Evaluating the Clinical Performance of a Novel External Electrical Stimulation Therapy for Urinary Incontinence - A Retrospective Case Series (N=104) – Study 1

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Introduction

Recent pilot data has shown a significant reduction in symptoms in female stress urinary incontinence (SUI)patients using an external electrical stimulation device for training the pelvic floor muscles.[1,2] While verifying the safety and efficacy of a novel intervention method using controlled research data is the first step in determining the widespread clinical use of a treatment modality, it is only when a treatment has been applied in real life clinical practice that the true potential of an intervention becomes apparent. This 2-part registry exercise looked retrospectively at the clinical outcome of a cohort of German incontinence patients using this approach in clinic for treatment of their incontinence issues.

Aims

The purpose of this study was to retrospectively investigate the treatment outcomes of patients using external electrical stimulation for treating UI symptoms in clinic.

Methods

Treatment outcomes were assessed by means of patients and clinicians completing a subjective treatment feedback form at the end of therapy which captured a host of symptom measures (E.g. no. of pads), quality of life assessments and an overall acceptance of the therapy and its impact on the patient's condition. Outcomes were evaluated in 104 patients across twenty five clinics over a monitoring period which ran from April 2013 to February 2014. The majority of patients were female with a small male cohort (n=12) also assessed. 54% (n=56) of the study population suffered from stress incontinence, 21% (n=22) suffered from urge incontinence and 25% (n=26) suffered from mixed incontinence. Data analysis was conducted using descriptive analysis and summary statistics.

Results

The number of incontinence pads used by the female SUI subgroup fell from 2.6 pads/day to 2.1 pads/ day at the end of the treatment. The impact of urinary incontinence on patients' quality of life was evaluated by means of the Incontinence Quality of Life Questionnaire (I-QOL) which improved from 49 (start) to 69 (end) during treatment with the device. At the first visit, 84% (n=87) of the study population classified the effect of their bladder problem on their daily life as moderate or severe, this decreased to 39% (n=41) at the final visit. The proportion of patients feeling bad or very bad if their current symptoms stayed intractable, dropped from 59% (n=61) to 22% (n=23) of all patients over the course of the study. Physician assessment of the treatment among clinicians who responded (n=60) after therapy showed that 44% of doctors were very satisfied, 40% were satisfied and 16% were not satisfied. The corresponding patient response (n=88) to the simple question of whether they were satisfied with the external approach showed that 36% of patients were very satisfied, 40% were satisfied and 24% were not satisfied. Of this group, 98% of clinicians and 90% of patients would recommend this modality for the treatment and management of UI.

Discussion and Conclusions

Subjective feedback from in-clinic practice has shown patients and physicians to respond favourably to this treatment method with the majority of patients and clinicians identifying it as a positive intervention in overall patient care. Further research among specific patient populations E.g. Male post prostatectomy, Faecal Incontinence patients who stand to benefit from enhanced pelvic floor musculature is warranted to determine if the promising results shown in pilot and clinical practice in other incontinence groups is achievable.

References

1. Soeder S, Tunn R. (2013) - Neuromuscular Electrical Stimulation (NMES) of the Pelvic Floor Muscles using a Non-Invasive Surface Device in the Treatment of Stress Urinary Incontinence (SUI); A Pilot Study. IUGA Conference, Dublin, Ireland.
2. Maher RM, Caulfied B. (2013) - A Novel Externally Applied Neuromuscular Stimulator for the Treatment of Stress Urinary Incontinence in Women—A Pilot Study. Neuromodulation Vol 16(6), pp590-594.

Evaluating the Clinical Performance of a Novel External Electrical Stimulation Therapy for Urinary Incontinence - A Retrospective Case Series (N=57) – Study 2

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Introduction

Pilot research presented at IUGA 2013 has shown the marked potential of a novel form of external electrical stimulation (NT Vital™) as a conservative treatment in the management of Urinary Incontinence (UI).[1] This non-invasive approach has been shown to reduce symptoms and elicit superior pelvic floor engagement compared to conventional invasive probe based methods.[1,2] This registry exercise looked at the clinical outcome of a cohort of German incontinence patients to establish if the promising pilot data is replicated in a wider population group in clinic.

Aims

The purpose of this study was to retrospectively investigate the treatment outcomes of patients using external electrical stimulation for treating UI symptoms in clinic.

Methods

Treatment outcomes were monitored by means of patients and clinicians completing a subjective treatment feedback form at the end of therapy which captured a host of symptom measures (E.g. No. of pads), quality of life assessments and an overall acceptance of the therapy and its impact on the patient's condition. Outcomes were evaluated in 57 patients across thirteen clinics over a monitoring period which ran from October 2013 to August 2014. The majority of patients were female with a small male cohort (11%) also assessed. 79% (n=45) of the study population suffered from stress urinary incontinence, 2% (n=1) suffered from urge urinary incontinence, and 19% (n=11) suffered from mixed urinary incontinence. Data analysis was conducted using descriptive analysis and summary statistics.

Results

According to the physicians, patient's compliance was very good or good in 93% of patients with treatment successful in 72% (n=41) of the study population. 98% of physicians identified this treatment as a suitable modality in this group. Prior to therapy, the median number of incontinence pads used per day was 4, this reduced to 2 pads per day after therapy. Physicians stated that when they queried their patients in relation to their satisfaction with the treatment 53% (n=30) of the study population were very satisfied, 28% (n=16) were satisfied and 12% (n=7) were not satisfied with treatment (missing data: 7%, n=4). When the patients themselves were queried in the absence of their physician 51% (n=29) were very satisfied, 33% (n=19) were satisfied and 14% (n=8) were not satisfied with treatment (missing data: 2%, n=1). Patients' quality of life as a result of their UI after therapy was rated as considerably improved or improved in 77% (n=44), as unchanged in 19% (n=11), and as deteriorated in 4% (n=2) of all patients. Finally, the handling of the device was rated as easy in 95% (n=54), and as not very easy in 5% (n=3) of the study population.

Discussion and Conclusions

Treatment outcomes from in-clinic practice have shown patients and physicians to respond favourably to this novel treatment method with the majority of patients and clinicians identifying it as a positive intervention. The results of this registry exercise have further highlighted the efficacy of this device in treating UI. Further research to isolate non-responders including a detailed assessment of the reasoning for the lack of treatment effect is warranted to identify the most suitable candidate likely to benefit in practice from this treatment method and ensure its optimal therapeutic application.

References

1. Soeder S, Tunn R. (2013) - Neuromuscular Electrical Stimulation (NMES) of the Pelvic Floor Muscles using a Non-Invasive Surface Device in the Treatment of Stress Urinary Incontinence (SUI); A Pilot Study. IUGA Conference, Dublin, Ireland.
2. Maher RM, Crockett J, Kozel C, Landers E, Vertucci J, Wilkes M. (2010) - A Comparison of 2 Delivery Methods of Neuromuscular Electrical Stimulation on Pelvic Floor Muscle Contraction in Healthy Subjects: Journal of Women's Health Physical Therapy 34(1), pp 18-23.