Received: 9 April 2021 | Revised: 28 May 2021 | Accepted: 9 June 2021

DOI: 10.1002/nau.24740

CLINICAL ARTICLE

Neurourology Urodynamics ICS SUFU WILEY

Efficacy of transcutaneous perineal electrostimulation versus intracavitary anal electrostimulation in the treatment of urinary incontinence after a radical prostatectomy: Randomized controlled trial

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Abstract

Aim: To compare the efficacy of the treatment with transcutaneous perineal electrostimulation versus intracavitary electrostimulation to reduce the frequency of urinary incontinence after radical prostatectomy and the impact on the quality of life (QoL).

Methods: This single-blind equivalence-randomized controlled trial equally (1:1) randomly allocated men with urinary incontinence post radical prostatectomy into surface electrodes perineal group (intervention group, IG) and intra-anal probe group (control group, CG). Outcomes included changes in the 24h-Pad Test (main variable), and ICIQ-SF (International Consultation on Incontinence Questionnaire Short-Form), SF-12 (Short Form Health Survey), and I-QOL (incontinence quality of life questionnaire) questionnaires. Clinical data were collected at baseline, 6 and 10 weeks. For the comparisons between variables, χ^2 test and Student's t test were used. Equivalence was analyzed by estimating the mean change (90% confidence interval) of urinary incontinence based on the Pad Test. The analysis was performed for the per-protocol and the intention-to-treat populations. Statistical significance level was set at $p < 0.05$.

Results: Seventy patients were included, mean age 62.8 (*SD* 9.4) years. Mean baseline 24h-Pad Test was 328.3 g (*SD* 426.1) and a significant decrease ($p < 0.001$) in the grams of urine loss at 5 weeks (159.1 g in the IG and 121.7 g in the CG), and at 10 weeks of treatment (248.5 g in the IG and 235.8 g in the CG) was observed. However, the final difference in the grams of urine loss between both treatments showed the absence of statistical significance ($p = 0.874$). In both groups, the ICIQ-SF, I-QOL, and SF-12 questionnaires revealed a significant improvement in QoL.

Conclusion: Surface and intra-anal electrostimulation treatments reduced significantly losses of urine, but differences in grams of urine loss throughout

the therapy between groups were not significant, suggesting that the efficacy of the two treatments is not statistically different. Nonetheless, the improvement observed in both groups was statistically significant and clinically relevant.

KEYWORDS
intra-anal probe electrostimulation, male urinary incontinence, postprostatectomy incontinence, randomized controlled trial, surface electrodes electrostimulation

1 | INTRODUCTION

Radical prostatectomy (RP) is the gold standard treatment for men with localized prostate cancer.[1] However, RP is associated with postoperative urinary incontinence (UI) that can persist for 2 years or longer and is linked to significant reductions in overall health-related quality of life (QoL).[2–5] Pelvic floor muscle training (PFMT) is the most common noninvasive intervention for UI derived from an RP. Available published evidence has long demonstrated that PFMT with muscular electrostimulation (ES) has a significant positive impact on the early recovery of UI after that surgical intervention.[6–8] Perineal ES can be applied to the patient with surface electrodes or by an intracavitary anal probe.[9] Each technique stimulates different anatomical points and remains unknown if both have the same efficacy or one of them is superior. Intracavitary application can be uncomfortable or annoying for patients; although perineal surface ES could become a simple therapeutic modality, easy to apply, and equal or more effective than intracavitary one. The study hypothesizes that perineal surface ES is as effective as intracavitary ES in the reduction of UI secondary to RP. We aim to compare the efficacy of both techniques in reducing the magnitude of UI secondary to RP, and to evaluate its impact on the patients' QoL.

2 | MATERIALS AND METHODS

Between February 2019 and July 2019, a total of 70 consecutive patients with persistent stress UI after RP were enrolled in a clinical trial sited in two clinics in Barcelona. Patients were randomized to receive ES by surface electrodes (intervention group, IG) or intra-anal probe (control group, CG) for 10 weeks. The detailed study protocol was published elsewhere.[10]

The sample size was estimated ($\alpha = 5\%$ and power = 80%), including 10% losses to follow up. The established equivalence range was between −22 and 22 g of urine loss.[8,11] A random allocation sequence was generated at 1:1 ratio. The estimation was made using weight leakage (24h-Pad test) as the main variable.

At baseline, all subjects underwent a detailed assessment, including a complete clinical history (age, date of surgery, surgical intervention technique, and days of catheterization), physical examination using the Oxford test (to measure the pelvic floor muscular strength), and the 24h-Pad test (to quantify the involuntary loss of urine). Additionally, all participants completed the UI questionnaire ICIQ-SF (International Consultation on Incontinence Questionnaire Short-Form), the SF-12 (Short Form Health Survey) questionnaire, and the specific I-QoL test (to assess their QoL). Patients who followed a pharmacological treatment for UI, presented anatomical malformations of the pelvic floor musculature, carried a pacemaker, presented anal fistulas, suffered serious psyche disorders, had a history of lower urinary tract infections, required radiotherapy as adjuvant treatment, diagnosed with urethral stricture after surgery, presented pelvic floor denervation, or suffered neuromuscular diseases were excluded. Patients were randomized into two groups using Sealed Envelope Ltd. 2015 online randomization (Create a blocked randomization list [Online] available in https://www.sealedenvelope.com). A total of 10 treatment physiotherapy sessions were held on a weekly basis.

According to the allocation group, the ES technique was applied using the Neurotrac Pelvitone® muscular electrostimulator, together with two round surface electrodes of 32 mm, or an Analys Plus® anal stimulation probe of 140 mm. Participants in the IG received the treatment through those round surface electrodes adhered to the patients' perineum and at the base of their penis. Patients in the CG received the same treatment by means of an anal stimulation probe, which was placed inside the rectal cavity. The treatment, consisting of 15 min of perineal ES (with surface electrodes or intra-anal probe according to the allocation group, IG or CG, respectively), was applied.

Selected parameters included 10 min of biphasic intermittent current, frequency 30 Hz, pulse width 0.25 ms,

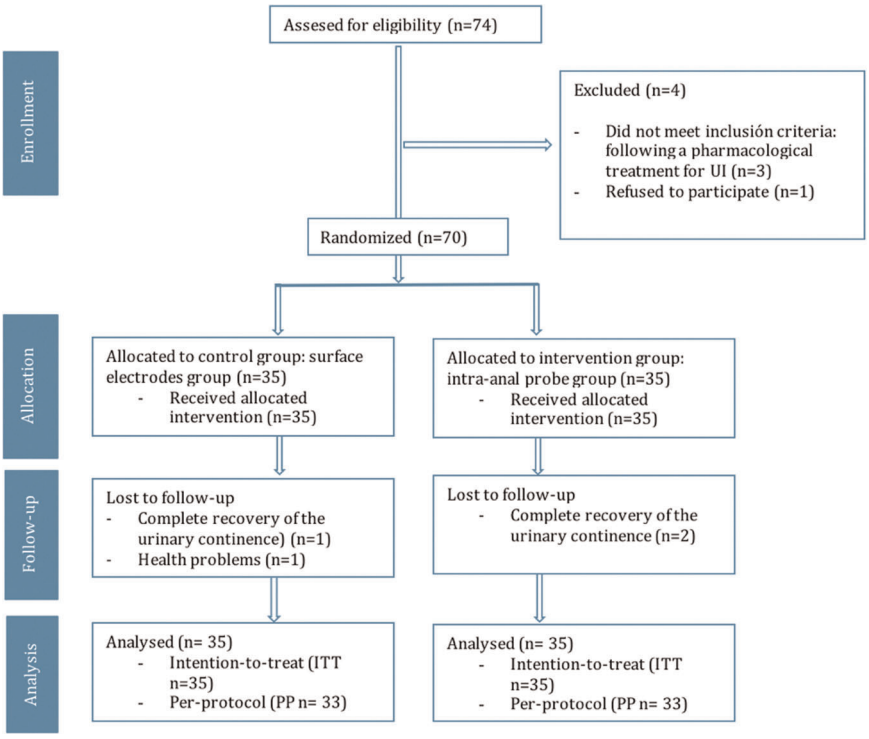

FIGURE 1 CONSORT participant flow diagram for randomized, controlled trials of nonpharmacologic treatment (equivalence trials)

and current intensity between 10 and 30 mA, with no on–off cycles. Additionally, a total of 5 min extra ES at a frequency of 50 Hz, pulse width 0.25 ms, and current intensity between 1 and 50 mA was given, with individually adapted on-off (duty) cycles on the basis of each man's ability to hold a voluntary contraction. On time ranged from 0.5 to 10 s, and off time from 10 to 30 s. If the ability to hold the contraction improved, the duty cycle was progressed each month. All patients were encouraged to tolerate as high an intensity as possible to get a contraction.

Furthermore, for PFMT Kegel active exercises were performed under the supervision and correction of the physiotherapist in each of the treatment sessions and also carried out at home in both groups. The regimen consisted of 10 slow and maintained contractions (8–10 s) and 10 fast contractions (3 s) of the perineal musculature to be done three times a day (twice in a supine position and once in a sitting or standing position) during the 10 weeks, the whole treatment lasted. In each session, treatment adherence and possible adverse effects of the therapy were identified and recorded in a database designed for the project.

The treatment protocol was the same in all sessions. In session 6, the results of the 24h-Pad test and the Oxford test were registered. Moreover, the satisfaction with the treatment was recorded for each patient. In the 10th session, the same tests were reevaluated.

The study took place at RAPbarcelona, a pelvic floor specialized physiotherapy center in Barcelona and at the pelvic floor rehabilitation unit of the Instituto Médico Tecnológico of Barcelona.

Descriptive data are reported as mean values and standard deviations (*SD*) when they are quantitative or with counts and percentages if qualitative. Within-group and between groups comparisons were conducted by the Student's t test and the χ^2 test. Equivalence was assessed by estimating the difference (along with its 90% confidence interval, 90% CI) between initial and final urine leakage mean values, as CONSORT recommendation. The analysis was performed per protocol (PP) and by intention-to-treat (ITT). Level of significance was set at $p < 0.05$ and statistical analysis was carried out using the SPSS 21.0 software.

3 | RESULTS

3.1 | Baseline characteristics

The eligible participants in the study were 74 patients. Of these, one patient did not agree to participate in the study, and three were excluded since they met an exclusion criterion (following a pharmacological treatment for UI). Figure 1 shows the flow diagram of participants.

A total of 70 patients with a mean age of 62.8 (*SD* 9.4) years were enrolled in the study. The 24h-Pad test was undertaken correctly at that moment resulting in a mean leakage of 328.3 g (*SD* 426.1). Mean baseline score for the Oxford scale was 1.4 (*SD* 1.1). Groups were comparable for demographic and clinical aspects, as shown in Table 1.

3.2 | Reduction in grams of urine loss

Throughout the transcutaneous and intracavitary treatment, the grams of urine loss in 24 h (24h-Pad test) significantly reduced. Table 2A shows a significant decrease in the grams of urine loss at 5 and at 10 weeks of treatment in both groups.

3.3 | Improvement in QoL

After 10 transcutaneous and intracavitary treatment sessions, some QoL parameters improved significantly. At final evaluation (Table 2B), the scores of ICIQ-SF, I-QOL, and SF-12 questionnaires showed a significant improvement in QoL expressed by increased values for ICIQ-SF and I-QOL and decreased values for mental and physical dimensions of SF-12 in both study groups.

3.4 | Equivalence analysis

In addition to the analysis based on the intragroup differences observed at the end of the treatment, the adjusted analysis of the differences between both treatments (Table 3) showed the absence of statistical significance for the main outcome, grams of urine loss ($p = 0.869$ in the PP analysis; $p = 0.874$ in the ITT analysis). Moreover, no statistically significant differences were found for the other variables.

The mean differences fell within the established equivalence margins, between −22g and 22 g of urine, (−12.7 g in the ITT analysis and 13.3 g in the PP analysis); however, their 90% CIs exceeded the limits

TABLE 1 Baseline demographic and clinical characteristics of surface electrodes group (IG) and intra-anal probe group (CG)

	Surface electrodes group, IG ($n = 35$)	Intra-anal probe group, CG ($n = 35$)
Age (years)	62.9 (8.8)	627 (10.2)
Surgical interventions, *n* (%)		
Laparoscopic radical prostatectomy	21 (60.0)	26 (74.7)
Robot-assisted radical prostatectomy	14 (40.0)	9 (25.3)
Time from surgery (months)	8.1 (4.3)	8.7 (4.0)
Catheterization (days)	10.8 (6.6)	10.3 (6.3)
Oxford Test score	1.4 (1.0)	1.4 (1.1)
Urinary incontinence		
Weight leakage (g) (24h-Pad test)	310.5 (431.1)	346.0 (426.5)
Quality of life perception		
Severity score (ICIQ-SF)	13.7 (4.7)	15.4 (3.8)
I-QOL total score	53.2 (30.9)	56.5 (25.0)
Mental health score (SF-12)	1.3 (3.7)	2.0 (3.7)
Physical health score (SF-12)	5.1 (4.0)	6.3 (3.7)

Note: Values expressed as mean (standard deviation, *SD*), otherwise stated.

Abbreviations: CG, control group; ICIQ-SF, International Consultation on Incontinence Questionnaire Short-Form; IG, intervention group; I-QOL, incontinence quality of life questionnaire; SF-12, Short Form Health Survey.

TABLE 2A Changes in grams of urine lost after 5 and 10 weeks of transcutaneous and intra-anal treatments. PP (33 patients) and ITT (35 patients) analysis

PP analysis								
	Surface electrodes group, IG ($n = 33$)				**Intra-anal probe group, CG ($n = 33$)**			
	Baseline	**Week 5**	**Difference (90% CI)**	***p* Value**	**Baseline**	**Week 5**	**Difference (90% CI)**	***p* Value**
24h-Pad test	335.2 (418.0)	202.8 (274.6)	132.5 (71.6; 193.3)	**0.001**	324.4 (440.1)	200.3 (347.5)	124.1 (69.2; 179.1)	**0.001**
	Baseline	**Week 10**	**Difference (90% CI)**	***p* Value**	**Baseline**	**Week 10**	**Difference (90% CI)**	***p* Value**
24h-Pad test	335.2 (417.9)	103.4 (182.6)	231.9 (134.4; 329.3)	**<0.001**	324.4 (440.1)	79.2 (182.4)	245.2 (149.6; 340.7)	**<0.001**
ITT analysis								
	Surface electrodes group, IG ($n = 35$)				**Intra-anal probe group, CG ($n = 35$)**			
	Baseline	**Week 5**	**Difference (90% CI)**	***p* Value**	**Baseline**	**Week 5**	**Difference (90% CI)**	***p* Value**
24h-Pad test	355.9 (428.9)	196.8 (272.6)	159.1 (84.9; 233.3)	**0.001**	310.5 (431.1)	188.8 (340.5)	121.7 (69.8; 181.5)	**<0.001**
	Baseline	**Week 10**	**Difference (90% CI)**	***p* Value**	**Baseline**	**Week 10**	**Difference (90% CI)**	***p* Value**
24h-Pad test	346.0 (426.5)	97.5 (178.8)	248.5 (148.3; 348.8)	**<0.001**	310.5 (431.1)	74.7 (177.9)	235.8 (145.2; 326.4)	**<0.001**

Note: Bold values are indicative of statistically significance for the *p* Values. Values expressed as mean (standard deviation) and adjusted differences of means (CI, confidence interval). *p* Value calculated by Student's t-test.

Abbreviations: CG, control group; CI, confidence interval; IG, intervention group; ITT, intention-to-treat; PP, performed per protocol.

TABLE 2B Changes in quality of life after 10 weeks of transcutaneous and intra-anal treatment sessions. PP (33 patients) and ITT (35 patients) analysis

PP analysis								
	Surface electrodes group, IG ($n = 33$)				**Intra-anal probe group, CG ($n = 33$)**			
	Baseline	**Week 10**	**Difference (90% CI)**	***p* Value**	**Baseline**	**Week 10**	**Difference (90% CI)**	***p* Value**
ICIQ-SF	15.2 (3.8)	11.2 (5.4)	4.0 (2.6; 5.5)	**<0.001**	13.6 (4.9)	9.2 (5.7)	4.4 (3.0; 5.7)	**<0.001**
I-QOL	55.7 (24.9)	29.1 (26.7)	26.6 (20.1; 33.0)	**<0.001**	51.9 (31.2)	29.6 (26.2)	22.4 (15.7; 29.0)	**<0.001**
SF-12 (mental)	2.3 (3.7)	3.9 (3.9)	−1.7 (−2.8; −0.5)	**0.017**	1.4 (3.7)	3.1 (3.2)	−1.7 (−2.4; −1.1)	**<0.001**
SF-12 (physical)	6.4 (37)	8.5 (4.5)	−2.2 (−3.1; −1.2)	**<0.001**	4.9 (4.1)	7.8 (4.2)	−2.9 (−3.9; −1.8)	**<0.001**
ITT analysis								
	Surface electrodes group, IG ($n = 35$)				**Intra-anal probe group, CG ($n = 35$)**			
	Baseline	**Week 10**	**Difference (90% CI)**	***p* Value**	**Baseline**	**Week 10**	**Difference (90% CI)**	***p* Value**
ICIQ-SF	15.4 (3.8)	11.6 (5.5)	3.8 (2.4; 5.2)	**<0.001**	13.7 (4.7)	9.5 (5.7)	4.1 (2.8; 5.5)	**<0.001**
I-QOL	56.5 (25)	31.4 (28.2)	25.1 (18.7; 31.4)	**<0.001**	53.2 (30.9)	32.1 (27.7)	21.1 (14.6; 27.5)	**<0.001**
SF-12 (mental)	2 (3.7)	3.6 (4.0)	−1.6 (−2.6; −0.5)	**0.017**	1.3 (3.7)	2.9 (3.2)	−1.6 (−2.3; −1.0)	**<0.001**
SF-12 (physical)	6.3 (3.7)	8.3 (4.5)	−2 (−2.9; −1.2)	**<0.001**	5.1 (4.0)	7.7 (4.1)	−2.7 (−3.7; −1.7)	**<0.001**

Note: Bold values are indicative of statistically significance for the *p* Values. Values expressed as mean (standard deviation) and adjusted difference of means (CI, confidence interval). *p* value calculated by Student's *t* test.

Abbreviations: CG, control group; ICIQ-SF, International Consultation on Incontinence Questionnaire Short-Form; IG, intervention group; ITT, intention-to-treat; PP, performed per protocol; SF-12, Short Form Health Survey.

TABLE 3 Adjusted analysis of the differences between transcutaneous and intra-anal treatments

PP analysis	**IG difference ($n = 33$)**	**CG difference ($n = 33$)**	**Adjusted difference (90% CI)**	***p* Value**
24h-Pad test 24 h (g)	−231.9 (330.4)	−245.2 (324.1)	13.3 (−147.8; 121.1)	0.869
ICIQ-SF	−4.0 (4.9)	−4.4 (4.6)	0.4 (−2.3; 1.6)	0.758
I-QOL	−26.6 (21.9)	−22.4 (22.5)	−4.2 (−4.9; 13.4)	0.442
SF-12 (mental)	1.7 (3.8)	1.7 (2.2)	0.1 (−1.2; 1.3)	0.937
SF-12 (physical)	2.2 (3.1)	2.9 (3.4)	−0.7 (−0.6; 2.0)	0.386
ITT analysis	**IG difference ($n = 35$)**	**CG difference ($n = 35$)**	**Adjusted difference (90% CI)**	***p* Value**
24h-Pad test 24 h (g)	−248.5 (350.7)	−235.8 (317.1)	−12.7 (−120.5; 146.0)	0.874
ICIQ-SF	−3.8 (4.9)	−4.1 (4.6)	0.3 (−2.2; 1.5)	0.763
I-QOL	−25.1 (22.2)	−21.1 (22.5)	−4 (−4.9; 12.9)	0.458
SF-12 (mental)	1.6 (3.7)	1.6 (2.2)	0.1 (−1.2; 1.3)	0.938
SF-12 (physical)	2 (3.0)	2.7 (3.4)	−0.7 (−0.6; 1.9)	0.394

Note: Values expressed as mean (standard deviation) and adjusted difference of means (CI, confidence interval). *p* value calculated by Student's *t* test.

Abbreviations: CG, control group; ICIQ-SF, International Consultation on Incontinence Questionnaire Short-Form; IG, intervention group; ITT, intention-to-treat; PP, performed per protocol; SF-12, Short Form Health Survey.

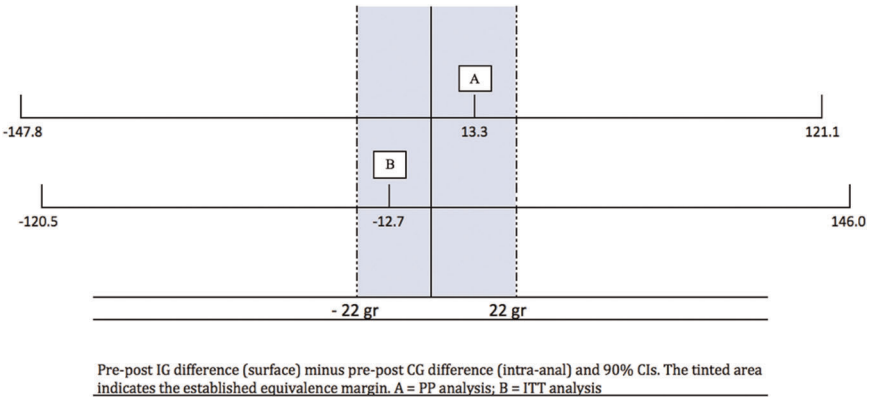

FIGURE 2 Adjusted differences and 90% confidence interval of the mean differences in the grams of urine loss according to the 24h-Pad test (pre–posttreatment) between the two treatments, surface and intra-anal, by type of analysis

making the results on therapeutic equivalence not conclusive (Figure 2).

3.5 | Adverse effects and adherence

No serious adverse events were recorded during the trial. In one of the patients in the intra-anal group, a specific discomfort appeared in the second session due to the presence of hemorrhoids; even so, this patient did not drop out of the study.

Overall adherence to treatment was 94.3%, with no difference between the two study groups.

4 | DISCUSSION

In the last two decades, numerous authors such as Manassero et al.,[12] Mariotti et al.,[8,13] Yamanishi et al.,[7] and Berghmans et al.[14] have long concluded that the application of ES together with PFMT exercises accelerate the early recovery of urinary continence after an RP. In the different investigations, the mode of application of the perineal ES has been mostly with an intra-anal probe, as shown by the studies by Manassero et al.,[12] Mariotti et al.,[8,13] and Yamanishi et al.[7]; however, in other reports, the application mode is not specified or is indifferent.

In clinical practice, it is usual to apply muscular ES with surface electrodes in the same way as it is done with an intra-anal probe.

Before the current trial, it remained unknown whether both techniques have the same efficacy or one of them provided a greater effect than the other, as there were no papers published on the matter.

After analyzing our data, the differences in grams of urine loss between the intra-anal group and the surface group are not statistically significant, and the mean of both differences lies within the established equivalence margins, between −22g and 22 g (12.7 g in the ITT analysis and −13.3 g in the PP analysis). Even so, and due to the great variability of grams that the 24h-Pad test presents which translates into large standard deviations, the CIs exceed the limits of equivalence and the results are not conclusive; therefore, it cannot be inferred that there is a therapeutic equivalence between the studied techniques. However, both techniques have achieved a statistically significant reduction in urine losses after 10 weeks of treatment (231.9 g in the IG and 245.2 g in the CG), this being a notorious decrease in the amount of urine loss for patients that become clinically relevant.

Recently, a study by Bernardes et al.[15] who evaluated the impact of post-prostatectomy UI on the QoL of the participants with the ICIQ-SF questionnaire, as was done in the present work, concluded that there is a significant impact on the QoL of men and that this problem deserves interventions to control it.

On the contrary, Nilssen et al.[16] studied the effect of postoperative PFMT on QoL parameters in patients treated with RP and observed that, although training of the pelvic floor muscles guided by physical therapists after RP significantly improved postoperative UI compared to those patients receiving standard care/training, this progress was not reflected in a better result on health-related QoL indicators.

Nevertheless, in the present study, there is evidence of an improvement in the QoL of the participants from the beginning to the end of the treatment, according to the scores obtained with the I-QOL and SF-12 questionnaires (mental and physical dimensions). At the end of treatment, a decrease in the initial perception of the severity of UI was also observed, measured with the ICIQ-SF questionnaire.

The questionnaires show that UI seriously alters QoL and affects people who suffer it in all aspects of their lives: Personal, work, family, social, and psychological.

It is well known that during the first year after surgery there is an evolution of UI,[17,18] however our clinical

experience indicates that patients who have not reversed their UI after 8 months hardly continue to improve appreciably, this fact undermining their self-esteem if they do not undergo treatment.

Finally, taking into account that intra-anal application of ES can be annoying for some patients and that this trial demonstrates no statistical differences in outcomes for the studied variables between intra-cavitary and transcutaneous ES, the results presented provide evidence of the usefulness of the transcutaneous application of ES in clinical practice.

5 | CONCLUSIONS

The results on the therapeutic equivalence between ES applied with surface electrodes and ES applied with the intra-anal probe are not conclusive and, therefore, it has not been possible to establish equivalence between both therapeutic modalities. Nonetheless, the differences in grams of urine loss throughout the treatment between the intra-anal and the surface groups are not significant, suggesting that the efficacy of the two treatments is not statistically different.

ES administered either with the intra-anal probe or surface electrodes involves a remarkable, clinically relevant decrease in the grams of urine loss in 24 h throughout the different treatment periods (after 5 weeks of treatment and after 10 weeks of treatment).

The use of ES improves the QoL of the participants equally in both modes of application.

ACKNOWLEDGMENTS

RAPbarcelona Physiotherapy Clinical Center and Instituto Médico Tecnológico Clinical Center, for contributing to the implementation of the clinical trial and data collection. Partially funded by a grant from the Societat Catalano-Balear de Fisioteràpia, Acadèmia de Ciències Mèdiques i de la Salut de Catalunya i de Balears (V Basic research grant in Physiotherapy).

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

This study has been fortunate to receive input and advice from a wide range of experts in their respective fields. Inés Ramírez-García and Regina Pané-Alemany were responsible for study concept and initial design. Both of them wrote the first draft of the manuscript and were involved in the interpretation and critical review of the manuscript. Regina Pané-Alemany and Emília Sánchez Ruiz were responsible for study design and statistical analysis. Regina Pané-Alemany and Andrea Carralero-Martínez were responsible for the acquisition of data and test reporting. Stéphanie Kauffmann and Laia Blanco-Ratto reviewed the scientific literature. All authors approved the final version of the manuscript.

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How to cite this article: Pané-Alemany R, Ramírez-García I, Kauffmann S, Blanco-Ratto L, Carralero-Martínez A, Sánchez Ruiz E. Efficacy of transcutaneous perineal electrostimulation versus intracavitary anal electrostimulation in the treatment of urinary incontinence after a radical prostatectomy: Randomized controlled trial. *Neurourol Urodyn*. 2021;1-9.
https://doi.org/10.1002/nau.24740