Evaluation of the 24-h pad weight test as continence rate assessment tool after artificial urinary sphincter implantation for postprostatectomy urinary incontinence: A Swedish retrospective cohort study

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CLINICAL ARTICLE

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Evaluation of the 24-h pad weight test as continence rate assessment tool after artificial urinary sphincter implantation for postprostatectomy urinary incontinence: A Swedish retrospective cohort study

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Abstract

Aim: Patient-reported pad-count as continence rate assessment tool after artificial urinary sphincter (AUS) implantation is common. However, lack of standardized continence definition using this method results in heterogeneous published efficacy outcomes. Data on 24-h pad weight tests (PWT) after primary AUS implantation for postprostatectomy urinary incontinence (PPUI) is scarce.

Our aim was to evaluate the 24-h PWT as an efficacy assessment tool and correlate it to qualitative outcomes using validated questionnaires.

Methods: This retrospective, single center, follow-up cohort study, evaluated 180 patients who underwent primary AUS implantation for PPUI from 2005 to 2018. Voiding diaries, 24-h PWT, validated patient satisfaction and quality of life (QoL) questionnaires were collected pre-operatively and at 3–6 months postactivation, using the institution's Electronic Medical Records.

Results: The median preoperative and postoperative 24-h PWT values were 494 (interquartile range [IQR]: 304–780) and 7 (IQR: 0–25) g respectively with a significant improvement in urinary leakage of 489.5 g 99.1% ($p < 0.001$). Median preoperative and postoperative I-QoL results increased from 33.5 (IQR: 19.3–63.6) to 86.4 (IQR: 73.9–94.3) points, with a significant 52.9 points improvement in QoL ($p < 0.001$). Similarly, the median preoperative and postoperative ICIQ-SF values decreased from 20 (IQR: 17–21) to 5 (IQR: 3–9)

points, showing a significant improvement of 15 points ($p < 0.001$). We also found a significant correlation between PWT and patient satisfaction.

Conclusion: The 24-h PWT provides a reliable and objective assessment of continence rates, with a strong correlation to qualitative outcomes, after primary AUS implantation for PPUI. Its use could help reduce reported outcome heterogeneity across studies.

KEYWORDS

artificial urinary sphincter, pad test, postprostatectomy urinary incontinence, quality of life, urinary incontinence

1 | INTRODUCTION

Patient-reported pad use as a tool for urinary incontinence (UI) efficacy assessment after artificial urinary sphincter (AUS) surgery is widely used.[1–3] Nonetheless, continence definitions based on patient-reported pad count are not standardized.[4,5] Consequently, result heterogeneity for success rate after AUS implantation varies considerably in the literature. For instance, continence achievement in terms of dry rate, that is, "*zero pad*," ranges from 4.3% to 85.7% and when social continence i.e "*0-1 pad*" definition is used, the percentages vary between 59% and 90%.[5,6]

Indeed, some authors suggest that pad tests should replace the pad count as an objective measure of UI when an accurate evaluation is recommended for research or clinical purposes.[7] Furthermore, pad weight tests are useful to assess postprostatectomy urinary incontinence (PPUI) severity (LE 1-2: grade of recommendation B).[2,5] However, there are no data on 24-h pad weight test (PWT) conducted before and after primary AUS implantation in patients with PPUI.

In addition, the FDA recommends that clinical investigations of implantable devices indicated for the treatment of UI "*should include pad weight testing to document quantitatively the severity of urine leakage at baseline*," either the 1-h in-clinic provocative pad weight test or three 24-h in-home pad weight tests (*Guidance for Industry and FDA staff, Clinical Investigations of Devices Indicated for the treatment of Urinary Incontinence; document issued on March 8, 2011*) (Annex 1). Finally, to our knowledge, patient qualitative outcomes correlation to pad-tests after AUS surgery for PPUI has been reported in only one prospective study.[8]

The aim of this study was to evaluate the 24-h PWT as a continence efficacy assessment tool in patients who underwent primary AUS implantation for PPUI. Correlation to qualitative outcomes was also analyzed using validated questionnaires.

2 | MATERIALS AND METHODS

2.1 | Study design

This is a retrospective, single tertiary center, cohort follow-up study of 180 consecutive men who underwent primary AUS implantation, by the same surgical team, between 2005 and 2018 at Karolinska University Hospital, Sweden.

2.2 | Inclusion and exclusion criteria

The study included men suffering from UI after radical prostatectomy. Only patients undergoing primary AUS implantations, that is, patients with no previous AUS surgery were considered. Those with prior history of failed UI procedures, such as Bulking agents, Advance slings, ATOMS, or ProACT were included, provided that they continued to exhibit persistent severe UI.

2.3 | Data collection

We retrospectively gathered data using the institution's Electronic Medical Record system existing since 2004. Over the past 15 years, we have implemented the use of the 24-h PWT, as well as gathered pre-and postoperative qualitative outcomes after AUS implantation, using international validated questionnaires.

The department's urotherapy team assisted the urologists with providing verbal and written information on the completion of the 24-h PWT and handing out an "*Urinary Incontinence Kit*" to patients before their first outpatient clinic appointment for UI assessment, and at 3–6 months post AUS activation. The kit contains an *information leaflet* on the completion of the 24-h PWT, a *two-day voiding diary*, an *International Consultation on Incontinence Questionnaire Short Form"* (ICIQ-UI SF)

(https://iciq.net/licences), and the *"Incontinence Quality of Life"* (I-QoL) (http://depts.washington.edu/seaqol/)[9] questionnaires. Patients were requested to fill the voiding diary on nonconsecutive days, a day where they are at home and a day when more active, to better assess the stress component of their symptoms.[10,11]

2.4 | Statistical analysis

The *Stata/SE 15.0* software was used. Descriptive statistics for main outcomes, that is, 24-h pad weight, were calculated. Statistical significance was defined as $p < 0.05$ for all analysis. The Wilcoxon signed rank test for paired comparison was used for comparing preoperative and postoperative data. Data is presented as median values and interquartile range (IQR).

A Spearman's correlation (r_s) was run to assess the correlation between the 24-h PWT, I-QoL, and ICIQ-UI SF. A correlation of $r_s = 0.2$–0.39 was considered as weak, $r_s = 0.4$–0.59 moderate, $r_s = 0.6$–0.79 strong, and $r_s = 0.8$–1.0 as a very strong correlation.

2.5 | Ethical considerations

The study obtained ethical approval from the Regional Ethical Review Committee.

2.6 | Funding

The project was funded by two regional grants awarded by the Swedish Urology Association (Svensk Urologisk Förening) and the Thure & Britta Grafströms Foundation.

3 | RESULTS

3.1 | Study flow and inclusion

A total of 221 registered patients underwent AUS implantation between 2005 and 2018. Forty-one patients were excluded: 3 women, 23 cases in which UI was not secondary to PPUI and 12 men with secondary AUS implantation. Additionally, 2 patients had no available pre- and postoperative data on the 24-h PWT or the QoL questionnaires. Additionally, another patient had a failed AUS procedure due to an intraoperative urethral injury and the surgery was therefore abandoned. Consequently, a total of 180 men were included.

3.2 | Continence outcomes

Mean reported 24-h PWT in grams (g) was available in 99.5% (179/180) of patients pre-operatively and in 87.8% (158/180) postoperatively. The percentage of patients who adequately completed the pad test both preoperative and postoperatively amounted to 87.2% (157/180).

Median preoperative and postoperative 24-h PWT values were 494 (IQR: 304–780) and 7.0 (IQR: 0–25) g respectively. The results are represented in Table 1.

Out of the 157 patients who successfully completed both preoperative and postoperative pad weight tests, a paired comparison was performed showing a significant decrease in urinary leakage comparable to the data found when using all measurements, $p < 0.001$ (Figure 1).

TABLE 1 Median preoperative and postoperative improvement in continence and qualitative outcomes showing: (A) median decrease in urinary leakage (grams); (B) median increase in QoL using the I-QoL index; an increase in I-QoL index indicates an increase in QoL; (C) median increase in QoL using the ICIQ-UI SF score; the higher ICIQ-UI SF score the lower QoL

Variable	*N*	Median	IQR	*p* value
All measurements				
Pre PWT	179	494.0	304–780	$p < 0.0001$
Post PWT	158	7.0	0-25	
Paired measurements				
Pre PWT	157	490.0	295–767	$p < 0.0001$
Post PWT	157	7.0	0-25	
All measurements				
Pre I-QoL	138	33.5	19.3–63.6	$p < 0.0001$
Post I-QoL	118	86.4	73.9–94.3	
Paired measurements				
Pre I-QoL	98	35.2	21.6–51.1	$p < 0.0001$
Post I-QoL	98	86.4	73.9–94.3	
All measurements				
Pre ICIQ-SF	123	20	17–21	$p < 0.0001$
Post ICIQ-SF	39	5	3–9	
Paired measurements				
Pre ICIQ-SF	36	19	17–20	$p < 0.0001$
Post ICIQ-SF	36	4.5	3–8.5	

Abbreviations: ICIQ-UI SF, International Consultation on Incontinence Questionnaire Short Form; I-QoL, incontinence quality of life; PWT, pad weight test.

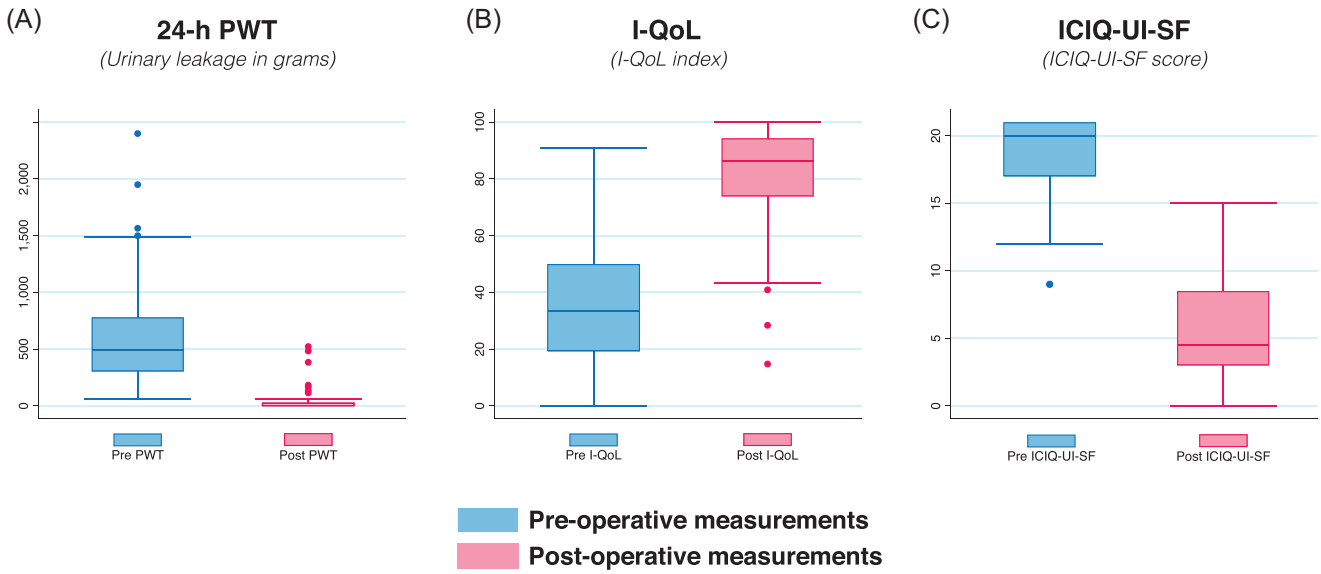

FIGURE 1 Paired comparison in continence and qualitative outcomes showing significant improvement after surgery ($p < 0.001$): Significant decrease in urinary leakage after surgery. Paired comparisons of $n = 157$ patients who had successfully reported 24-h PWT both preoperatively and postoperatively. Significant increase of quality of life according to I-QoL index. Paired comparison in $n = 98$ patients who filled in the questionnaire both preoperatively and postoperatively. Significant improvement in QoL shown by a decrease in ICIQ-UI SF score. paired comparison in $n = 36$ patients who filled in the questionnaire both preoperatively and postoperatively. ICIQ-UI SF, International Consultation on Incontinence Questionnaire Short Form; I-QoL, incontinence quality of life; PWT, pad weight test

3.3 | Qualitative outcomes

The survey compliance for quality of life was 76.7% (138/180) for the I-QoL questionnaire pre-operatively and 65.6% (118/180) postoperatively. However, only 54.4% (98/180) adequately completed the I-QoL questionnaire both pre-operatively and postoperatively. We observed a median pre- and postoperative I-QoL index increase from 33.5 (IQR: 19.3–63.6) to 86.4 (IQR: 73.9–94.3) points, with a significant 52.9 points improvement ($p < 0.001$). The results are presented in Table 1. Ninety-eight patients correctly filled in both preoperative and postoperative I-QoL questionnaires and a paired comparison showed a significant increase in QoL comparable to the data found when using all measurements, $p < 0.001$ (Figure 1).

The ICIQ-UI SF had an even lower compliance with only 68.3% (123/180) and 21.7% (39/180) response rates preoperatively and postoperatively. Only 20% (36/180) completed the questionnaire in both instances as instructed. We found that the median pre-and post-operative ICIQ-UI SF values decreased from 20 (IQR: 17–21) to 5 (IQR: 3–9) points, showing 15 points improvement ($p < 0.001$). The results are also summarized in Table 1. Paired comparison for the 36 patients who correctly completed the questionnaire both pre- and postoperatively showed a significant improvement comparable to the data found when using all measurements, $p < 0.001$ (Figure 1).

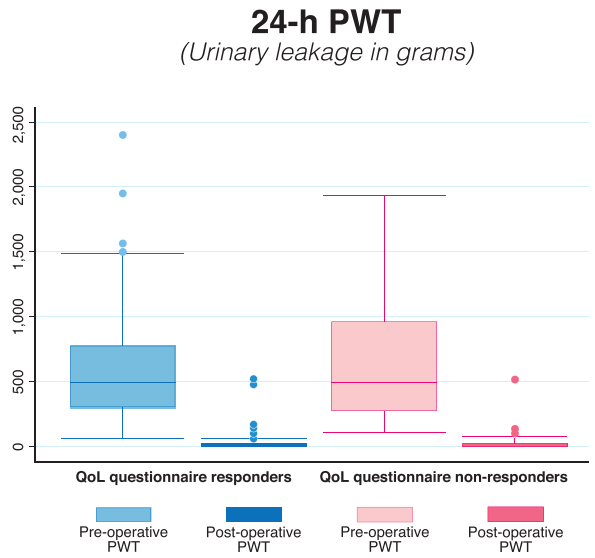

FIGURE 2 Comparison in preoperative and postoperative 24-h PWT between patients who completed postoperative qualitative questionnaires ($n = 120$) and those who did not ($n = 37$). I-QoL, incontinence quality of life; PWT, pad weight test. $p = 0.898$

To further evaluate the low compliance rates in qualitative outcomes and identify causal factors, we have subtracted the 120 patients having completed any pre-and postoperative qualitative questionnaire, from the cohort of 180 patients. These included 16 patients who filled-in a different form preoperatively and postoperatively (e.g., I-QoL

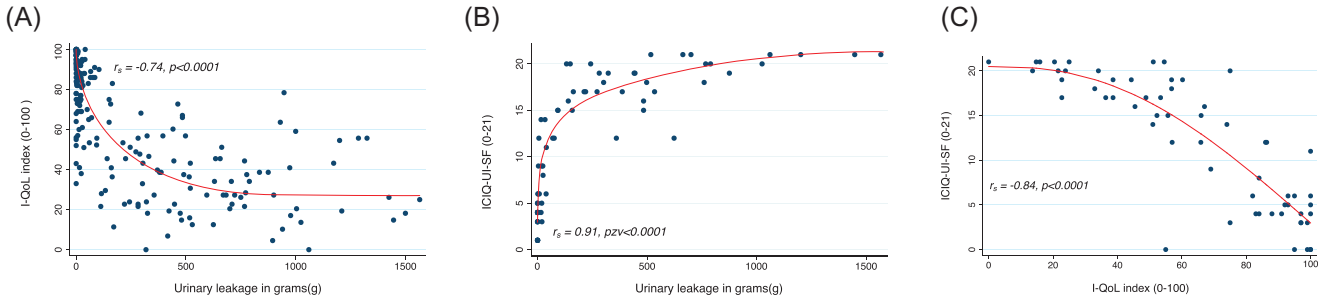

FIGURE 3 Correlation between amount of leakage and quality of life showing: Strong negative monotonic correlation between leakage in (g) and I-QoL index. The correlation shows that an increase in leakage results in a decrease in QoL measured by the I-QoL index. Spearman's correlation $r_s = -0.74$, $p < 0.0001$. Very strong positive monotonic correlation, between leakage in (g) and ICIQ-UI SF score. The plot shows that an increase in leakage results in an increase of the ICIQ-UI SF score. The higher the ICIQ-UI SF score, the lower the QoL. Spearman's correlation $r_s = 0.91$, $p < 0.0001$. A strong negative monotonic correlation was also found between I-QoL and ICIQ-UI-SF measurements in our cohort. ICIQ-UI SF, International Consultation on Incontinence Questionnaire Short Form; I-QoL, incontinence quality of life. Spearman's correlation $r_s = 0.84$, $p < 0.0001$

before surgery and ICIQ-UI SF after). The remaining 33% (60/180) of patients had no available QoL data after AUS implantation.

We found that 15% (9/60) had no pre-nor postsurgical QoL data for which no obvious reason was found. An additional 18% (11/60) were explanted before AUS activation/follow-up and 20% (12/60) were followed-up in another center. This leaves us with 46% (28/60) who filled-in preoperative qualitative measurements but failed to answer any questionnaire after AUS implantation.

No difference in urinary leakage improvement between those who did not fill-in their postoperative QoL-questionnaires and those who did ($p = 0.898$, Figure 2) was observed, nor did we find increased postoperative complications or adverse events upon activation in this subgroup.

3.4 | Correlation between amount of leakage and quality of life

A Spearman's rank correlation (r_s) was performed to evaluate the relationship between the amount of leakage (24-h PWT) and I-QoL, using measurements from the 98 patients who successfully completed the questionnaire both before and after AUS implantation. We found a strong negative correlation between the amount of leakage measured by the 24-h PWT and I-QoL, which was statistically significant, with $r_s = -0.74$, $p < 0.0001$, as shown in Figure 3.

Similarly, the Spearman's rank correlation (r_s) was run to assess the correlation between the 24-h PWT and ICIQ-UI SF, using a sample of 35 patients. A very strong positive correlation was found, which was also statistically significant, with $r_s = 0.91$, $p < 0.0001$, as presented in Figure 3. The strong correlation seen in both cases shows that there is a robust monotonic correlation between improvement in QoL in relation to a decrease in urinary leakage. We also ran a Spearman's rank correlation (r_s) on the 36 patients having successfully filled in both I-QoL and ICIQ-UI SF and reported a very strong negative correlation between both surveys, with $r_s = -0.84$ (Figure 3).

4 | DISCUSSION

To our knowledge, this is the first retrospective cohort follow-up study and the largest of its kind, which assesses AUS continence rates using the 24-h PWT in men with PPUI. In addition, the fact that our institution is a tertiary center contributes to reduce selection bias. Our results show a significant decrease in postoperative pad weight at 3–6 months post-device activation compared to baseline preoperative values. Our results are within the reported ranges of 59%–90% when continence rate post-AUS implantation is defined as "*zero to one pad/day*."[5,7]

Interestingly, the compliance for both preoperative and postoperative 24-h PWT completion was very high, 87.8%. This further supports that this test is a reproducible and reliable tool to measure urine leakage, as stated by various authors.[1,2,7] Sacco et. al also showed the absence of correlation between pad weight test and pad count.[7] Due to the poor pad count information available from our records, we were unable to conduct a proper comparison between the two assessment tools, which would have brought additional valuable information. Historically, our institution has performed the 24-h PWT as an objective continence assessment tool since 2005. Our standard practice is to

hand out the "*Urinary Incontinence Kit*" to the patient, as described above, which accounts for the poor pad count reporting in this study.

On the other hand, preoperative and postoperative compliance rates were much lower when assessing qualitative outcomes, with preoperative I-QoL and ICIQ-UI SF response rates of 76.7% and 68.3% falling to 65.6% and 21.7% postoperatively respectively. The compliance rates for validated patient satisfaction questionnaires, both preoperatively and postoperatively, was surprisingly low for I-QoL (54.4%) and even lower for ICIQ-UI SF surveys (20%).

The explanation is multifactorial. Low patient compliance in completing and returning postoperative questionnaires is a classical finding in clinical practice, in spite of significant efforts invested in postoperative data gathering. It is also possible that patients who are sufficiently satisfied with their postoperative results may deem unnecessary to complete/return the surveys. One may similarly surmise that poor postoperative outcomes might prompt unwillingness to comply. Furthermore, awareness of the importance of questionnaire data collection and/or reporting for quality control and research purposes may vary among urologists. Finally, clerical failure to electronically archive the completed forms may equally have played a role.

Two thirds of patients in our cohort have responded to both preoperative and postoperative qualitative measurements. No difference in urinary leakage improvement nor increased complication rates or adverse events on AUS activation was observed, compared to those who did report postoperative qualitative data.

We believe that these findings constitute a strength to our study, as they motivate the development of alternative solutions to help improve patient compliance. The implementation of the use of online forms is ongoing in our department. However digital illiteracy, poor eyesight/hand function or dependance on a next of kin for help are among the most frequent challenges encountered. Alternatively, software creation, such as mobile applications for QoL control are worth considering, bearing in mind the ensuing related data confidentiality issues.

Moreover, we reported a high QoL improvement, in keeping with the reported high satisfaction rates in the literature. Comparison with other studies remains challenging, due to the fact that various types of questionnaires were used [6,10–14] and bearing in mind the short to midterm character of our results. Data on QoL after AUS for PPUI is a relatively recent concept, and few data are actually available in the literature. Most studies have used Lickert scales, non-validated questionnaires and subjective qualitative assessments tools, as stated by Van der Aa and Averbeck.[5,6]

When looking into secondary outcomes, we have shown that lower pad weights correlated with a higher quality of life in a strong monotonic relationship. In other words, the more continent the patient will be, the higher the likelihood that QoL would improve. Our study is in keeping with the findings of Nitti et. al., who have previously reported a correlation of pad weight with quality of life in a prospective cohort of 235 patients.[8]

When calculating the correlation between PWT and I-QoL, as well as PWT and ICIQ-UI SF, a strong correlation in both cases was observed; however, it is noteworthy to mention that even patients achieving zero-gram leakage failed to reach the highest levels for the I-QoL. This may be attributed to other factors that may influence patient quality of life, which the design of the ICIQ-UI SF and I-QoL questionnaires fail to evaluate, such as the poor AUS scrotal pump ergonomics or persistent erectile dysfunction. Interestingly, the correlation curve between ICIQ-UI SF and 24-h PWT revealed a logarithmic pattern, implying that patient dissatisfaction and quality of life were affected even by a small amount of urine leakage. Adding validated erectile dysfunction questionnaires, patient satisfaction of the use of the AUS as well as new Patient Reported Outcome Measures could add some insight in future prospective studies. Additionally, some patients report high satisfaction rates although they are not completely dry, which is the case of 59% as stated by Averbeck.[5] Further improvement in patient satisfaction assessment is required in AUS studies.

Although our study shows that the PWT is a feasible, objective and reproducible tool, it has its weaknesses. The retrospective, single-center design and short follow-up cohort aspects of this study constitute its main drawbacks. To address the lack of data regarding 24-h PWT as an assessment tool for AUS implantation for PPUI, a retrospective analysis is often the first step before considering prospective and randomized studies. Furthermore, many centers in Sweden and worldwide still use the pad count as an effectiveness tool after AUS surgery, which makes it even more difficult to collect multi centric retrospective long-term data using this tool.

In addition, multi-center, randomized control trials are costly and funding for functional urology-related clinical research is not easily available in Nordic settings, especially for functional evaluation and quality of life studies. The results of the MASTER trial,[15,16] a randomized non-inferiority controlled study comparing male slings and AUS (article in press), showed an overall preoperative response rate of 83.7% (159/190) and only 27.8% (44/158) postoperatively using the 24-h PWT to assess urinary leakage. The authors acknowledged in

their discussion, that the 24-h PWT was "*A useful metric at baseline*" and stated that "*From experience that it would probably be hard to get a lot of men to repeat their 24-h pad tests at 12 mo if they were more or less dry, and the research nurses confirmed this to be so*."[16] In our study higher pre-and postoperative response rates of 99.5% and 87.8% at 3 months respectively were observed and it would be interesting to compare outcomes at 12 months in the near future.

These results allow us to take a step closer to implementing changes in international practices by encouraging the adoption of the 24-h PWT, as recommended by the FDA for AIMDs.

Similarly, the PROSPECT study, (https://clinicaltrials.gov/ct2/show/study/NCT03323554) a randomized prospective international study evaluating the efficacy and safety of the Ustrap device comparatively with the AMS 800 for the treatment of postprostatectomy stress UI also uses the 24-h pad weight test as UI assessment tool. Both studies will help fill the gap on much needed information regarding the use of this tool in a very near future. In the meantime, our study endeavors in contributing to reduce reported outcome heterogeneity across studies.

5 | CONCLUSION

This retrospective cohort study shows that the 24-h PWT is a reliable, accurate and reproducible continence rate assessment tool that could be used for standardized continence definition and help reduce reported outcome heterogeneity across studies. We show that a low postoperative 24-h PWT is correlated with high patient satisfaction and quality of life, using validated questionnaires. We therefore recommend its use over pad count whenever accurate and objective evaluation is required for research and clinical purposes.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Christine Reus completed data collection, analysis/interpretation and drafted the manuscript. Izabelle Brattås completed data collection, analysis/interpretation, helped drafting the manuscript and critically revised the manuscript. Daniela Volz and Filip Sydén completed data collection, analysis/interpretation and critical revision of the manuscript. Katarina Hallén Grufman completed study design, drafted the ethical approval application, analysis/interpretation, critical revision and approval of the manuscript. Pierre Mozer completed study design, statistical analysis support, critical revision of the article and article approval. Lotta Renström-Koskela completed study design and concept, project supervision, data collection, analysis/interpretation, statistical analysis, critically revised and approved the manuscript. All authors provided critical feedback and helped shape the research, analysis and manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ANNEX 1: FDA DOCUMENT

Guidance for Industry and FDA staff, Clinical Investigations of Devices Indicated for the treatment of Urinary Incontinence; document issued on March 8, 2011.

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