Efficacy of High-frequency Magnetic Stimulation of the Sacral Root in Patients with Urinary Incontinence Following a Radical Prostatectomy

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Objectives: We report on our initial data from a prospective study to determine the efficacy of high-frequency magnetic stimulation on the sacral root (MSSR) for the intractable post-radical prostatectomy, stress urinary incontinence (SUI).

Methods: A total of 14 men with persistent SUI after a radical prostatectomy underwent treatment once every 2 weeks over a 40-week period for a total of 20 sessions. The outcome was assessed by these variables at baseline, at immediately after the first session, and at immediately after the final (20th) session.

Results: Mean leak episodes (per day) consistently decreased after the first to the final session (from 6.1 ± 2.9 to 3.5 ± 2.6, and to 3.0 ± 2.3, P < 0.01), and it remained to be decreased following 2 months after the final session. The mean pad weight (per h) also decreased after the treatment (but no statistically significant change compared to the pretreatment level). The cystometric bladder capacity at the first desire to void and the capacity at the strong desire to void increased significantly following the high-frequency MSSR (first desire to void: from 146 ± 43 to 182 ± 52 mL; strong desire to void: from 224 ± 69 to 258 ± 60 mL, P < 0.01). No obvious complication was observed in any patients during or after the treatment.

Conclusion: This study provides the preliminary evidence that high-frequency MSSR may potentially afford a useful option with minimal invasiveness for the patients with obstinate SUI after a radical prostatectomy.

Key words magnetic stimulation, radical prostatectomy, stress urinary incontinence

1. INTRODUCTION

Magnetic stimulation of the sacral root (MSSR) and pelvic floor has been described as a minimally invasive and painless treatment alternative for incontinence and irritative voiding symptoms which are refractory to conservative therapies, such as medication and pelvic floor exercise.1 Persistent stress urinary incontinence (SUI) may occur after a radical prostatectomy (RP) for prostatic cancer. It has been reported that a complete recovery of urinary incontinence is observed in about 93% of cases within 2 years after surgery.2 However, this conversely means that a substantial number of cases suffer from intractable SUI for several years after a RP, significantly deteriorating the patient’s quality of life (QOL). The treatment option of delayed SUI after a RP with low invasiveness, such as retrograde collagen injection in the urethra, has only a limited efficacy.3 The results of several surgical procedures such as urethral sling procedure and artificial sphincter placement seem to be encouraging,4 however, they are all highly invasive and may risk many complications. In contrast, although several reports have shown that activating the sacral root by magnetic stimulation seems to effectively improve SUI in females with minimal invasiveness,5–7 we have little information regarding the treatment efficacy on male SUI. This prospective study was, therefore, conducted to identify and compare the short-term and long-term efficacy of high-frequency MSSR for patients with intractable long-lasting SUI following a RP.

2. METHODS

From 2000 to 2004, 14 males suffering from SUI which lasted more than 1 year after a RP were consecutively enrolled in the treatment protocol for MSSR. Patients with...
anastomotic urethral stenosis and recurrence of prostatic cancer, including the elevation of serum prostate specific antigen level, were all excluded. Incontinence showed only a minimal response to conservative treatments to include pelvic floor exercise in six patients, anticholinergic and/or tricyclic anti-depressant combined with pelvic floor exercise in eight. Preoperatively, all patients were neurologically intact and free of urinary incontinence without detrusor overactivity. Operation had been performed with a retrograde approach for clinically localized prostate cancer (T1-2N0M0). The unilateral neurovascular bundle was preserved in three patients. The 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.

2.1. Treatment protocol

Treatment was performed with the patient in a prone position using a 90 mm circular coil (Magstim Rapid, Magstim Co., Ltd, Whitland, Wales, UK). The center of coil was fixed over the tip of the tail bone. The generating coil of magnetic stimulation was fixed above the optimal position at which the strong muscle contraction in the buttocks and lower extremities could be observed by preliminary stimulation. The study protocol is shown in Figure 1. Each treatment session consisted of the repetitive magnetic stimulation (15 Hz) at 50% maximum output for 5 sec/min. The stimulation was carried out without anesthesia for 30 min resulting in a total of 2250 stimuli in each session. Treatment was repeated once every 2 weeks for 40 weeks, thus resulting in a total of 20 sessions for each patient.

2.2. Assessment of efficacy

All patients were assessed before the first session, at 1 week after the first session and at 1 week after the final (20th) session, with the filling cystometry, urethral pressure profile, 1-h pad test, completion of a 3-day voiding diary and disease specific QOL by using King’s Health Questionnaire (KHQ). The voiding diary was checked again at 2 months after the final session in order to evaluate the frequency of leak episodes (Fig. 1). Filling cystometry and urethral pressure profile were performed transurethrally using a 12 Fr. single lumen catheter. Filling cystometry was recorded at the saline infusion rate of 50 mL/min. Urethral pressure profile was recorded at an infusion rate of 5 mL/min and catheter withdrawal speed was 5 cm/min. The clinical outcome of the therapy was judged as complete response when the patients reported no incontinence episode or leakage of <1 g in the pad test. The outcome was considered as partial response when the frequency of incontinence or the pad weight decreased >50%.

2.3. Statistical analysis

The results were presented as the mean plus or minus standard deviation. An analysis of variance was used for repeated measures to assess treatment effects with post-hoc least significant difference tests where appropriate, with P < 0.05 considered to be statistically significant.

3. RESULTS

3.1. Patient characteristics

The mean age at the initial treatment was 65.4 ± 7.1 years (range, 47–75 years). The mean duration from the surgery to the onset of MSSR was 432 days (range, 382–625).

3.2. Treatment efficacy

The overall results of the treatment are presented in Table 1. A significant decrease in the number of leaks during the day assessed by a voiding diary was consistently observed from the first session to the end of the final session. The leak episodes continued to decrease at 2 months after the cessation of the final session. The amount of urinary leakage assessed by a 1-h pad test seemed to be reduced, but there was no statistically significant change at any time after the treatment. Urodynamically estimated bladder capacity at the first desire to void (FDV) and the capacity at the strong desire to void (SDV) increased significantly after both the first and the final treatment. FDV and SDV increased 120–115% of the pretreatment level at the end of the final session. Although maximum urethral closing pressure (MUCP) also increased following MSSR, we could not find a statistically significant change even after the final treatment session. The mean values obtained after the final session did not show any statistically significant difference when compared with the value obtained after the first session, neither in objective symptoms (amount or frequency of urinary leaks) nor urodynamic parameters (FDV, SDV and MUCP).
TABLE 1. The overall results of the treatment

<table>
<thead>
<tr>
<th></th>
<th>Before the 1st session</th>
<th>After the 1st session</th>
<th>After the 20th session</th>
<th>2 months after the 20th session</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of leaks (g/h)</td>
<td>63.1 ± 56.8</td>
<td>45.4 ± 40.9</td>
<td>37.3 ± 34.1</td>
<td>–</td>
</tr>
<tr>
<td>Frequency of leaks (/day)</td>
<td>6.1 ± 2.9</td>
<td>3.5 ± 2.6*</td>
<td>3.0 ± 2.3*</td>
<td>2.6 ± 2.2*</td>
</tr>
<tr>
<td>FDV (ml)</td>
<td>146 ± 43</td>
<td>175 ± 48*</td>
<td>182 ± 52</td>
<td>–</td>
</tr>
<tr>
<td>SDV (ml)</td>
<td>224 ± 60</td>
<td>258 ± 50*</td>
<td>258 ± 60*</td>
<td>–</td>
</tr>
<tr>
<td>MUCP (cmH2O)</td>
<td>48 ± 26</td>
<td>68 ± 33</td>
<td>63 ± 23</td>
<td>–</td>
</tr>
</tbody>
</table>

*P < 0.01 (before vs after treatment).

TABLE 2a. Number and amount of urine leaks before first session, after first session, and after final session

<table>
<thead>
<tr>
<th>Patients no.</th>
<th>Number of leaks (per day)</th>
<th>Amount of leaks (g/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>First</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>1</td>
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<tr>
<td>2</td>
<td>4</td>
<td>1</td>
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<tr>
<td>3</td>
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<td>141</td>
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<td>4†</td>
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<td>9†</td>
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</tr>
<tr>
<td>13</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>14†</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

†Patients with mixed urinary incontinence.

The individual data of each patient are summarized in Table 2. After the initial treatment session, a partial response in the frequency of incontinence or the pad weight was observed in 6 of the 14 subjects (43%). After the final treatment session, a complete response was observed in two of the 14 subjects (14%) in addition to a partial response in seven (50%). There was a complete response of the frequency of leak episode in three subjects (21%), and a partial response in six (50%) at 2 months after the cessation of the final treatment (Table 2a). An increase in FDV or SDV compared with the baseline level was observed in 13 (93%) subjects after the initial and final treatment session. On the other hand, an increase of MUCP was observed in seven (50%) subjects after the initial treatment session, and in 10 (71%) after the final treatment session (Table 2b).

No obvious complications were observed in any patients during or after treatment.

3.3. Effect on quality of life

The effect of urinary incontinence on a patient’s QOL was assessed using KHQ. As shown in Table 3, the scores in each domain of KHQ all decreased after the final treatment. As statistically significant improvement was observed in three domains: physical limitation, emotion, and incontinence severity measures.

4. DISCUSSION

Several clinical studies have been performed regarding the effect of magnetic stimulation on urinary incontinence.1,6,8 Furthermore, magnetic stimulation is performed on patients of all ages, and urinary incontinence of various types is treated for in later years.9,10 Although a symptomatic improvement has been reported in about 70–80% of females with SUI, to our knowledge, few
studies have been conducted regarding the long-term efficacy of magnetic stimulation in a cohort of males with SUI. Persistent urinary incontinence, a significantly negative factor regarding a patient’s QOL, is a well-known complication in men who undergo a RP with a reported incidence of 5–12%. The cause of long-lasting SUI following a RP was thought to mainly be associated with intrinsic sphincter deficiency due to the surgical impairment.1 In this prospective study, we noted the long-term beneficial effect of MSSR on objective symptoms (decrease in the frequency of the leak episode), as well as on some urodynamic parameters (increase in the bladder capacity at FDV and SDV) in males with obstinate SUI after a RP. Although we could not elucidate any statistically significant improvement due to the small sample size, MSSR also might have a positive effect on the urethral continence mechanism, as demonstrated by the increase in the average value of MUCP, which has been shown in a previous study. However, the current study has several shortcomings, particularly because of the lack of placebo-controlled subjects. We speculated that it would be unlikely that the recorded significant improvement in cystometric parameters and objective symptoms could be attributed to a placebo effect. However, this should be confirmed by further studies including a sham group. Although the improvement of urinary incontinence supposes to be due to the effect of MSSR, it should be considered that the spontaneous regression after surgery partly account for the recovery.

It is most critical to establish both good selection criteria and optimal treatment conditions if we can systematically attempt magnetic therapy on a clinical level. As far as we know, only the vesical leak point pressure value has been documented to be a predictive parameter for selecting patients with SUI who can obtain a good treatment efficacy. Although Almeida et al. mentioned the positive relationship between the beneficial effects and the number of treatment sessions on female stress and/or mixed urinary incontinence, we could not find any cumulative beneficial effect of MSSR in the present results, thus suggesting the possibility that the beneficial effects observed during the initial treatment session can roughly predict the long-term efficacy of MSSR on subjects with SUI following a RP. Although we defined the stimulation protocol in this study according to the report by Fujishiro et al., it is recently supposed that a magnetic stimulation with higher frequency (20–50 Hz) is adequate for the treatment of SUI. The stimulation condition with low frequency applied in the current study may affect the efficacy of MSSR.

In addition, great variations have been found in the carry-over effects of magnetic stimulation on urinary incontinence. On the other hand, Unsal et al. demonstrated a 79% of the cumulative success rate at 12 months after the treatment, and a higher reduction rate (70%) of the number of pad used was also reported by Galloway et al. at 6 months after the final stimulation. However, a higher recurrence rate of 47% at 3 months and 62% at 6 months after the treatment was reported in women with stress or mixed urinary incontinence. Although we observed the patients for only 2 months after the final treatment in the present study, the frequency of leak episodes decreased in 93% of subjects without any additional interventions, thus suggesting that MSSR may have a carry-over effect on male SUI following a RP. The inter-study differences regarding the efficacy of magnetic stimulation may be attributed to the wide variations in the treatment design, including the frequency and duration of treatment (total number of treatment sessions) and the combination of stimulation parameters in each session, and the patient selection criteria (sex and type of urinary incontinence) between each study.

Our present data demonstrate that MSSR offers a certain degree of efficacy on male SUI with minimal invasiveness, suggesting that it is worth trying as a first-line conservative treatment option for male obstinate SUI after a RP. Further investigations, especially comparative studies among different combinations of stimulation parameters, including the duration, intensity and frequency of stimuli should be performed to clarify the optimal treatment plan for male patients with SUI.

5. CONCLUSION

High-frequency MSSR appears to be effective for obstinate SUI after a RP. These results suggest that this method may be a useful option for male urinary incontinence if we can establish an optimal treatment protocol based on further examinations.

Disclosure

The Authors have nothing to disclose.
REFERENCES


