency magnetic stimulation of the sacral root may afford a useful option with minimal invasiveness for the patients with obstinate stress urinary incontinence after a RP.

**Table 1 Short and long-term effect of magnetic stimulation**

|                                   | Before treatment | After the first session | After the final session |
|-----------------------------------|------------------|-------------------------|-------------------------|
| Amount of urinary leakage (g/Hr.) | 63.1 (56.8)      | 45.4 (40.9)*            | 37.3 (34.1)*            |
| Number of urinary leakage (/day)  | 6.1 (2.9)        | 3.5 (2.6)*              | 3.0 (2.3)*              |
| FDV (ml)                          | 146.0 (42.6)     | 175.3(48.0)*            | 181.6 (52.2)*           |
| SDV (ml)                          | 224.1 (59.7)     | 257.6 (50.4)*           | 258.4 (60.0)*           |
| MUCP (cmH <sub>2</sub> O)         | 48.1 (26.4)      | 68.3 (33.3)*            | 62.6 (23.4)*            |

mean (standard deviation)

\*P < 0.05 (for the comparison with before treatment)

**Table 2 Comparison of baseline factors between patients with and without successful treatment**

|                                   | Success (6) | No success (8) |
|-----------------------------------|-------------|----------------|
| Age (years)                       | 65.6 ± 6    | 67.0 ± 9       |
| Duration of incontinence (days)   | 427 ± 126   | 470 ± 176      |
| Amount of urinary leakage (g/Hr.) | 68.1        | 58.2           |
| Number of urinary leakage (/day)  | 6.9         | 5.4            |
| FDV (ml)                          | 153 (53)    | 141 (36)       |
| SDV (ml)                          | 243 (64)    | 210 (56)       |
| MUCP (cmH <sub>2</sub> O)         | 48.2 (23.5) | 44.4 (33.4)    |

mean (standard deviation)