ORIGINAL CONTRIBUTION

Randomized Pilot Study: Anal Inserts Versus Percutaneous Tibial Nerve Stimulation in Patients With Fecal Incontinence

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BACKGROUND: Anal inserts and percutaneous tibial nerve stimulation may be offered to those with fecal incontinence in whom other conservative treatments have failed.

OBJECTIVE: We aimed to compare anal inserts and percutaneous tibial nerve stimulation.

DESIGN: This was an investigator-blinded randomized pilot study.

SETTINGS: The study was conducted at a large tertiary care hospital.

PATIENTS: Adult patients with passive or mixed fecal incontinence were recruited.

INTERVENTIONS: Patients were randomly assigned to receive either the anal inserts or weekly percutaneous tibial nerve stimulation for a period of 3 months.

MAIN OUTCOME MEASURES: The primary end point was a 50% reduction of episodes of fecal incontinence per week as calculated by a prospectively completed 2-week bowel diary. Secondary end points were St Mark's incontinence score, International Consultation on Incontinence Questionnaire-Bowel scores (for bowel pattern, bowel control, and quality of life), use of antidiarrheal agents, estimates of comfort and acceptability.

RESULTS: Fifty patients were recruited: 25 were randomly assigned to anal inserts and 25 were randomly assigned to percutaneous tibial nerve stimulation. All completed treatment. A significant improvement of scores in the 2-week bowel diary, the St Mark's scores and the International Consultation on Incontinence Questionnaire-Bowel scores, was seen in both groups after 3 months of treatment. A reduction of ≥50% fecal incontinence episodes was reached by 76% (n = 19/25) by the anal insert group, compared with 48% (n = 12/25) of those in the percutaneous tibial nerve stimulation group ($p = 0.04$). The St Mark's fecal incontinence scores and the International Consultation on Incontinence Questionnaire-Bowel scores for bowel pattern, bowel control, and quality of life ($p = 0.01$) suggest similar improvement for each group.

LIMITATIONS: A realistic sample size calculation could not be performed because of the paucity of objective prospective studies assessing the effect of the insert device and percutaneous tibial nerve stimulation.

CONCLUSIONS: Both anal insert and percutaneous tibial nerve stimulation improved the symptoms of fecal incontinence after 3 months of treatment. The insert device appeared to be more effective than percutaneous tibial nerve stimulation. Larger studies are needed to investigate this further. See **Video Abstract** at http://links.lww.com/DCR/B460.

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ESTUDIO PILOTO ALEATORIZADO DE INSERCIONES ANALES CONTRA LA ESTIMULACIÓN PERCUTÁNEA DEL NERVIO TIBIAL EN PACIENTES CON INCONTINENCIA FECAL

ANTECEDENTES: Las inserciones anales y la estimulación percutánea del nervio tibial (PTNS) se pueden ofrecer a las personas con incontinencia fecal que han fallado en otros tratamientos conservadores.

OBJETIVO: Nuestro objetivo fue comparar inserciones anales y estimulación percutánea del nervio tibial.

DISEÑO: Este fue un estudio piloto aleatorio ciego para investigadores.

AJUSTE: El estudio se realizó en un hospital de atención terciaria.

PACIENTES: Se reclutaron pacientes adultos con incontinencia fecal pasiva o mixta.

INTERVENCIONES: Los pacientes fueron asignados al azar para recibir inserciones anales o estimulación del nervio tibial percutáneo semanal durante un período de tres meses.

PRINCIPALES MEDIDAS DE RESULTADO: El principal resultado fue una reducción del 50% de los episodios de incontinencia fecal por semana, según lo calculado mediante un diario intestinal de dos semanas completado de forma prospectiva. Los criterios de valoración secundarios fueron la puntuación de incontinencia de St Mark, las puntuaciones del ICIQ-B (para patrón intestinal, control intestinal y calidad de vida), uso de agentes antidiarreicos, estimaciones de comodidad y aceptabilidad.

RESULTADOS: Se reclutaron 50 pacientes: 25 fueron asignados al azar a inserciones anales y 25 a PTNS. Todo el tratamiento completado. Se observó una mejora significativa de las puntuaciones en el diario intestinal de dos semanas, la puntuación de St Mark y la puntuación del ICIQ-B en ambos grupos después de 3 meses de tratamiento. Se alcanzó una reducción de ≥ 50% de los episodios de incontinencia fecal en un 76% (n = 19/25) en el grupo de inserción anal, en comparación con el 48% (n = 12/25) de los del grupo de estimulación percutánea del nervio tibial (p = 0,04). Las puntuaciones de incontinencia fecal de St Mark, las puntuaciones del ICIQ-B para el patrón intestinal, el control intestinal y la calidad de vida (p = 0,01) sugieren una mejora similar para cada grupo.

LIMITACIONES: No se pudo realizar un cálculo realista del tamaño de la muestra debido a la escasez de estudios prospectivos objetivos que evaluaran el efecto del dispositivo de inserción y la estimulación percutánea del nervio tibial.

CONCLUSIONES: Tanto la inserción anal como la estimulación percutánea del nervio tibial mejoraron los síntomas de incontinencia fecal después de 3 meses de tratamiento. El dispositivo de inserción parecia ser más efectivo que la estimulación percutánea del nervio tibial. Se necesitan estudios más amplios para investigar esto más a fondo. Consulte **Video Resumen** en http://links.lww.com/DCR/B460. *(Traducción—Dr. Gonzalo Hagerman)*

NÚMERO DE REGISTRO DE PRUEBA: Clinicaltrials.gov No. NCT04273009.

KEY WORDS: Anal plug; Bowel leakage; Fecal incontinence; Percutaneous tibial nerve stimulation; Renew anal insert.

Fecal incontinence (FI) is a common condition that affects over 200 million people worldwide.[1,2] Prevalence rates up to 1.4% in the general population and 46% in institutionalized elderly patients have been reported.[3,4] Fecal incontinence can be a distressing and embarrassing problem with a negative effect on quality of life.[5,6] Conservative and surgical treatments are available.[7,8] Conservative management ranges from dietary modifications and antidiarrheal medication to bowel habit retraining and biofeedback.[9,10] A significant number of patients do not respond to these treatments and may be left with significant symptoms. Surgical options include injectable bulking agents, neuromodulation, artificial sphincter implantation, and sphincteroplasty.[11–16] These treatments can cause extra morbidity. The reported success rates vary widely and may be disappointing in the long term.[15,17–20] This has led to a search for better alternatives to help those with FI.

The Renew anal insert is a single-use anal device that is designed to physically obstruct the anal opening and prevent the involuntary passage of stool (Fig. 1). It seems to be well tolerated by patients, perhaps because of its soft consistency.[21] A few prospective pilot studies have been published with promising results.[22–24] Patients have reported that the Renew insert is virtually imperceptible when used and a noticeable reduction in FI has been experienced.[24]

Percutaneous tibial nerve stimulation (PTNS) is a form of neuromodulation that offers a minimally invasive outpatient treatment. Previous nonrandomized studies reported good results[25–27]; however, doubts about the efficacy of PTNS have been raised. A randomized controlled study by Knowles and colleagues[28] has suggested that its effect is no better than placebo. Furthermore, PTNS is labor intensive and requires regular attendance at a hospital. This normally requires a regular attendance that can vary between 1 or 2 sessions in outpatient clinics for 12 weeks.

Both the Renew device and PTNS may be offered to those with therapy-refractory FI before more invasive treatments such as sacral nerve stimulation, sphincter-bulking

FIGURE 1. The Renew Anal Insert with its finger applicator.

agents, and artificial sphincters. Percutaneous tibial nerve stimulation has been offered to this group for several years.[25,26] However, given the concerns about its effectiveness,[28] an alternative treatment may be more desirable. The Renew device has had encouraging initial results[24] without the drawbacks of PTNS. It is cheap and can be used from home. The aim of this study is to compare directly the Renew anal insert and PTNS in patients with passive or mixed FI.

MATERIALS AND METHODS

This investigator-blinded randomized controlled trial of the Renew anal insert versus PTNS in patients with FI received an institutional review board approval by the Health Research Authority (London: Harrow Research Ethics Committee, REC reference 16/LO/1821) before initiation. Because there is a paucity of objective prospective studies on the effect of the Renew device and PTNS in patients with FI, no realistic sample size calculation could be performed. The sample size was limited to 50 patients by the medical ethical committee before this study started. This study was also registered at clinicaltrials.gov (No. NCT04273009).

Patients

Adult patients with passive or mixed FI with a minimum of 2 or more episodes of FI per week, as assessed by prospectively collected bowel diaries, were eligible to be enrolled. Previous treatment with biofeedback, pelvic floor physiotherapy, or other medical management had failed in the patients recruited to the study, and these patients were able to self-administer the Renew anal insert. Eligible patients were approached in the outpatient clinic of St Mark's Hospital by one of the investigators, or by telephone or by mail. The inclusion and exclusion criteria are listed in Table 1.

Randomization

Patients were randomly assigned to receive either the Renew device or PTNS by using the sealed envelope method by means of a one-to-one treatment allocation. The randomization was performed by a clinician not involved in this study. Treatment assignments were generated using a pseudorandom number generator. Recruitment was continued until 25 patients were allocated to each group. All patients signed a written consent form before the study. Patients received either PTNS or the Renew device for a period of 3 months. All participants were free to withdraw at any time from the allocated treatment without giving reasons and without prejudicing further treatment. At the end of the 3-month period, patients exited the study and were offered further treatment as deemed appropriate by the treating clinician. The principal investigator was blinded to patient allocation until after the study and data analyses had been completed.

Renew Anal Insert

The Renew anal insert (Renew Medical Inc, Menlo Park, CA) is placed by the patient using a fingertip applicator. All patients randomly assigned to use the Renew device were given the regular and large sizes to use for 2 days before starting the trial to determine which size they preferred. The number of inserts used was recorded by the patient. Patients had direct access to the investigating team if they had any concerns, or if problems occurred.

Percutaneous Tibial Nerve Stimulation

Percutaneous tibial nerve stimulation was given using a NeuroTrac TENS transcutaneous electrical nerve stimulator (Verity Medical Ltd, Hampshire, UK) via two 50 mm × 50 mm electrode pads. A fine needle was inserted next to the tibial nerve above the ankle, a ground pad was attached to the arch of the foot, and a barely perceptible electric current was delivered. Continuous stimulation at a pulse width of 200 ms and a frequency of 10 Hz was used. The amplitude was set to produce a sensory stimulus in the ipsilateral foot, at an intensity tolerable to the patient. The treatment was given in 12 outpatient sessions of 30 minutes each, once a week at the St Mark's Hospital.

Data Collection

At enrollment in the study, baseline data were collected: patient demographics, duration of symptoms, and type of

TABLE 1. Inclusion and exclusion criteria of this study

Inclusion criteria	*Exclusion criteria*
Female or male, >18 years old	Pregnancy
Passive or mixed fecal incontinence	Inability to given informed consent
Minimum 2 or more episodes of fecal incontinence per week as assessed by prospectively collected bowel diaries	Known allergy to silicone
Failed biofeedback, pelvic floor physiotherapy, or other medical and conservative management	Patients who are mentally or physically unable to comply with the protocol of the study.
Able to self-administer the Renew anal insert	IBD, any active rectal inflammation, per rectal bleeding, perianal sepsis
Competent and willing to fill in questionnaires and attend clinics throughout the study	Rectal prolapse, third- or fourth-degree hemorrhoids, anal stricture, anal or rectovaginal fistula, previous rectal surgery

FI, and previous surgical and obstetric history. Anorectal physiology tests were always performed to objectively measure the degree of incontinence. Clinical parameters of FI were measured at baseline and after 3 months of treatment. The primary outcome measure was a ≥50% reduction of episodes of FI per week as calculated by a prospectively completed 2-week bowel diary.[29] This was chosen as a primary outcome measure because it reflects the patient's perspective rather than a constructed score by a physician.[30] It is also the only validated clinically meaningful and useful primary outcome measure available.[31] This outcome measure was analyzed with an intention to treat. Secondary outcome measures were the St Mark's FI score.[32] International Consultation on Incontinence Questionnaire-Bowel (ICIQ-B) subdivided in bowel pattern, bowel control, and quality of life[33]; antidiarrheal agent use; completion of treatment; comfort using a 10-point visual analogue scale (1 = comfortable, 5 = ambivalence, 10 = uncomfortable); and acceptability using a similar 10-point visual analogue scale.[34]

Data Analysis and Statistical Considerations

For consistency, pre- and posttreatment data for both cohorts were summarized as the median and interquartile range (IQR); however, the distribution of data varied between study outcome measures as assessed by D'Agostino-Pearson normality testing. Differences between groups were assessed for statistical significance with the unpaired *T* test (Gaussian distribution) or Mann-Whitney *U* test (non-Gaussian distribution). Changes in outcome measures over time were analyzed using either a *t* test (Gaussian distribution) or the Wilcoxon matched-pairs test (non-Gaussian distribution). The χ^2 test was used to calculate differences in antidiarrheal medication use between groups. Statistical significance was defined as $p < 0.05$. Statistical tests were performed using SPSS version 24 (International Business Machines Corporation, Armonk, NY).

RESULTS

Between March 2017 and September 2018, 92 patients were assessed for eligibility. Of these patients, 32 did not meet the inclusion criteria, 8 declined to participate, and 2 patients were not included because they opted for a more invasive treatment for their symptoms. Therefore, a total of 50 patients were recruited to this study (Fig. 2). No adverse events were reported by the study participants during the study period.

Baseline Data

The median age was 56 years (SD ±11.33) in the PTNS group and 58 years (SD ±14.76) in the Renew group ($p = 0.59$). At baseline there was no statistical difference between the 2 groups when comparing manometry results (resting pressure, $p = 0.27$; maximum voluntary squeeze increment pressure, $p = 0.74$; endurance in 5 seconds, $p = 0.30$; involuntary squeeze pressure, $p = 0.12$). At baseline there was also no statistical difference between the groups when comparing the frequency of FI recorded by the 2-week pretreatment bowel diary (Renew: median of 18 (IQR 11–19); PTNS 15 (IQR 14–18); $p = 0.71$). Significantly lower St Mark's incontinence (18 (14–20) vs 20 (IQR 18–20); $p = 0.02$) and ICIQ-B bowel pattern scores (11 (10–12) vs 12 (11–15); $p = 0.04$) were noted at baseline for the Renew group in comparison with the PTNS group. No statistical differences were found between the baseline scores of ICIQ-B bowel control ($p = 0.13$), ICIQ-B quality of life ($p = 0.86$), and the use of antidiarrheal medication ($p = 0.12$). All baseline data are shown in Table 2.

Results After 3 Months

All patients completed treatment; there were no withdrawals or crossovers within the study period. In the Renew group, 13 patients used the regular-sized inserts, 12 used the large-sized inserts. In this group, a median of 5 inserts was used per week (IQR 3–6), with a median of 2 (1–2) inserts per day.

In the Renew group 100% (n = 25) reported a reduction in episodes of FI as recorded by the posttreatment 2-week diary, versus 88% in the PTNS group (n = 22/25; $p = 0.07$). A ≥50% reduction of episodes of FI recorded by the 2-week posttreatment diary was achieved in 75% of the Renew anal insert group (n = 19/25) and in 48% (n = 12/25) of the PTNS group ($p = 0.04$). After 3 months

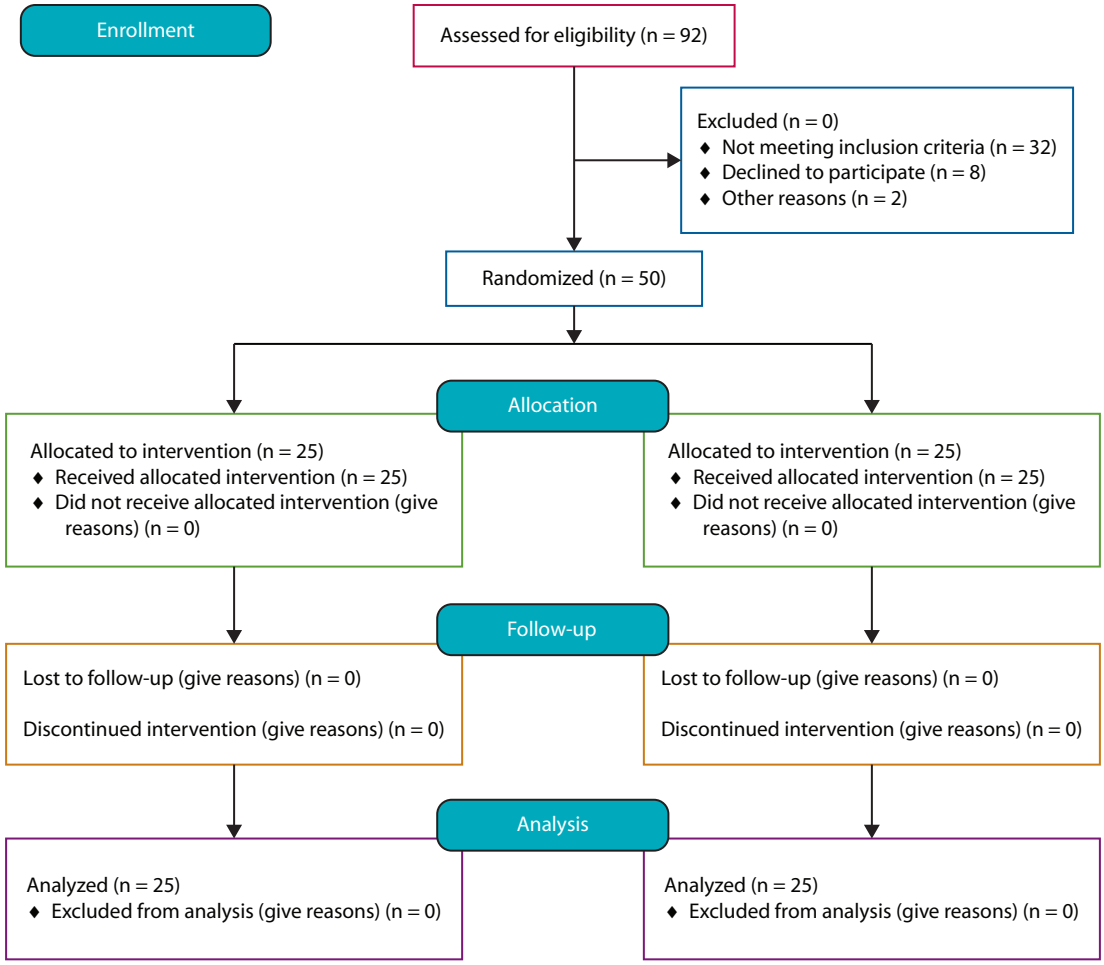

FIGURE 2. Consolidated Standards of Reporting Trials diagram of the progress through the phases (enrollment, intervention allocation, follow-up, and data analysis) of a 2 parallel group randomized controlled trial in adult patients with passive or mixed fecal incontinence that compared the anal inserts group with the weekly percutaneous tibial nerve stimulation group.

of treatment, the median number of episodes of FI in the posttreatment 2-week diary was not statistically different between the 2 groups (Renew: 6 episodes per week (IQR 5–8); PTNS: 8 episodes per week (6–9); $p = 0.08$). There was a 28% (95% CI, 2.2%–53.8%) difference between the groups when assessing the ability of these treatments to achieve a 50% reduction in FI (Renew 76%; PTNS 48%).

Both groups showed a significant improvement of the St Mark's FI score and the ICIQ-B scores for FI after 3 months of treatment. The Renew group had significantly better outcomes than the PTNS group for the St Mark's FI, ICIQ-B bowel pattern, ICIQ-B bowel control, and ICIQ-B quality-of-life scores. Fewer people used antidiarrheal medication after 3 months in the Renew group (Renew: yes/no 10/15, 40%; PTNS 16/9, 64%; $p = 0.09$ by χ^2 test). These results are reported in Table 3 and depicted in Figure 3.

Some patients reported some degree of discomfort using the Renew insert. When assessed using a visual analogue scale for discomfort, 8 patients did not report any discomfort, 15 patients reported a score of between 1 and 3, whereas 2 patients reported a score of 4. When assessing acceptability using a visual analogue score, 17 patients reported that it was entirely comfortable; 8 patients reported scores of between 1 and 3, indicating some degree of minor discomfort, but no patients reported major pain or distress. None of the patients in the PTNS group reported any discomfort of treatment, with all patients reporting zero for both discomfort and acceptability.

DISCUSSION

This single blinded randomized controlled pilot study showed a significant reduction in symptoms of FI after 3 months of treatment with both the Renew anal insert and PTNS. Although both groups achieved a significant improvement in FI frequency (number of episodes per week), some of the outcome measures suggest that the Renew anal insert proved to be slightly more effective. It should also be considered that some of the patients showed no differences and did not consistently report these results. Seventy-five percent of those who received

TABLE 2. Characteristics of study subjects at baseline

Baseline	*Data distribution*	*Characteristics*	*Renew*	*PTNS*	*p*
Sex	NA	Male/female	2/23	3/22	0.99[a]
Age, y	G ($p = 0.2635$)	Mean	58 (SD ±14.76)	56 (SD ±11.33)	0.59[b]
Type of incontinence					
Passive		N 17	4/25	21/25	
Mixed		N 33	5/25	20/25	
Duration of symptoms in months		Median 37 mo	Median 31 mo	Median 38 mo	
Obstetric injury		Yes/no	18/7	21/4	0.30[a]
FI frequency (episodes/wk)	NG ($p = 0.0031$)	Median	18 (IQR 11–19)	15 (IQR 14–18)	0.71[c]
St Mark's incontinence score	G ($p = 0.9591$)	Median	18 (IQR 14–20)	20 (IQR 18–20)	0.02[b]
ICIQ-B bowel pattern (/21)	G ($p = 0.3778$)	Median	11 (IQR 10–12)	12 (IQR 11–15)	0.04[b]
ICIQ-B bowel control (/28)	G ($p = 0.7108$)	Median	20 (IQR 16–21)	22 (IQR 18–24)	0.13[b]
ICIQ-B quality of life (/26)	NG ($p = 0.0165$)	Median	22 (IQR 19–26)	23 (IQR 18–24)	0.86[c]
Antidiarrheal medication	NG ($p < 0.0001$)	N	14/25	20/25	0.12[c]

FI = fecal incontinence; G = Gaussian distribution of data; ICIQ-B = International Consultation on Incontinence Questionnaire – Bowel; IQR = interquartile range; NA = not available; NG = non-Gaussian distribution of data as assessed by D'Agostino-Pearson normality test with associated *p* values; PTNS = percutaneous tibial nerve stimulation. Statistical significance tested with [a] χ^2 test, [b] *T* test, [c] Mann-Whitney *U* test.

the Renew device achieved a ≥50% reduction of episodes of FI in the 2-week diary compared with 48% in the PTNS group. The St Mark's and the ICIQ-B FI scores also seemed to favor the Renew anal insert. These results suggest that this relatively new treatment is an attractive alternative for PTNS in patients with FI in whom conservative treatment has failed, and the presented data will prove helpful when counseling patients who are about to start this therapy.

Another advantage of the Renew anal insert over PTNS is that the patient can apply the insert at home and does not have to attend hospital on a weekly basis. This could save time and cost for both the patient and the National Health Service. The Renew anal insert in the United Kingdom costs £2.60 per insert and is available on prescription from the UK National Health Service. Conversely, the cost for a full PTNS treatment course (12 sessions) is £456.83. This does not account for the cost of the reusable machine (£990.77) and the cost of running the clinic, including staff salaries. This arrangement may differ in other countries. It will be important in the future to investigate the cost of the Renew insert and PTNS further in a separate cost analysis.

The Renew device also appears to be well tolerated. The soft texture of the Renew device means that it may have overcome some of the disadvantages of the older Peristeen anal plug[35–37] that, in a recently published systematic review,[37] seems to have poor patient acceptability. In that review, patients reported offensive smell, leakage, local irritation, and a sensation of urgency.

TABLE 3. Comparison within the groups between clinical parameters of fecal incontinence at baseline and after 3 months of treatment

Group	*Data distribution*	*Characteristics*	*Baseline*	*3 months*	*p*
Renew anal insert					
FI frequency (episodes/wk)	NG ($p = 0.0031$)	Median	18 (IQR 11–19)	6 (IQR 5–8)	<0.001[a]
Any improvement		% (N)		100 (25/25)	
≥50% improvement		% (N)		75 (19/25)	
St Mark's incontinence score	G ($p = 0.9591$)	Median	18 (IQR 14–20)	11 (IQR 9–13)	<0.001[b]
ICIQ-B bowel pattern (/21)	G ($p = 0.3778$)	Median	11 (IQR 10–12)	6 (IQR 5–10)	<0.001[b]
ICIQ-B bowel control (/28)	G ($p = 0.7108$)	Median	20 (IQR 16–21)	11 (IQR 9–16)	<0.001[b]
ICIQ-B quality of life (/26)	NG ($p = 0.0165$)	Median	22 (IQR 19–26)	15 (IQR 12–16)	<0.001[a]
Antidiarrheal medication		Y/N	14/11 (56%)	10/15 (40%)	
PTNS					
FI frequency (episodes/wk)	NG ($p = 0.0031$)	Median	15 (IQR 14–18)	8 (IQR 6–9)	<0.001[b]
Any improvement		% (N)		88 (22/25)	
≥ 50% improvement		% (N)		48 (12/25)	
St Mark's incontinence score	G (p=0.9591)	Median	20 (IQR 18–20)	12 (IQR 12–15)	<0.001[b]
ICIQ-B bowel pattern (/21)	G ($p = 0.3778$)	Median	12 (IQR 11–15)	8 (IQR 8–12)	0.002[a]
ICIQ-B bowel control (/28)	G ($p = 0.7108$)	Median	22 (IQR 18–24)	17 (IQR 11–20)	0.001[b]
ICIQ-B quality of life (/26)	NG ($p = 0.0165$)	Median	23 (IQR 18–24)	16 (IQR 14–20)	<0.001[a]
Antidiarrheal medication		Y/N	20/5 (80%)	16/9 (64%)	

FI = fecal incontinence; G = Gaussian distribution of data; ICIQ-B = International Consultation on Incontinence Questionnaire – Bowel; IQR = interquartile range; NG = non-Gaussian distribution of data as assessed by D'Agostino-Pearson normality test with associated *p* values; PTNS = percutaneous tibial nerve stimulation. Statistical significance tested with [a] *T* test, [b] Mann-Whitney *U* test.

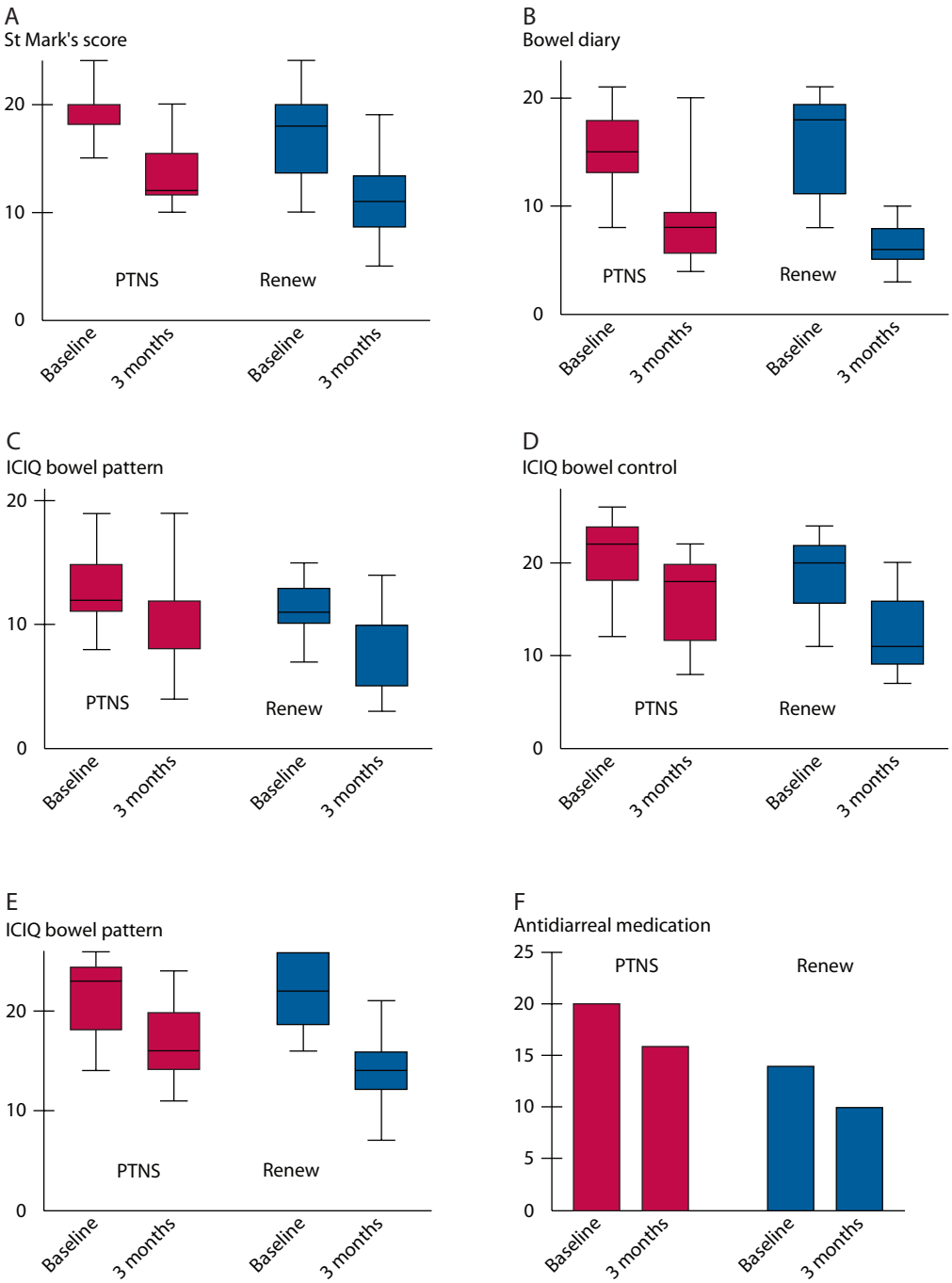

FIGURE 3. In A, B, C, D, and E, scores are represented in box-and-whisker plots: the boxes represent quartiles, the band inside the box represents the median. The whiskers represent the total range of data. In F, the number of patients that are using antidiarrheal medication is indicated. ICIQ = International Consultation on Incontinence Questionnaire; PTNS = percutaneous tibial nerve stimulation.

A previous study by Lukacz et al[23] reported similar results for the Renew anal insert. Ninety-one patients with passive, urge, or mixed FI were treated with the Renew device for a 12-week period. Eighty percent completed the treatment; 77% of these patients achieved a >50% reduction in the frequency of FI episodes and were extremely satisfied with the device. The authors concluded that the anal insert device provides a conservative, safe, and effective treatment for those with FI, with high patient satisfaction and low adverse event rates. It is notable that, in the study by Lukacz et al, the device worked for patients with urge FI as well. This suggests that anal inserts are not only suitable for patients with passive soiling, and patients with urge FI should be included in future studies.

The results of Lukacz et al[23] agree with previous work from our group. A recent retrospective audit of patients

treated with Renew in 2016 demonstrated that 67% (20/30) of patients reported significant improvement, 23% (7/30) reported no change, and only 10% (10/30) reported a deterioration of their symptoms. Seventeen patients (57%) wanted to continue this treatment in the long term.[24] A further small prospective study from our center demonstrated improved symptoms when using the Renew insert for 15 patients who had undergone restorative proctocolectomy with IPAA and were experiencing FI. In this specific group, the Renew device was acceptable to 53% (8/15) and was effective in 40% (6/15) of patients.[22]

To our knowledge, this is the first study that has directly compared the Renew device with PTNS. The strengths of this study include the prospective randomized design and the single-blind fashion in which the investigator analyzed the results. This study also has some limitations. First, a relatively small sample of patients was recruited. Although there is a bigger body of data around PTNS, there was a paucity of data assessing the effect of Renew; therefore, no realistic sample size calculation could be performed. The only other study that reports the use of the Renew plug for FI was fully sponsored by Renew Medical Inc; consequently, it was felt that the data were not adequate to power a large blinded randomized controlled trial. Moreover, the sample study size was limited to 50 patients by the medical ethical committee before commencement of the trial. Second, it could be argued that PTNS and Renew anal insert have different mechanisms of action and thus do not have to be compared in a randomized way, given that both these treatments are safe and efficacious for some FI cohorts and therefore can be trialed for patients in whom conservative treatment measures have failed. However, the hospital and patient costs associated with PTNS therapy are significantly greater in the shorter term. Because the Renew anal insert proved to be slightly more effective in this study, it would seem to be the preferred first-line treatment for patients in whom the conservative treatment measures described previously have failed. Conversely, if the Renew insert is used in the long term, the cost of using several inserts per day may ultimately prove more expensive than PTNS therapy including any additional therapeutic sessions at the hospital that are required. It is important to highlight that only short-term follow-up data are presented by this study for the Renew insert and the long-term efficacy remains unknown. Although the long-term results from PTNS have already been widely demonstrated, it is not clear if patients will continue to use the Renew insert on an ongoing basis every day, which may limit the utility of this device.

CONCLUSION

This randomized pilot study suggests that both the Renew device and PTNS are effective treatments for FI. It also suggests that the Renew device may be more effective than PTNS. Larger studies will be required to investigate the long-term efficacy of the Renew insert.

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