Evaluation of the EmbaGYN™ pelvic floor muscle stimulator in addition to Kegel exercises for the treatment of female stress urinary incontinence: a prospective, open-label, multicenter, single-arm study

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Aim: To assess the efficacy and safety of the EmbaGYN™ Pelvic Floor Exerciser, a battery-powered neuromuscular stimulation device with a vaginal, two-electrode stimulation probe in women with stress urinary incontinence. **Materials & methods:** In this prospective, open-label, multicenter, single-arm study, patients with stress urinary incontinence (n = 83) underwent 12 weeks of treatment with EmbaGYN with Kegel exercises. **Results:** At week 12, the mean number of incontinence episodes/day (primary end point) fell 56.2% (p = 0.152). A ≥50% decrease from baseline in incontinence episodes was seen in 65.3% of subjects (p = 0.006). The mean number of incontinence pads/day fell 57.1% (p = 0.001). Mean 24-h and 1-h in-office urine loss declined 59.0% (p < 0.001) and 67% (p = 0.019), respectively. There was one nonserious device-related adverse event. **Conclusion:** EmbaGYN with Kegel exercises resulted in significant reductions in urine loss, incontinence pad use and improved incontinence-related quality of life, but did not have a significant effect on incontinence episodes/day.

Stress urinary incontinence (SUI), as defined by the International Continence Society, is the involuntary leakage of urine associated with effort or exertion, or with sneezing, coughing or laughing [101]. SUI may result from urethral hypermobility as a result of childbirth, pelvic surgery, obesity, frequent prolonged straining or strenuous exercise [1]. SUI may also be caused by poor urethral function or intrinsic sphincter deficiency as a result of aging, hormonal changes, nerve injury during childbirth, pelvic surgery and other factors [1].

The prevalence of urinary incontinence among women in the USA has been increasing as the population ages. Survey-based reports indicate that 37% of adult women from representative US households experienced symptoms of incontinence within the past month and, of those reporting symptoms, 86% were bothered by their incontinence episodes [2]. Approximately half of women with urinary incontinence who leak ≥1-times per month are classified as having SUI, with a further 30% experiencing mixed incontinence [3].

Abundant evidence suggests that SUI can have a profound clinical and psychosocial impact on women's lives; in fact, the impairment in quality of life associated with urinary incontinence is comparable to that of other chronic diseases [4]. Although some reports suggest that SUI confers less impairment than urge or mixed urinary incontinence [3], other studies indicate that it is not the type, but rather the severity of urinary incontinence that is the primary predictor of decreased quality of life [5].

There is no optimal therapy for all patients with SUI. For most patients with SUI, first-line management often involves behavioral modification [6]. Conventional management of SUI often involves surgery; however, there is a lack of large, randomized trials examining the effectiveness of specific surgical interventions. Furthermore, while improvements in sling materials and the use of less invasive surgical approaches have reduced morbidity and shortened hospital stays, surgical intervention carries considerable risks, including infection, postoperative pain, erosion of synthetic sling material into the urethra and bladder, and *de novo* urge incontinence [7]. Submucosal injection of bulking agents has also been successfully used in this setting [8]; however, the long-term durability of this treatment remains open to question [7].

There is renewed interest in conservative treatments for SUI, potentially because of heightened awareness of SUI among women and increased

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Keywords

• Kegel exercises • pelvic floor electrical stimulation • pelvic floor muscle exercises • pelvic floor physical therapy • quality of life • stress urinary incontinence • urinary incontinence

concern about the costs and morbidities associated with surgery. Conservative therapies for SUI include electrical stimulation, pelvic floor (Kegel) exercises and weighted vaginal cones. Electrical stimulation of the pelvic floor muscles has been used since 1952 for the treatment of urinary incontinence [9], and has demonstrated effectiveness in improving pelvic muscle strength and symptoms of incontinence in some, but not all, studies of widely varying quality [10–14]. It is thought to provide clinical benefit by passively eliciting contraction of smooth and striated periurethral muscles and striated pelvic floor muscles, ultimately improving the urethral closure mechanism [15]. Kegel exercises, which improve pelvic muscle tone by strengthening the pubococcygeus muscles of the pelvic floor, are also frequently recommended for the management of SUI [16]. Kegel exercises have been shown to improve symptoms in mild-to-moderate stress and urge incontinence when performed consistently and correctly [17,18]; however, many patients find isolating and exercising pelvic floor muscles difficult, and some require considerable time and instruction in order to perform exercises properly. Bump and colleagues found that 25% of women attempting to use the Kegel technique actually did so in a way that aggravated incontinence. Overall, in this study, only 49% exercised properly [19]. Similarly, a second study found that 70% of patients attempting pelvic floor exercises did so in the wrong way [20].

The EmbaGYN™ Pelvic Floor Exerciser is an inexpensive, small, lightweight, battery-powered, single-channel neuromuscular stimulation device supplied with a vaginal, two-electrode stimulation probe that is intended for home use by women with urinary incontinence. This device is marketed in Europe under the brand name 'itouch Sure' (TensCare, Surrey, UK) and has been in broad use since 2009.

This prospective, open-label, single-arm, postmarketing study was designed to evaluate the effectiveness of pelvic floor muscle electrostimulation with the EmbaGYN Pelvic Floor Exerciser in combination with Kegel exercises in reducing episodes of urinary incontinence in women with SUI.

Materials & methods

Subjects

To be scheduled for an evaluation, women had to be aged between 21 and 75 years with symptoms consistent with SUI, based on the Questionnaire for Urinary Incontinence (QUID), a six-item, 5-point ('none of the time' = 0, to 'all of the time' = 5) symptom questionnaire developed to distinguish between stress and urge incontinence [21]. The sum of the scores for QUID questions 1, 2 and 3 (which focus on SUI) was required to be ≥4 and the sum of the scores for questions 4, 5 and 6 (which focus on urge incontinence) was required to be ≤6. Potential patients were contacted by the site coordinator via telephone to determine interest in the study, complete a preliminary evaluation of inclusion/exclusion criteria and to assess whether the individual could physically comply with study requirements and was motivated to participate. Subjects who qualified and were interested were scheduled for a screening appointment. Informed consent procedures were approved by a central institutional review board and all patients provided informed consent. The study was conducted at obstetrician/gynecologist generalist offices from May 2012 to February 2013.

Inclusion & exclusion criteria

Female patients were included who were aged between 21 and 75 years who were willing to complete written informed consent and could understand and comply with study procedures. They must have a chief complaint of SUI based on the screening QUID score, and either objective findings of urine loss of >1 g of pad weight based on the 1-h pad test performed in the medical office during the screening phase of the study or objective findings of average urine loss >1.3 g of pad weight based on pad weight measurements from two 24-h home pad tests performed during the screening period. Women of reproductive age were required to use contraception if sexually active. Verbal written English language skills, sufficient to understand study instructions and read/respond to voiding diary questions were required. Major exclusion criteria were urinary incontinence other than SUI, prior surgery for SUI, current urinary tract infection at screening or a positive history of frequent, recurrent urinary tract infections, prominent uterovaginal prolapse, morbid obesity (defined as BMI ≥40 kg/m^2), neurological or significant psychiatric disease, current or contemplated pregnancy or a history of delivery within 12 weeks prior to enrollment, current or prior use of a pelvic floor muscle stimulator, or current use of an antimuscarinic medication for overactive bladder or a pessary for management of pelvic organ prolapse. Patients were also excluded who had a change in hormone replacement therapy medication or dose within 3 months of enrollment, implanted electrical stimulation or impulse-generating

devices, current active vaginal infection, irritation or genital sores, a history of colorectal, cervical vaginal or ovarian cancer, current use of a copper intrauterine device, a history of Essure® tubal sterilization (Bayer, NJ, USA), undiagnosed vaginal, rectal or urinary bleeding, pelvic floor spasms or a known allergy to any of the materials in the vaginal probe.

Screening procedures

The initial clinical evaluation consisted of completion of written informed consent, a medical history and a urine dipstick test on a clean-catch specimen. Concomitant use of prescription and nonprescription medications was recorded. Patients were asked to complete the QUID, a six-item, self-report, symptom questionnaire developed to distinguish between stress and urge incontinence [21]. Patients who qualified underwent a physical examination, including vital signs and a continence examination including a Valsalva urinary leakage assessment and pelvic examination with manual assessment of muscle strength. Among patients who continued to meet eligibility criteria, a 1-h pad test, urine pregnancy test and urine culture on a clean-catch specimen was conducted. If no exclusions were identified, the subject was asked to complete two 24-h pad tests at least 4 days apart, excluding days of menses.

The 1-h pad test was conducted after voiding. The subject was asked to put on a preweighed Prevail® Bladder Control Pad (First Quality Products, PA, USA; moderate absorbency). Over a 15-min period, the subject drank 500 ml of water while sitting and resting. The subject was asked to perform maneuvers to provoke stress incontinence (physical activity for 30 min; during the final 15 min, the subject sat and stood ten-times, coughed ten-times, ran in place for 1 min, picked up an object from the floor five-times and then washed her hands for 1 min with water running). After 1 h, the used pad was weighed to determine the volume of urine loss.

Materials for the 24-h pad test were provided to subjects in a kit that included Prevail Bladder Control Pads in zip-sealed, labeled plastic baggies, labels and an indelible felt-tip marker for labeling. Extra pads were provided for subjects who required >1 pad for a 24-h period. Start and stop times were recorded on each baggie, and the pad/baggie weighed at the study site. To measure pretreatment frequency of incontinence, patients were given an electronic diary (e-Diary, PHT ePRO Solutions, MA, USA) device and instructed on its use. Incontinence episodes were reported on the e-Diary as they occurred, including severity, perceived urge and trigger event(s). Patients were also asked to record daily activities, including normal voiding activity, daily fluid intake and level of physical activity (all ranked as less than usual, usual or more than usual), presence/absence of menses and pad use. The e-Diary data were autodownloaded daily.

Device

The EmbaGYN Pelvic Floor Exerciser is a small, lightweight, battery-powered, single-channel neuromuscular stimulation device supplied with a vaginal, two-electrode stimulation probe (Figure 1). The probe connects to the control unit by a cable and plug. The device uses two AA batteries. The unit is intended for home use by the subject. It has four preset treatment programs, an adjustable treatment timer, a compliance monitor and open circuit detectors. Specific device parameters are summarized in Table 1.

Design & interventions

The study was a prospective, open-label, multicenter, single-arm postmarketing study conducted at six sites in the USA, with a 2-week screening period and 12 weeks of active treatment.

Patients who met inclusion and exclusion criteria, including acceptable (≥90%) compliance with e-Diary procedures, completed the Incontinence Quality of Life Questionnaire. This is a disease-specific, self-administered questionnaire for measuring incontinence-related quality of life that consists of 22 items (such as "I worry about not being able to get to the toilet on time"; "I worry about coughing or sneezing because of my urinary problems or incontinence") that are ranked on a 5-point scale ranging from 5 (not bothered at all) to 1 (extremely bothered) and transformed to a scale score ranging from 0 to 100 for ease of interpretation, with higher scores indicating better incontinence-related quality of life [22–24].

Figure 1. The EmbaGYN™ Pelvic Floor Muscle Stimulator.
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Table 1. Device specifications.

Parameter	EmbaGYN™ Pelvic Floor Exerciser specifications
Intended use	Treatment of stress urinary incontinence
Programmable features	Intensity, program session length
Preset programs	Four
Power source	2 x 1.5V AA batteries
Mode of operation	Intermittent
Frequency (Hz)	10/20/35/50
Pulse width (uS)	200/250/300
Duty cycle	5/10 and 3/6
Output current	0–45 V = 0–90 mA over 500 Ohm
Intensity steps	200
Output type	Constant current 160–500 Ohm Constant voltage 500–1500 Ohm
Number of electrodes	One
Usage conditions	Intermittent
Controls	Six push buttons plus lock button
Probe length	88 mm
Probe diameter	28 mm
Electrode orientation	Axial
Electrode material	Stainless steel
Electrode placement	Vaginal
Waveform type	Biphasic
Waveform shape	Rectangular at positive

At this visit, patients were instructed to perform EmbaGYN treatment once daily, starting with 5–10 min and increasing gradually, as tolerated, to 20 min over the first 2 weeks of use, with gradual increase in the signal intensity to 30–50 mAmp. An initial EmbaGYN treatment session was completed during this study visit. Subjects were instructed, in a standard method, to execute Kegel exercises and were provided with a take-home video and written instructions, which were reviewed by a trained member of the site staff. The Kegel exercise regimen consisted of ten contractions, holding each for 6 s with a 12 s rest between contractions, followed by five contractions, holding each for 2 s, conducted once daily.

Use of the e-Diary was reviewed, with an emphasis on the portions of the diary not used during screening, including compliance with Kegel exercises and EmbaGYN device use (documentation of daily pelvic muscle stimulation treatment compliance, session duration and signal strength settings at the start and end of treatment). The method for performing the 24-h test pad procedure was also reviewed at this visit.

Follow-up assessments were scheduled at 4 weeks (visit three), 8 weeks (visit four) and 12 weeks (visit five), and were conducted by a trained member of the site staff or the responsible physician. At visits three and four, subjects completed the Incontinence Quality of Life Questionnaire, medications and adverse events were reviewed, compliance with the e-Diary and 24-h pad test was reviewed and a 1-h in-office pad test was conducted. A urine dipstick test was conducted and, if positive, a urine sample was sent for culture and sensitivity testing and treatment initiated per local standard of care. At these visits, 24-h pad test supplies for the next month were also dispensed. Patients were contacted by telephone 2 weeks after study visits three and four.

Between visits, patients were responsible for once daily performance of Kegel exercises, daily use of the EmbaGYN device for 20 min, daily recording in the e-Diary and completion of two 24-h pad tests at 2-week intervals. The last signal intensity and average use time was recorded from the subject's EmbaGYN device.

At visit five (end of study), the Incontinence Quality of Life Questionnaire was completed, and medications, adverse events and e-Diary compliance were reviewed. A urine dipstick test and a 1-h in-office pad test were conducted. As in previous visits, the last signal intensity and average use was recorded from the EmbaGYN device. In addition, patients were asked to complete the Benefit, Satisfaction with Treatment and Willingness to Continue Treatment Questionnaire: a three-item, subject-rated, interviewer-administered instrument that assesses perceived benefit from treatment satisfaction with treatment, and willingness to continue treatment [25]. An informal six-item survey was conducted to assess satisfaction with the EmbaGYN device itself. Five items (ease of use, clarity of instructions, comfort, time commitment and overall satisfaction) were rated on a scale ranging from 1 (very) to 7 (not at all), with scores ranging from 1 (very) to 4 (somewhat) considered to be positive responses. The remaining item, whether the subject would recommend the device to a friend, was a yes/no question.

End points

The primary end point (the key outcome of interest for which the study was powered) was a ≥50% decrease from baseline in the number of incontinence episodes per day at 12 weeks or

at early discontinuation. Overall study success was defined as >60% of subjects meeting primary end point criteria. Secondary end points included change from baseline in total Incontinence Quality of Life score at 12 weeks or end of study; percentage change from baseline in average number of incontinence pads used per day; percentage change from baseline in mean urine loss, measured in grams, on pad test weights from 24-h home pad tests at month 3; change from baseline in urine loss, as measured by the 1-h in-office pad test weight at week 12; responses on the Benefit, Satisfaction with Treatment and Willingness to Continue Treatment Questionnaire; and responses on a device satisfaction survey. *Post hoc* subanalyses were also conducted for median number of SUI episodes at baseline (≤1.4 vs >1.4 episodes/day); median urine loss by 1-h in-office pad test in grams at baseline (≤3.5 vs >3.5 g/day); and menopausal versus postmenopausal women. The cutoffs for these *post hoc* subanalyses were based on the median values for the enrolled population. The incidence and severity of adverse events were recorded at each study visit.

Statistical analysis

It was estimated that 70–80 of these 100 subjects will have evaluable data to assess the treatment effectiveness. It was expected that the proportion of subjects meeting criteria for clinical improvement following treatment with the EmbaGYN Pelvic Floor Stimulator when used with Kegel exercises would be ≥60%. Using a one-sided exact binomial test (5% type I error rate and 80% power), 70–80 evaluable subjects were deemed sufficient to detect a 15% difference from a reference treatment effect size of ≤45%, which was considered to be an average effectiveness derived from the literature for Kegel exercises when used without intense supervision. Assessment of the effectiveness of EmbaGYN treatment, when used with Kegel exercises, was based on the primary end point using a one-sided exact binomial test. The primary end point was evaluated in the intent-to-treat population (all patients who received ≥1 treatment), with the last observation carried forward. Descriptive statistics are used to summarize safety data.

Results

A total of 205 patients were screened and 83 consented and were included in the intent-to-treat analysis. A total of 69 subjects completed the study; of the 14 patients who did not complete the study, one subject each withdrew due to an adverse event, lack of effectiveness or physician decision, and one subject was lost to follow-up. Ten patients proactively withdrew from the study. Characteristics of the intent-to-treat population are presented in Table 2.

Clinical end points

In the intent-to-treat population, the mean number of incontinence episodes per day fell over time from a mean of 2.2 ± 2.31 episodes/day at baseline to 1.1 ± 1.49 episodes per day at week 12, translating to a 56.2% mean reduction in incontinence episodes from baseline (p = 0.152) (Table 3 & Figure 2A). At week 12, clinical improvement (i.e., ≥50% decrease from baseline in incontinence episodes) was seen in 65.3% (p = 0.006). At baseline, the mean number of incontinence pads used per day, according to e-Diary recordings, was 2.8. After 12 weeks of treatment with the EmbaGYN device with Kegel exercises, the mean number of incontinence pads used per day fell to 1.2, corresponding to a 57.1% reduction from baseline (p = 0.001) (Figure 2B). Mean daily urine loss, as measured using 24-h pad test weights, fell from 17.3 g at baseline to 7.1 g at week 12 (59.0%; p < 0.001) (Figure 2C). Mean urine loss, as measured using the in-office 1-h pad test, fell from 9.1 to 3.0 g at week 12 (67%; p = 0.019) (Figure 2D).

Subgroup analyses

A *post hoc* analysis was conducted to further elucidate the effect of EmbaGYN on these parameters. The primary (reduction in SUI episodes) and key

Table 2. Baseline characteristics.

Characteristic	
Mean age ± SD (years)	48.0 ± 10.0
Mean BMI (kg/m^2)	28.4
Race, n (%) – White – Black/African–American	 79 (95.2) 4 (4.8)
Current menstrual status, n (%) – Still menstruating – Postmenopausal	 43 (51.8) 19 (22.9)
Surgically sterile	21 (25.3)
Median number of births (n)	2.0
Nonsmoker, n (%)	78 (94.0)
SUI episodes/day, n (%) – ≤1.4 – >1.4	 41 (49.4) 42 (50.6)
Median 1-h in-office urine loss (%, g) – ≤3.5 – >3.5	 42 (50.6) 41 (49.4)

SD: Standard deviation; SUI: Stress urinary incontinence.

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Table 3. Absolute changes from baseline in the prespecified primary and secondary end points.

	Baseline	Week 12	Change from baseline	Percentage change from baseline
Average number of incontinence episodes/day				
n	83	72		
Mean (SD)	1.6 (1.82)	-0.6 (1.1)	-1.2 (1.5)	-56.2 (50.65)
Median	1.0	-0.4	-0.8	-67.0
Min, max	0.07, 9.46	-6.1, 3.3	-6.3, 1.5	-100.0, 207.6
p-value				0.152
Incontinence pads used daily				
n	82	70	69	
Mean (SD)	2.8 (5.78)	1.2 (2.28)	-1.8	
Median	1.1	0.3	-0.7	
Min, max	0.0, 39.79	0.0, 13.4	-26.6, 4.0	
p-value			0.001	
Mean daily urine loss (24-h pad test, g)				
n	83	70	70	
Mean (SD)	17.3 (23.22)	7.1 (8.73)	-9.2 (17.93)	
Median	9.5	4.8	-3.2	
Min, max	1.40, 158.20	0.25, 58.50	-99.70, 19.45	
p-value			<0.001	
Mean urine loss (in-office 1-h pad test, g)				
n	83	70	70	
Mean (SD)	9.1 (14.69)	3.0 (12.48)	-4.9 (17.23)	
Median	3.5	0.7	-2.1	
Min, max	0.76	0, 103	-75.10, 89.50	
p-value			0.019	

Max: Maximum; Min: Minimum; SD: Standard deviation.

secondary (average urine loss as assessed by 1- and 24-h pad tests) end points were also analyzed for three clinically relevant subgroups: median number of SUI episodes at baseline (≤1.4 vs >1.4 episodes/day); median urine loss by 1-h in-office pad test in grams at baseline (≤3.5 vs >3.5 g/day); and menopausal versus postmenopausal women.

A consistently greater absolute reduction in the mean number of incontinence episodes was observed among patients with >1.4 SUI episodes/day at baseline (-1.80 ± 1.78 at week 12) compared with those with ≤1.4 SUI episodes/day (-0.51 ± 0.42; p < 0.001). There was no significant difference between subgroups for either 1- or 24-h pad tests.

There was no significant difference in mean SUI episodes at week 12 between patients whose median urine loss by 1-h in-office pad test was ≤3.5 vs >3.5 g. However, there was a smaller reduction in mean urine loss by 1-h in-office pad test among patients who lost ≤3.5 g urine at baseline versus those who lost >3.5 g (-0.79 ± 1.05 vs -9.31 ± 24.11 g, respectively; p = 0.04). Similarly, there were smaller reductions in mean urine loss by 24-h in-office pad test among those who lost ≤3.5 g urine at baseline versus those who lost >3.5 g (-4.25 ± 8.63 vs -14.7 ± 23.44 g, respectively; p = 0.01).

Menstrual status influenced the reduction from baseline in mean SUI episodes/day (-0.81 ± 0.90 vs -1.87 ± 1.94 for menstruating and postmenopausal women, respectively; p = 0.01), but had no significant impact on the amount of urine lost on either 1- or 24-h pad tests.

Quality of life

Quality of life was measured using the Incontinence Quality of Life Questionnaire, a 22-item

measurement tool with scores ranging from 0 to 100, with higher scores indicating improved quality of life. A total of 75 patients completed the study questionnaire at all visits.

Significant improvements were observed in the total score in addition to the avoidance and limiting behavior, psychosocial impacts and social embarrassment subscores of the Incontinence Quality of Life Questionnaire (Table 4). Significant improvements in the total score and all subscores were observed as early as week 4, and continued to increase through week 12. A total of 77% of patients had an improved quality-of-life score within 4 weeks of using EmbaGYN; by week 12, the percentage with improved quality-of-life scores had increased to 93% (Figure 3).

Treatment satisfaction

A final, informal survey was conducted in order to further elicit subject feedback on the device itself. A total of 92% of patients indicated that they were at least somewhat willing to continue with EmbaGYN, 93% felt that they had benefited from EmbaGYN treatment and 89.2% expressed overall satisfaction with the device. In terms of use, 97.3% of patients found that EmbaGYN was easy to use, 94.7% felt that it was comfortable to use and 98.7% found the instructions for use clear. Overall, 86.7% felt that the time commitment needed to use the device was satisfactory. Among study participants, 94.7% would recommend the device to a friend.

Compliance

Compliance with the study protocol was high at each study visit. At week 12, mean compliance with the EmbaGYN device was 93.4 ± 12.3%; compliance with Kegel exercises was 95.6 ± 10.3%. At each visit, compliance was ≥92%.

Adverse events

There were no serious adverse events. Of the 31 reported treatment-emergent adverse events in the intent-to-treat population, only one (medical device discomfort) was probably attributable

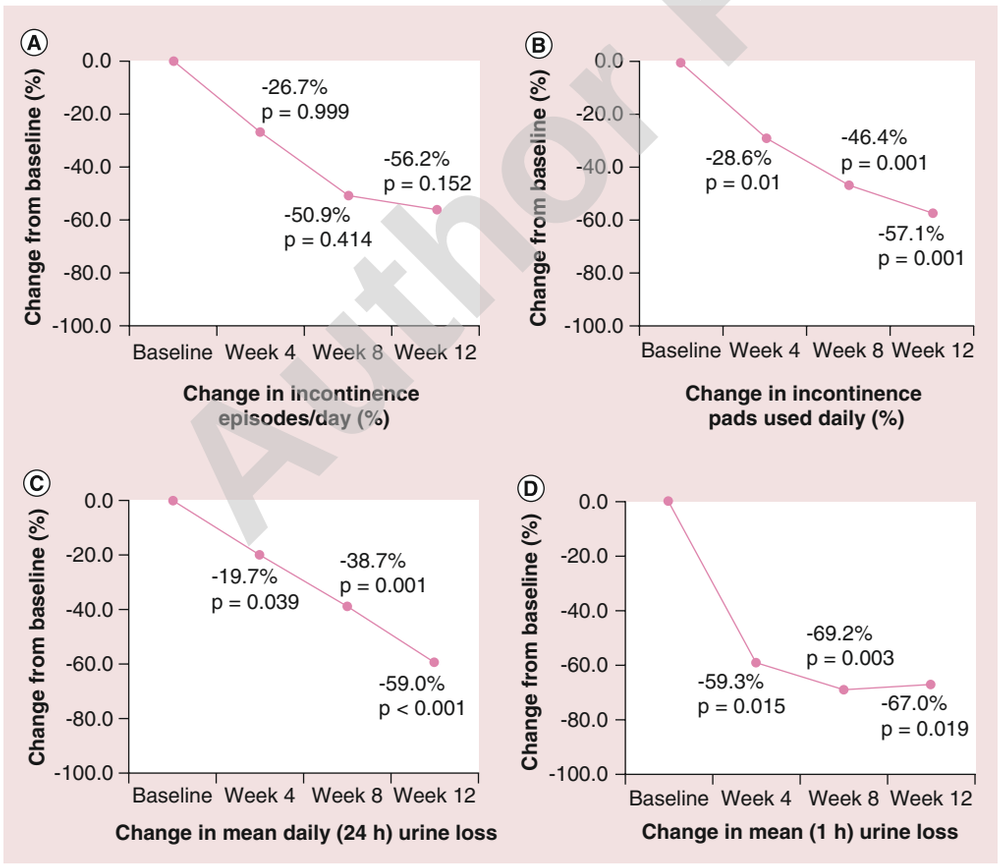

Figure 2. EmbaGYN™ efficacy outcomes. (A) Percentage change in incontinence episodes/day (p = 0.152 vs baseline at week 12); **(B)** percentage change in incontinence pads used daily per electronic diary records (p = 0.001 vs baseline at week 12); **(C)** percentage change in mean daily urine loss (24-h pad test, p < 0.001 vs baseline at week 12); **(D)** percentage change in mean urine loss (in-office 1-h pad test, p = 0.19 vs baseline at week 12).

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Table 4. Incontinence Quality of Life Questionnaire total score, avoidance and limiting behavior, psychosocial impacts and social embarrassment subscores.

	Total score	Avoidance and limiting behavior subscore	Psychosocial impacts subscore	Social embarrassment subscore
Baseline				
n	82	83	83	83
Mean (SD)	62.9 (20.01)	71.1 (21.65)	63.9 (22.93)	46.1 (19.02)
Median	65.9	78.1	66.7	45.0
Min, max	15.90, 95.50	18.80, 100.00	-8.30, 97.20	10.00, 90.00
Week 4				
n	75	75	75	75
Mean (SD)	71.6 (17.30)	78.7 (17.70)	73.8 (18.82)	56.1 (19.31)
Median	75	84.4	80.6	60.0
Min, max	21.60, 97.70	21.90, 100.00	19.40, 100.00	15.00, 95.00
Week 8				
n	72	72	72	72
Mean (SD)	78.1 (15.24)	84.1 (15.60)	79.7 (15.49)	65.5 (19.16)
Median	83	87.5	84.7	75.0
Min, max	38.60, 98.90	43.80, 100.00	41.70, 100.00	25.00, 100.00
Week 12				
n	75	75	75	75
Mean (SD)	82.9 (14.43)	87.6 (14.29)	84.8 (15.11)	72.1 (17.82)
Median	88.6	90.6	91.7	75.0
Min, max	42.00, 100.00	46.90, 100.00	38.90, 100.00	30.00, 100.00

Max: Maximum; Min: Minimum; SD: Standard deviation.

to use of the system. One subject discontinued the trial owing to an adverse event that was deemed unrelated to device use.

Discussion

The results of this single-blind, open-label study suggest that the EmbaGYN device, when used with Kegel exercises, can improve many of the parameters used to measure SUI burden. EmbaGYN plus Kegel exercises resulted in a substantial, albeit not statistically significant, reduction in the mean number of incontinence episodes per day. In part, the failure to provide statistically significant reductions in SUI episodes/day may be due to the relatively low number of episodes/day in the overall population at baseline, as is suggested by the fact that the mean number of incontinence episodes was reduced significantly among the subgroup of subjects with >1.4 SUI episodes/day at baseline. Notably, the reduction in incontinence episodes per day was progressive, with increasing reductions noted at weeks 4, 8 and 12. Given this pattern, it is also possible that continued use of the EmbaGYN device, in combination with Kegel exercises, may ultimately result in significant reductions in incontinence episodes per day, even in women with fewer episodes/day. The results for all other clinical end points, including change from baseline in incontinence pads used daily, mean 24-h urine loss and mean 1-h urine loss, statistically significantly favored EmbaGYN in combination with Kegel exercises at week 4, with further progressive and substantial improvements at weeks 8 and 12.

SUI is associated with a considerable decrement in patient quality of life [4]. For this reason, this study prospectively evaluated changes in quality of life using the validated Incontinence Quality of Life Questionnaire. Notably, statistically significant improvements in quality of life were noted on the total score, as well as the avoidance and limiting behavior, psychosocial impacts and social embarrassment scores. Compliance with the device and Kegel exercises was high, and the majority of patients were satisfied with treatment.

A number of studies have evaluated the use of pelvic floor electrical stimulation, usually in combination with other modalities, in the management of urinary incontinence. These studies have yielded mixed results and interpretation is hampered by substantial heterogeneity in both interventional and methodological quality. A large, albeit uncontrolled, study provides evidence that pelvic floor electrical stimulation alone has a potentially positive effect on SUI. This study enrolled 359 patients (including 207 with SUI) and identified a 'cure rate' of 63.5% as well as significant improvements in quality of life [10]. A small study reported that adding pelvic floor electrical stimulation improved the outcomes of intensive pelvic floor muscle training in patients with genuine SUI [11]. More recently, a two-arm study compared transvaginal electrical stimulation combined with surface electromyography-assisted biofeedback with placebo in 102 patients with proven SUI [12]. This study identified significant differences in favor of the intervention for mean urinary leakage, muscle strength and quality of life. A third, prospective, randomized controlled trial found that, on a background of intensive education, pelvic floor electrical stimulation added little incremental benefit when added to anorectal biofeedback-assisted training [13]. A fourth study allocated 32 patients with urinary incontinence to one of three intervention groups: pelvic floor muscle exercises alone (n = 11), pelvic floor muscle exercises combined with biofeedback (n = 10) and pelvic floor muscle exercises combined with electrical stimulation (n = 11) [14]. Although there were significant improvements in pelvic muscle contraction strength, quality of life and episodes of urine leakage across all three groups, the sample size was clearly too small to examine whether there were differences among treatments.

It has been suggested that biofeedback and pelvic floor electrical stimulation provide at least partially overlapping benefits in women with SUI, in that both facilitate recognition of muscles to be further strengthened through pelvic floor muscle training, and that only one is needed in conjunction with pelvic floor muscle training [13].

The clinical benefit of pelvic floor electrical stimulation may be twofold. First, the device provides a degree of passive exercise to strengthen the smooth and striated periurethral muscles and striated pelvic floor muscles involved in retention of urine. Second – and perhaps more importantly – it facilitates recognition of these muscles, which can be further exercised through properly conducted Kegel exercises. In this, it achieves much the same objective as biofeedback. The ability to effectively discriminate the appropriate musculature is critical. As noted in the introduction, while Kegel exercises are effective, many women do not execute them correctly and, in fact, some may conduct the exercises in a way that actively exacerbates urinary incontinence.

The choices between biofeedback and pelvic floor electrical stimulation may be driven by relative cost and differences between the two technologies in individual patient acceptability. Thus, pelvic floor electrical stimulation, together with Kegel exercises, may be considered an appropriate option in patients who might otherwise be considered for biofeedback.

Aside from the single-arm, unblinded design, a limitation of this study is that it is not possible to distinguish the effects of the EmbaGYN Pelvic Floor Exerciser from those of Kegel exercises. Apparent compliance, as recorded in the e-Diary, was very high for both the device and exercises, thus, there are no subsets of patients in whom the relative performance of the device and the exercises can be compared. As noted above, however, the efficacy of pelvic floor electrical stimulation and Kegel exercises may be inseparable, as a substantial proportion of the benefit

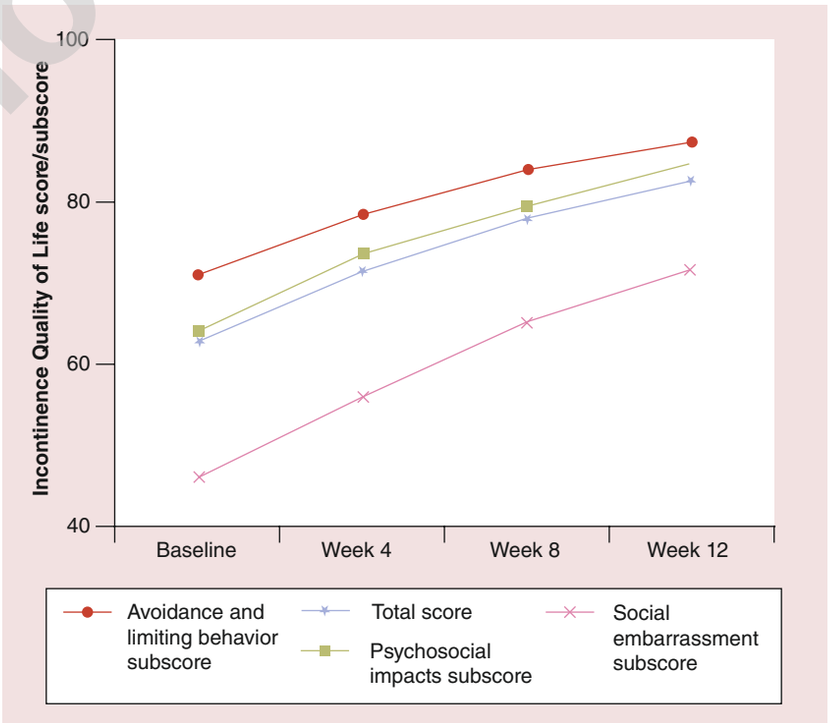

Figure 3. Incontinence Quality of Life Questionnaire total score, avoidance and limiting behavior, psychosocial impacts and social embarrassment subscores. $p < 0.001$ for change from baseline for the total score and all subscores at all time points.

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of the device may lie in facilitating recognition of the muscles used during Kegel exercises. Finally, the EmbaGYN device has not been evaluated in longer-term studies, and the duration of improvement after a 12-week training period has not been examined.

Although this study is suggestive of a benefit associated with this device, there are several avenues for additional research, including a study that incorporates a Kegel exercise-alone group and a study including randomized withdrawal from therapy to identify the duration of benefit. Further delineation of the potential physiological benefit of pelvic floor electrical stimulation (e.g., whether the benefit is derived from facilitating recognition of the appropriate musculature or from hypertrophy of the relevant muscles) would be desirable. The results of this study should not be extrapolated to other electrical stimulation devices, as the EmbaGYN device is likely to be different from other devices in terms of design, use and energy delivery.

In conclusion, short-term use of the EmbaGYN Pelvic Floor Exerciser, in combination with Kegel exercises, results in improvement of multiple voiding parameters, is associated with rapid improvements in quality of life and is safe in patients with SUI. It is noteworthy that the protocol used in this study was highly acceptable to patients despite requiring considerable time commitment.

Disclaimer

S Eder had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Financial & competing interests disclosure

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Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Executive summary

Method

- This was a prospective, open-label, multicenter, single arm study in which 83 patients underwent 12 weeks of treatment with the combination of pelvic floor electrical stimulation with the EmbaGYN™ device and Kegel exercises.

Results

- At study end point, the mean number of incontinence episodes/day fell to 56.2% (p = not significant).
- Mean number of incontinence pads used/day, mean 24-h urine loss and 1-h urine loss all fell significantly by week 12.
- The total score and the avoidance and limiting behavior, psychosocial impacts and social embarrassment subscores of the Incontinence Quality of Life Questionnaire improved significantly by week 4 of the study and continued to improve through week 12.
- There was one treatment-emergent device-related adverse event (device discomfort) and no serious adverse events.

Conclusion

- Short-term use of the EmbaGYN Pelvic Floor Exerciser, in combination with Kegel exercises, results in improvement multiple voiding parameters, is associated with rapid improvements in quality of life and is safe in patients with stress urinary incontinence.
- The protocol used in this study was highly acceptable to patients despite requiring considerable time commitment.

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