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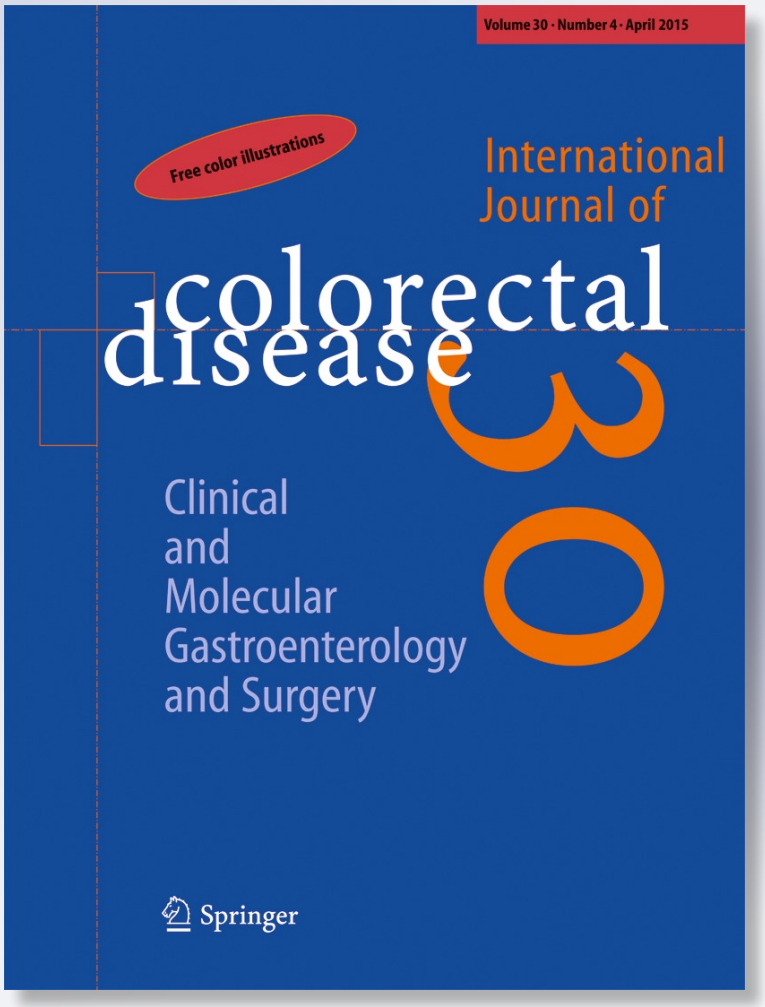

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ORIGINAL ARTICLE

Home electrical stimulation for women with fecal incontinence: a preliminary randomized controlled trial

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Abstract
Purpose The purpose of this study is to compare the effectiveness and cost of home electrical stimulation and standardized biofeedback training in females with fecal incontinence
Methods Thirty-six females suffering from fecal incontinence were randomized into two groups, matched for mean age (67.45±7.2 years), mean body mass index (kg/m^2) (26.2±3.9), mean disease duration (4.1±0.8 years), mean number of births (2.7±1.3), and reports of obstetric trauma (25 %). Questionnaires were used to evaluate their demographics, medical, and childbearing history. Subjects were randomized to home electrical stimulation or standardized biofeedback training for a period of 6 weeks.

Subjective outcome measures included the frequency of fecal, urine, and gas incontinence by visual analog scale, Vaizey incontinence score, and subjects' levels of fecal incontinence related anxiety. Objective outcome measures included pelvic floor muscle strength assessed by surface electromyography. We also compared the cost of each treatment modality.
Results Only females who received home electrical stimulation (HES) reported a significant improvement in Vaizey incontinence score (p=0.001), anxiety (p=0.046), and in frequency of leaked solid stool (p=0.013). A significant improvement in pelvic floor muscle strength was achieved by both groups. HES was much cheaper compared to the cost of standardized biofeedback training (SBT) (US$100 vs. US$220, respectively).

Our study comprised a small female population, and the study endpoints did not include objective measures of anorectal function test, such as anorectal manometry, before and after treatment.
Conclusions Home electrical stimulation may offer an alternative to standardized biofeedback training as it is effective and generally well-tolerated therapy for females with fecal incontinence.

Keywords Fecal incontinence · Home electric stimulation · Biofeedback therapy

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Introduction

Fecal incontinence (FI) is an involuntary loss of solid or liquid stools. It has been estimated that FI affects approximately 2–24 % of the adult population and is a major health care problem as it significantly impairs quality of life [1, 2]. The prevalence of FI increases with age and is more prevalent in

females, usually as a sequela of obstetric trauma to the anal sphincter or to the pelvic floor [3]. In most instances, a conservative physiotherapy intervention, such as biofeedback training, is considered the first-line approach [4, 5]. Biofeedback training is used to instruct patients how to strengthen the power and endurance of external anal sphincter contraction, thus assisting in the reduction of incontinent episodes [3, 6]. Despite a high symptomatic improvement rate, standardized biofeedback training (SBT) has some drawbacks. Due to its muscle selectiveness, it is impossible to strengthen all of the muscles involved in maintaining continence [7]; patients with impaired rectal sensation due to neurological damage may fail to respond to SBT [8], and SBT requires highly qualified therapists, is a time consuming and expensive procedure due to the high cost of implicated professional time [9].

Endoanal electrical stimulation is an alternative option for the treatment of chronic FI. In this technique, the pudendal nerve and the anal sphincter are chronically stimulated using an anal probe. Such chronic stimulation may possibly lead to decreased synaptic resistance, increased motor unit size, conduction rate of the pudendal nerve, increased muscle blood flow, as well as reduced fatigability [7, 8]. Nevertheless, it is still unknown whether the clinical effect is related to muscle strengthening, or to sensitization [10, 11]. There is a paucity of studies that randomized incontinent women to treatment with electrical stimulation or biofeedback. The few studies that examined electrical stimulation were small, used diverse stimulation parameters, and included a very limited investigation plane [12–16].

Our hypothesis was that home electrical stimulation (HES), used on a daily basis for 6 weeks, would improve symptoms of fecal and gas incontinence comparable, or superior to SBT, and at a lower cost.

Methods

Patients

Consecutive female patients with chronic FI, referred for pelvic floor disorders to our Neurogastroenterology Service, were assessed for eligibility. Inclusion criteria were females with chronic FI, age 18 years or older (upper age limit 75 years), fluency in the Hebrew language (all questionnaires were administered in Hebrew), normal colon, and intact anal sphincters as confirmed by the preliminary colonoscopy and endoanal ultrasonography, respectively. Exclusion criteria were as follows:

1. Presence of a severe systematic disease, such as scleroderma, diabetes mellitus with severe complications, myopathy, pelvic malignancy, multiple sclerosis, Parkinson's disease, myelopathy, or severe liver, lung, renal, hematological, or other comorbidity.
2. Painful active hemorrhoids or fissures.
3. Fear of endoanal electrical stimulation.
4. Previous usage of an electric stimulator for the treatment of urinary or fecal incontinence.
5. Patient's unwillingness or inability to provide informed consent.
6. Patient's inability to fully complete all phases of the study and the study questionnaires. We also excluded pregnant or lactating females and those who were not using a medically acceptable form of birth control.

Study design

This preliminary, prospective, comparative, randomized control trial was conducted at the Rabin Medical Center, Israel, and was performed in accordance with the principles of the Declaration of Helsinki, Good Clinical Practice and was approved by the Human Subjects Protection Program of the Rabin Medical Center (Local IRB Registry No. 6588).

Eligible females were invited to the first session with an experienced physiotherapist (N.C-Z.) and the principal investigator (R.D.) and were provided with information regarding the aim and different phases of the study. All patients provided written informed consent to R.D. before enrollment. Patients were interviewed by R.D. at baseline and at the end of treatment in both treatment arms. The principal investigator recorded demographic parameters and collected the questionnaires, assessed compliance by asking about adherence to treatment instructions, checked for adverse effects of treatment, and verified complete numerical responses to the questionnaire items. Patients were randomly assigned to a clinical protocol of SBT, or (in parallel) to the endoanal HES, by using a computer-generated sequence of random assignments. The study was conducted over a period of 6 weeks and comprised two parallel treatment arms (Fig. 1).

Procedure

Patients in both treatment arms were personally trained by N.C-Z. throughout the entire study duration. At entry, all enrolled patients completed a self-administered demographic questionnaire, a visual analog scale (VAS) for the assessment of the frequency of fecal and gas incontinence, as well as the Vaizey incontinence score (VIS) [17]. Participants were given charts to facilitate them in recording daily bowel accidents and toilet movements.

Standard biofeedback training arm

A 30 to 45-min SBT was provided weekly for 6 weeks, at our biofeedback service. Patients were instructed in anal sphincter and pelvic floor muscle (PFM) exercises according to a fixed exercise regimen. Patients received training via

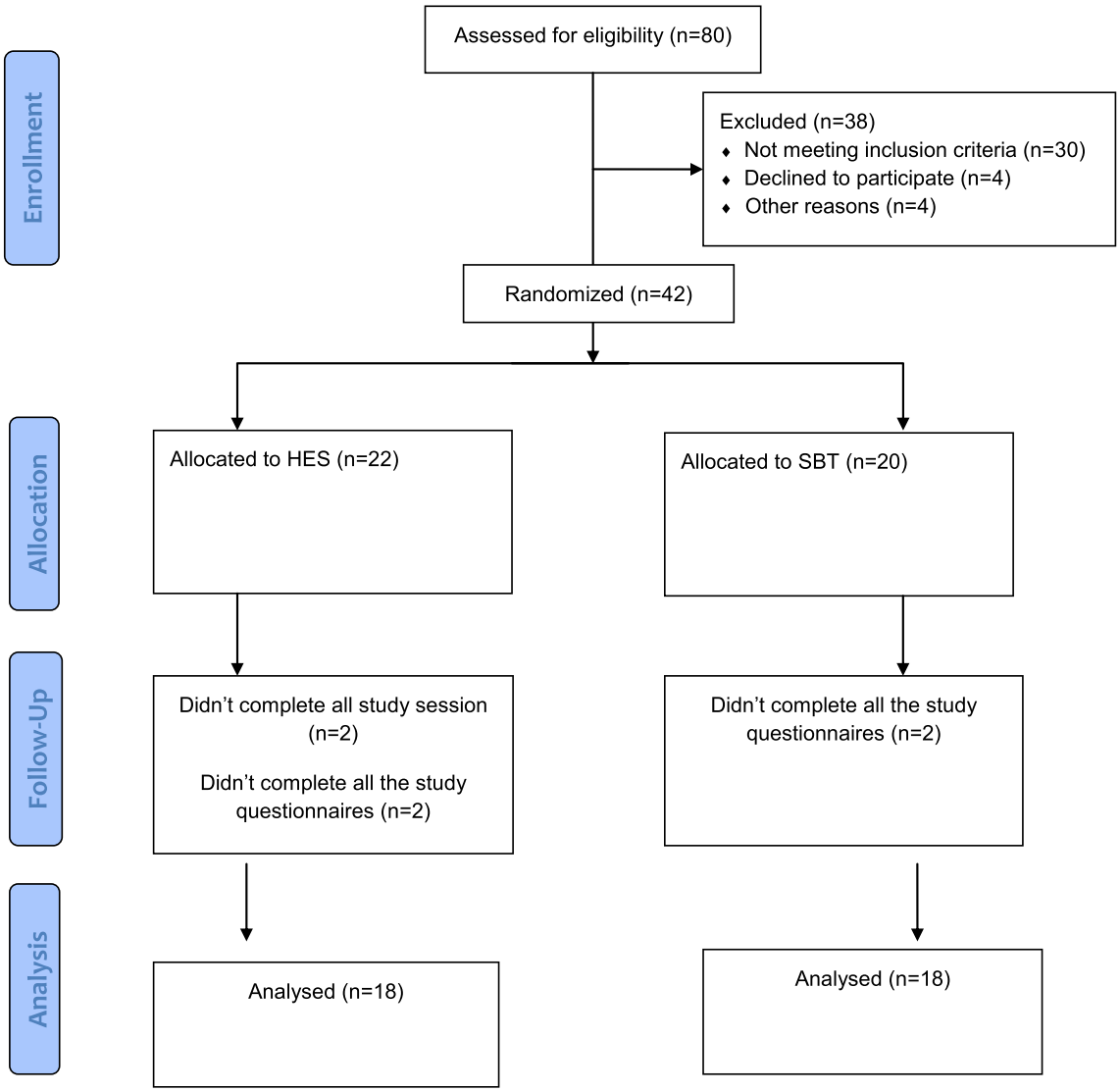

Fig. 1 Study flow diagram

electromyographic (EMG) and pressure feedback (Myomed 932, Enraf-Nonius, Delft, The Netherlands) using an anal catheter and a rectal balloon inflated to sensory threshold. At EMG feedback, electrical muscle activity was registered by means of surface and cavity electrodes and was visual to both the therapist and the patient on a large LCD screen. At pressure feedback, pressure changes, as a result of contractions of the PFMs, were measured by means of cavity electrodes. Patients were coached to link pressure changes observed on the computer monitor with the exercises that they had performed and with the sensations that they had felt. During SBT, patients were also instructed to use these exercises and techniques to reduce urgency and frequency and to improve sensitivity, anorectal coordination, and continence. Each patient was also prescribed exercises to practice at home, twice daily, i.e., three sets (with 5-min rest in between each set) of 10 contractions lasting 10 s each.

Home electrical stimulation arm

The HES group was trained to use this device preprogrammed to strengthen the PFMs (Pericalm N400 Pelvic Floor Stimulation Unit, Neen Healthcare, Dereham, United Kingdom). Each device was supplemented by an anal electrode (Anuform, Anal Electrode Probe, Neen Healthcare, Dereham, United Kingdom). At their first meeting with N.C-Z., all patients were taught how to insert the probe and operate the device. For the entire study duration (6 weeks), the device was used for 25 min twice daily. Electrical stimulation was set at 50 Hz with a ramp up time of 1 s, 8 s on, ramp down time of 1 s, and 20 s off cycle. Pulse width was 200 ms. Patients were not requested to perform any additional exercises at home. Compliance with HES (timing and duration) was assessed by the patients' diaries.

Measures of treatment effectiveness

Symptomatic measures

At entry and at completion, in both treatment arms, all patients completed a battery of self-report questionnaires on the effects of treatment.

1. Vaizey incontinence score (VIS). Validated Hebrew version assesses the severity of FI and ranges from 0 (complete continence) to 24 (complete incontinence) [17]. The VIS is a reproducible score that correlates with clinical impression [17].
2. Visual analog scale (VAS). Patients in both groups rated the frequency of their solid or liquid stool, urine and gas accidents on a VAS of 0 to 10 (0 indicated perfect control, and 10 indicated very severe or no control).
3. Hospital Anxiety and Depression Scale (HADS). Subjects' levels of anxiety were assessed by using a Hebrew version of HADS, originally designed by Zigmond and Snaith [18]. The HADS includes the HADS-Anxiety and the HADS-Depression subscales (7 items each). Each item is graded on a Likert-type scale with four possible choices (0–3) for situational scoring of anxiety and depression. According to the sum of the scores for each subscale, patients are considered to have normal (0–7), mild (8–10), moderate (11–14), or severe (15–21) levels of anxiety or depression.

Objective measures

Quantification of muscle strength was assessed by intra-anal surface EMG. At the end of each SBT session, the difference (delta) from baseline to peak PFM contraction was recorded. Patients were asked to contract their PFMs with maximum strength, and a delta >4 was considered to be a good level of PFM peak squeeze pressure. We also compared mean delta scores for the first and last sessions in each group.

Study endpoints

Primary endpoints of the study were degree of improvement of frequency of fecal (solid and liquid), urine and gas incontinence (mean VAS scores), the VIS (severity score), and subjects' levels of anxiety. Additional endpoints were an improvement in muscle strength as assessed by surface EMG and the degree of cost reduction in both treatment arms. Cost reduction was considered positive if a reduction of >50 % was achieved.

Tolerability and safety

Adverse events were recorded on the basis of practitioner observations or patient responses during treatment.

Statistical analysis

Data analysis was performed with the SPSS version 20 (Chicago, IL, USA). All comparisons were two-tailed, with $p<0.05$ signifying statistical significance. Due to the small sample sizes, and potentially low power of the statistical analysis, we considered $p<0.1$ as marginally significant. Power analysis was not performed prior to the study as we assessed for eligibility all referred female patients with FI during the study period. All data are presented as mean and standard deviations (m±SD). Measurements for both groups were taken before and after treatment. Treatment effect was evaluated for each group separately using a paired sample *t* test. Furthermore, a mixed-model analysis of variance was performed in order to compare effects between methods by testing for significant time by treatment interactions. Independent sample *t* tests and chi-square tests were used to compare group demographics and initial symptom levels.

Results

This preliminary study was conducted between January 2010 and July 2012. Eighty consecutive female patients with FI were assessed (Fig. 1), and a total of 42 eligible female patients who met inclusion and exclusion criteria were enrolled (22 for the HES arm and 20 for the SBT arm). Subsequently, six patients were excluded from the study; two females failed to fully complete first sessions of the study, and the other four did not complete all the questionnaires at baseline as required. In order to avoid the risk of having biased results, patients who were excluded during the initial phase of the study were not included in the analysis. Thus, 36 females completed the study. Eighteen patients received HES and 18 patients received SBT (Fig. 1). All patients had a normal colon and intact anal sphincters.

Demographic characteristics

Demographic characteristics were similar between the two groups (Table 1). One third of the patients had past abdominal surgery (37 %) and a mean duration of FI of >3 years.

Symptom assessment at baseline

Independent sample *t* tests (and a Mann–Whitney test for anxiety) were performed for the baseline status with respect to

Table 1 Demographic and baseline clinical characteristics of the home electrical stimulation (HES) and standardized biofeedback training (SBT) groups

	HES Mean±SD/%	SBT Mean±SD/%	*p* value
Number	18	18	
Age	66.6±6.6	68.3±6.9	0.515
Body mass index (kg/m^2)	26.2±4.38	26.2±3.52	0.106
Duration of FI (years)	3.5±3.16	5.94±4.09	1.0
Diabetes mellitus	27.8 %	5.5 %	0.177
Past abdominal surgery	37 %	37 %	1.0
Number of births	3±1.5	2.55±1.19	0.332
Past obstetric trauma	23.7 %	30 %	0.702
Solid stool incontinence. (VAS)	1.1±2.1	2.9±2.8	0.031
Liquid stool incontinence (VAS)	2.6±2.0	2.7±2.5	0.886
Gas incontinence (VAS)	0.7±0.5	0.9±0.3	0.218
Urine incontinence (VAS)	0.39±0.5	0.5±0.51	0.516
Vaizey incontinence Score	12.8±4.4	13.9±4.7	0.494
Anxiety score	0.44±0.7	0.94±1.1	0.203

SD standard deviation, *FI* fecal incontinence, *VAS* visual analog scale

mean VAS scores for fecal (solid or liquid), urine and gas incontinence, VIS, and level of anxiety, to determine equivalence of both groups (Table 1). No analyses were statistically significant other than that for incontinence of solid stool.

Muscle strength assessment at baseline

An independent sample *t* test was performed for baseline EMG data with respect to mean scores for muscle strength (level of PFM peak squeeze pressure) to determine equivalence of the two groups. Analysis showed no statistically significant difference ($t(33)=1.625$, $p=0.114$). Table 2 summarizes the mean scores for muscle strength at baseline and at end of treatment for each group.

Symptom burden assessment

Observed power estimates showed that the power of the between-group comparisons for the various outcome measures was low and ranged mostly between 0.3 and 0.6. This analysis may explain the lack of significance in many of the comparisons. Consequently, we preferred to focus our study on within-subject comparisons and evaluate the two methods separately by testing for improvement in each method. The baseline mean VAS scores for fecal (solid and liquid), urine and gas incontinence, VIS, anxiety levels, and the changes after treatment with SBT and HES are shown in Table 2. Scores for solid FI, VIS, and anxiety levels decreased significantly from baseline to completion of HES treatment, indicating clinical improvement. Comparison of the baseline scores with scores after completion of SBT treatment yielded significant differences only for urinary incontinence but not for fecal (solid and liquid), or gas incontinence, nor for VIS (Table 2).

Anxiety assessment

The baseline mean scores for the patients' level of anxiety and the changes after treatment with HES and SBT are shown in Table 2. With HES, mean values for anxiety score improved significantly (Wilcoxon signed rank test, $p=0.046$), indicating clinical improvement. Conversely, SBT yielded no significant differences ($p=0.429$).

Muscle strength assessment

Between baseline and the completion of each treatment arm, mean delta values for muscle strength (level of PFM peak

Table 2 Mean scores of the visual analog scale (VAS), Vaizey incontinence, anxiety level and muscle strength, before and after home electrical stimulation (HES) and standardized biofeedback training (SBT)

	HES			SBT		
Measure	m±SD Start	m±SD End	*p* value	m±SD Start	m±SD End	*p* value
Solid stool incontinence (VAS)	2.9±2.8	0.9±0.9	0.013	1.1±2.1	0.3±0.5	0.101
Liquid stool incontinence. (VAS)	2.7±2.5	1.3±2.1	0.07	2.6±2.0	1.2±1.5	0.052
Gas incontinence (VAS)	0.9±0.3	0.7±0.5	0.187	0.7±0.5	0.9±0.3	0.083
Urine incontinence (VAS)	0.5±0.5	0.5±0.5	1	0.4±0.5	0.2±0.4	0.042
Vaizey incontinence score	13.9±4.7	9.1±3.1	0.001	12.8±4.4	10.8±5.0	0.064
Anxiety score	0.9±1.1	0.5±0.8	0.046	0.4±0.7	0.3±0.7	0.429
Muscle strength (Delta EMG)	10.7±7.5	20.6±8.2	<0.001	7.4±4.1	17.1±6.2	<0.001

***m±SD* mean±standard deviation, *Start* baseline values at entry, *End* values at completion, *Delta electromyography (EMG)* the net difference between baseline and end of session muscle strength (a delta >4 is considered efficacious)**

squeeze pressure) improved significantly in each treatment arm (Table 2).

Cost assessment for HES and SBT

We compared the cost of the equipment and professional time in each treatment arm. For HES, local prices of the reusable stimulator (5 patients/year), single use anal probe, and cost for the dedicated professional time were much cheaper compared to the cost (mainly due to professional time) of SBT (US$100 vs. 220, respectively). Additional advantages are the increased availability of HES and the avoidance of frequent visits to the biofeedback service for SBT.

Comparisons between SBT and HES

Testing for differences between SBT and HES in the magnitude of improvement, we found no statistically significant difference between the two methods on any of the outcome measures other than that for gas incontinence. We found a significant treatment by time interaction affecting gas incontinence ($F(1,34)=4.8$, $p=0.034$). It is evident that the HES group experienced a small, insignificant decrease in gas incontinence, whereas the SBT group showed an almost significant increase.

Tolerability and safety

The entire course of both SBT and HES was completed by all participants, and none reported any related adverse effects.

Discussion

The major finding of this preliminary, prospective, and randomized study was that only those females who received HES reported a significant improvement from baseline for almost all study endpoints. However, due to the small number of patients in each arm, there were almost no significant differences in objective or subjective measures between SBT and HES. For the same reason, it was not possible to claim that both treatments are on a par. Nevertheless, HES emerged as a reasonable therapeutic option in view of its simplicity, cost, and relative efficacy. Comparisons between our findings and those from other studies are complicated because of significant variations in study designs, evaluation of outcome, patient selection, as well as the diversity of the techniques used for biofeedback or HES [19–21]. For instance, there are several scoring systems that are currently used for the evaluation of the rehabilitating effect of electrical stimulation and biofeedback training. In this study, we utilized the Vaizey scoring system because it is a widely used summary score and includes important and practical incontinence-specific items [17]. Deutekom et al. have shown that changes in the Vaizey score reflect a patient's subjective perception of improvement [22, 23].

In regard to the improvement of incontinence to solid stool, it appears that the biofeedback group had significantly less severe incontinence to solid stool at baseline ($p=0.013$). This may be the reason for nonsignificant improvement compared to HES. On the other hand, although without statistically significance, diabetes was more prevalent in biofeedback group. Diabetes, by damaging the nervous system, is one of the known risk factors for fecal incontinence in men and women as well [24, 25, 26]. Therefore, perhaps this comorbidity and its associated neural damage have also contributed to the nonsignificant improvement in continence compared to the HES group. Overall, our results indicated that almost all continence scores improved significantly after treatment with HES. Similar results were reported by a large multicenter study from the Netherlands [3]. We attributed the success rate of HES to our patient selection and to the fact that all patients were personally trained and supervised by an experienced physiotherapist.

In this study, patients were provided with an HES device, preprogrammed at 50 Hz, for 6 weeks. It is possible that different stimulation parameters would have been more beneficial and that a period of >6 weeks would have yielded different results. There are no clear guidelines regarding the optimal number and duration of HES sessions [20]. We decided to limit SBT to six sessions because the vast majority of patients in Israel receive financial reimbursement for six sessions only. It is impossible to decide whether this limited number of sessions prevented some patients from achieving better outcome measures. Moreover, our decision to preprogram electrical stimulation at 50 Hz was not based upon robust evidence from the literature. In fact, it is not known whether the electric current is necessary for this effect or if the proper insertion of an anal probe would have a similar result. Norton et al. [15] found no statistically significant difference in bowel control between groups that were treated with electrical stimulation at 35 or at 1 Hz, raising the possibility that the main effect is not sphincter contraction but sensitization of the patient to the anal sphincter or simply the effect of intervening per se [15].

Cost reduction was a secondary endpoint in our study. Based on our local cost analysis of reimbursements for professional time, reusable equipment and single-patient-use anal probes, we found that HES is more affordable than SBT. In an extensive literature search, we could not find comparable studies that conducted a similar cost analysis.

In addition, use of the home unit has important implications for those who are unable to frequently attend SBT sessions with a physiotherapist, often due to geographical or economic reasons. Moreover, we believe that a home treatment unit is invaluable to all patients, as it facilitates active participation in their therapy (i.e., they should practice independently in order

to achieve good responses) and provides them with the ability to control their own success.

The limitations of our study lie in its two relatively small groups of only female patients. However, despite the limited power that may have been the result of the small sample size, within groups, statistical analyses yielded a large number of significant effects. We enrolled only females due to the nature of treatment dealing with very personal matters that prevented our physiotherapist from treating males. Males with FI are regularly treated by a dedicated male physiotherapist from a biofeedback service situated in a different campus of the Rabin Medical Center and were not enrolled for this study. However, while it could be argued that our study included only females, we believe that it could also be advantageous as our cohort was more homogenous and had similar personal medical backgrounds, such as child birth, surgical procedures, among others. Another major limitation of our study is the short treatment and observation period (6 weeks). However, as we mentioned previously, the optimal number and duration of HES sessions is varied among different studies and not accepted yet [20, 27, 28]. Therefore, we believe that a sequential study is needed in order to conclude whether HES therapy is beneficial than SBT also during a longer period.

An additional limitation was related to the study endpoints that did not include objective measures of anorectal function test, such as anorectal manometry, before and after treatment. Nonetheless, there is disagreement regarding the utility of manometry for assessing the anal resting and squeeze sphincter pressures in FI. Norton et al. [15] found no statistically significant difference between groups in post stimulation resting pressure, squeeze increment, or cough pressure increment. In a prospective evaluation of the importance of anorectal physiology in the management of FI, Liberman et al. concluded that only if surgical repair of the anal sphincter (anterior sphincteroplasty) is being considered should specialized diagnostic testing for FI be contemplated [24]. Assessment of compliance with HES may serve as an additional limitation as we could not verify from the device if patients administered the treatment as instructed. However we presumed that compliance was good based on returned patients' diaries. Finally, surface EMG may not represent the absolute measure of muscle, as most muscles give nonlinear responses that vary within subjects on different occasions, and because the risk of cross talk from other muscles is high [25]. However, no single measurement tool provides a complete picture of PFM strength or function.

Conclusions

In this preliminary, prospective, and randomized study, the majority of patients who used HES found it beneficial in improving their FI and related level of anxiety. However, due to the small sample size, for most study primary endpoints, there did not appear to be any statistically significant differences between the treatments; HES may offer an alternative to SBT as it is a relatively cheaper and generally well-tolerated therapy in the conservative treatment of FI.

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CONSORT 2010 checklist of information to include when reporting a randomized trial*

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and ?pragmatic trials. Additional extensions are forthcoming for those and for up-to-date references relevant to this checklist, see www.consort-statement.org