Pad Weight, Pad Number, and Incontinence-Related Patient-Reported Outcome Measures After Radical Prostatectomy

Cecile T. Pham,[1] Manish I. Patel,[✉1,2] Sean F. Mungovan[3,4]

[1]Specialty of Surgery, Faculty of Medicine and Health, University of Sydney, Camperdown, Australia [2]Department of Urology, Westmead Private Hospital, Westmead, Australia [3]Westmead Private Physiotherapy Services, Westmead, Australia [4]The Clinical Research Institute, Westmead, Australia

Abstract

Objectives To evaluate the correlation between 3- and 6-week postoperative 24-hour pad weight, daily pad number, and the International Consultation on Incontinence Questionnaires for Male Lower Urinary Tract (ICIQ-MLUTS), ICIQ-Short Form (ICIQ-SF) and UCLA Prostate Cancer Index (UCLA-PCI) in patients undergoing robotic-assisted radical prostatectomy (RARP).

Methods This prospective study included patients undergoing RARP between February and November 2019. Patients completed a 24-hour pad test, assessing pad weight and number, and 3 validated patient-reported outcome measures (PROMs); the ICIQ-MLUTS, ICIQ-SF and UCLA-PCI, preoperatively and at 3 and 6 weeks postoperatively.

Results A total of 47 patients were included in the study. There was a strong correlation between 24-hour pad weight and the ICIQ-SF at 3 weeks ($r = 0.71$, $P < 0.001$) and 6 weeks ($r = 0.68$, $P < 0.001$). There was a strong correlation between 24-hour pad weight and ICIQ-MLUTS incontinence ($r = 0.80$, $P < 0.01$) and incontinence QoL burden ($r = 0.79$, $P < 0.01$) at 6 weeks. There was a moderate correlation between the 24-hour pad weight and UCLA-PCI urinary function ($r = 0.58$, $P < 0.001$) and urinary QoL burden ($r = 0.66$, $P < 0.001$) at 6 weeks. The correlation between pad number and 24-hour pad weight was weak at 6 weeks ($r = 0.34$, $P < 0.001$).

Conclusion PROMs may be used as a substitute for the 24-hour pad weight test for post-prostatectomy incontinence (PPI) assessments in the early post-RARP period. The ICIQ-SF and UCLA-PCI urinary function and QoL scores correlate with 24-hour pad weight. However, the ICIQ-MLUTS incontinence and QoL scores provide the strongest correlation with PPI.

Introduction

Prostate cancer is a major public health concern and the second most commonly diagnosed cancer in men globally[1]. Organ-confined disease is treated surgically by radical prostatectomy (RP). Despite improvement in surgical technique, post-prostatectomy incontinence (PPI) affects 49% to 63% of patients in the early postoperative period (first 6 weeks)[2–5]. Estimates of the incidence of PPI and continence recovery time vary because of the lack of a

Key Words

Prostatectomy, prostate cancer, urinary incontinence, surveys and questionnaires

Competing Interests

None declared.

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Abbreviations

BMI body mass index
ICIQ-MLUTS International Consultation on Incontinence Questionnaires for Male Lower Urinary Tract
ICIQ-SF International Consultation on Incontinence Questionnaire Short Form
ICSmaleSF International Continence Society Male Short Form
IQR interquartile range
PPI post-prostatectomy incontinence
PROM patient-reported outcome measure
PSA prostate specific antigen
QoL quality of life
RARP robotic-assisted radical prostatectomy
RP radical prostatectomy
SD standard deviation
UCLA-PCI University of California Los Angeles Prostate Cancer Index

universally accepted definition of continence, the variety of assessment methods used to determine severity of PPI, and variability in PPI assessment time points. In clinical practice, PPI is commonly quantified by patient-recorded numbers of pads used daily. However, some studies have reported that the reliability of pad number may be limited by patient recall and poor correlation with the actual amount of urine loss[6,7]. Pad weight testing protocols are used for the objective measurement of PPI with testing durations ranging from 20 minutes to 72 hours[6,8–10]. Increasing the duration of the testing protocol to 48 or 72 hours increases reliability but has not been recommended, as it can result in decreased patient compliance[10]. The 24-hour pad weight test is considered the gold standard for objective measurement of urinary incontinence[11,12]. However, it can be burdensome and result in poor patient compliance. Moreover, it does not take into consideration other markers of urinary function, such as frequency of incontinence and voiding.

This has led to the development of accessible and validated patient-reported outcome measures (PROMs) for routine PPI assessments. However, there are limited data on whether PROMs for PPI assessment correlate with objective measures and whether they can be used as a reliable substitute for 24-hour pad weight. To our knowledge, no study has compared PROMs with the 24-hour pad weight test in the 6-week period following RP. Commonly used PROMs include the International Consultation on Incontinence Questionnaire for Male Lower Urinary Tract Symptoms (ICIQ-MLUTS), the ICIQ-Short Form (ICIQ-SF) and the University of California Los Angeles Prostate Cancer Index (UCLA-PCI). In this study, we evaluated the correlation between 24-hour pad weight, daily pad number, and the ICIQ-MLUTS, ICIQ-SF and UCLA-PCI in patients undergoing robotic-assisted radical prostatectomy (RARP).

Materials and Methods

Patient selection

Patients undergoing RARP by a single surgeon at a high-volume robotic centre in a private metropolitan hospital were prospectively recruited between February and November 2019 during their initial consultation prior to surgery. Patients who had a history of pad usage, pelvic surgery or pelvic radiotherapy were excluded. This study was approved by the Western Sydney Local Health District Human Research Ethics Committee (ETH02769). All participants provided written informed consent.

Patient-reported outcome measures

The ICIQ-MLUTS is derived from the International Continence Society male short-form (ICSmaleSF) questionnaire and is used to evaluate male lower urinary tract symptoms across multiple domains, including incontinence, voiding, leakage frequency, and impact on quality of life (QoL)[13,14]. The ICIQ-MLUTS is a 13-item questionnaire consisting of 5 items forming the voiding subscale, 6 items forming the incontinence subscale and 2 items regarding leakage frequency. Each item is scored from 0 to 4, and each subscale is calculated. The ICIQ-SF is an abbreviated version that evaluates frequency and severity of urinary incontinence[15]. It consists of 4 items regarding leakage frequency, volume, and impact on QoL. The first 3 items are scored from 0 to 5, 0 to 6 and 0 to 10, respectively, and they are added to produce a total score ranging from 0 to 21. The fourth item allows the patient to report when urinary incontinence occurs and does not contribute to the overall score. The UCLA-PCI assesses the impact of treatment (surgery and/or radiotherapy) on QoL[16]. It is a 20-item questionnaire consisting of function and bother across 3 domains: sexual, urinary, and bowel function. The items are scored from 0 to 100, with higher scores representing better QoL, and an average score for each domain is calculated.

Data collection

At the time of recruitment, each participant's demographic information, including age and body mass index (BMI), and information on prostate cancer disease characteristics, including prostate specific antigen (PSA) and histopathology, was collected. All participants were referred to an independent physiotherapy clinic one month prior to surgery for the prescription of a preoperative pelvic floor muscle training program[17]. All patients were reviewed by the physiotherapist at 3 and 6 weeks postoperatively for a continence review

that included prescription of a postoperative pelvic floor muscle training program, until continence recovery had been achieved. Referral for preoperative physiotherapy is standard of care; however, close postoperative physiotherapy follow-up is not routine.

The patients were asked to complete 3 validated PROMs, the ICIQ-SF preoperatively and at 3 and 6 weeks postoperatively and the ICIQ-MLUTS and UCLA-PCI preoperatively and at 6 weeks postoperatively. At 3 weeks postoperatively, only the ICIQ-SF was conducted because of its brevity.

The patients were also provided with an analytical weighing scale (accurate to 0.1g) and asked to weigh each pad before and after use for 24 hours on 3 consecutive days prior to the 3- and 6-week postoperative assessment. The 24-hour pad weight used in the analysis was the mean 24-hour weight of the 3 consecutive days.

Statistical analysis

Statistical analysis was conducted using IBM SPSS Statistics version 26 (IBM, Armonk, US). P-values < 0.05 were considered statistically significant. Continuous variables were summarized as means and standard deviations or medians and interquartile ranges. The correlations between variables were assessed using Spearman's rank correlation. The strength of the relationships was interpreted as follows: 0 to 0.19, very weak positive correlation; 0.20 to 0.39, weak positive correlation; 0.40 to 0.59, moderate positive correlation; 0.60 to 0.79, strong positive correlation; and 0.80 to 1, very strong positive correlation[18].

Results

A total of 54 consecutive patients were recruited. Five patients were lost to follow-up, and 2 did not complete the PROMs. Thus, a total of 47 patients were included in the analysis. All patients underwent RARP. The patients' demographic, clinical, and operative characteristics are summarized in Table 1. The median preoperative scores for the ICIQ-MLUTS incontinence domain, ICIQ-SF, and UCLA-PCI urinary function domain were 0, 1, and 100, respectively (Table 2).

The mean 24-hour pad weight was 24.2 ± 42.6g (0g to 200g) at 3 weeks and 7.6 ± 17.7g (0g to 77g) at 6 weeks. With continence defined as a 24-hour pad weight of ≤ 1g, 38% and 70% of the patients were continent at 3 and 6 weeks, respectively.

The daily pad number ranged from 0 to 5 at 3 weeks and 0 to 2 at 6 weeks. The pad number correlated strongly with 24-hour pad weight at 3 weeks (r = 0.64, $P < 0.001$) and weakly at 6 weeks (r = 0.34, $P < 0.001$).

The correlations between 24-hour pad weight and the PROMs are shown in Figure 1. There was a strong and statistically significant correlation between 24-hour pad weight and the ICIQ-SF at 3 weeks (r = 0.71, $P < 0.001$) and 6 weeks (r = 0.68, $P < 0.001$).

There was a strong and statistically significant correlation between 24-hour pad weight and ICIQ-MLUTS incontinence (r = 0.80, $P < 0.01$) and incontinence QoL burden (r = 0.79, $P < 0.01$) at 6 weeks. There was a moderate and statistically significant correlation between the ICIQ-MLUTS nocturia score and 24-hour pad weight (r = 0.44, $P = 0.049$) but no significant correlation

TABLE 1.

Demographic, clinical and operative characteristics

Characteristic	Mean ± SD or n (%)	Median (IQR)
Age	65.2 ± 7.6	65 (59–71)
Ethnicity		
Caucasian	34 (72.34)	
Middle Eastern/ Mediterranean	10 (21.28)	
Asian	3 (6.38)	
BMI (kg/m^2)	29.1 ± 4.2	28.3 (59–71)
PSA (ng/mL)	8.5 ± 7	6.8 (4.2–9.2)
Prostate weight (g)	41.2 ± 15.1	40 (30–50)
Gleason grade group		
2	25 (53.19)	
3	15 (31.91)	
4	2 (4.26)	
5	5 (10.64)	
Clinical stage		
T2	17 (36.17)	
T3	30 (63.83)	
D'Amico risk group		
Intermediate	17 (36.17)	
High	30 (63.83)	
Nerve sparing procedure		
Not performed	2 (4.26)	
Unilateral	12 (25.53)	
Bilateral	33 (70.21)	

SD: standard deviation; IQR: interquartile range; BMI: body mass index; PSA: prostate specific antigen

TABLE 2.

Median and interquartile ranges for incontinence assessment methods

	Preoperative	3 Weeks Postoperative	6 Weeks Postoperative
24-hour pad weight (g)	Nil	6 (0–21)	0 (0–4.5)
Pad number	Nil	1 (0–2)	0 (0–1)
ICIQ-SF	0 (0–0)	6 (4–9)	1 (0–6)
ICIQ-MLUTS incontinence score	1 (0–2)		2 (1–4)
UCLA-PCI urinary function score	100 (81–100)		75 (58–100)

PROM: patient-reported outcome measure; ICIQ-SF: International Consultation on Incontinence Questionnaires Short Form; ICIQ-MLUTS, International Consultation on Incontinence Questionnaires for Male Lower Urinary Tract; UCLA-PCI, University of California Los Angeles Prostate Cancer Index

between nocturia QoL burden (P = 0.67) and the 24-hour pad weight. There were no statistically significant correlations between 24-hour pad weight and the other ICIQ-MLUTS domains, including voiding (P = 0.73), voiding QoL burden (P = 0.41), leakage frequency (P = 0.64), and leakage frequency QoL burden (P = 0.44).

There was a moderate correlation between the 24-hour pad weight and UCLA-PCI urinary function (r = 0.58, P < 0.001) and a strong correlation between 24-hour pad weight and urinary QoL burden (r = 0.66, P < 0.001) at 6 weeks. There were no significant correlations between 24-hour pad weight and the UCLA-PCI bowel function (P = 0.41), bowel QoL burden (P = 0.83), sexual function (P = 0.61), or sexual QoL burden (P = 0.31) domains at 6 weeks.

Discussion

This study evaluated multiple methods of assessing PPI to determine the most accurate and reliable. Several assessment methods are currently used, including 24-hour pad weight, pad number and validated PROMs. The 24-hour pad weight test is widely accepted as the gold standard for objective measurement of incontinence but can be burdensome for patients. Most studies require patients to seal used pads in containers to minimize evaporation until the pads are submitted for evaluation. This may be seen by patients as an unacceptable, unsanitary practice and may lead to poor patient compliance[19,20]. A recent study showed that if patients are motivated and well-instructed, pad weight compliance can be high[21]. To increase patient satisfaction and compliance, we provided patients with analytical weighing scales and clear instructions to allow them to perform the measurements themselves at home. Although this was well-received, pad weight measurements can still be a demanding and complex task for patients. To date, there is no consensus on the best substitute for the 24-hour pad weight test for PPI assessment.

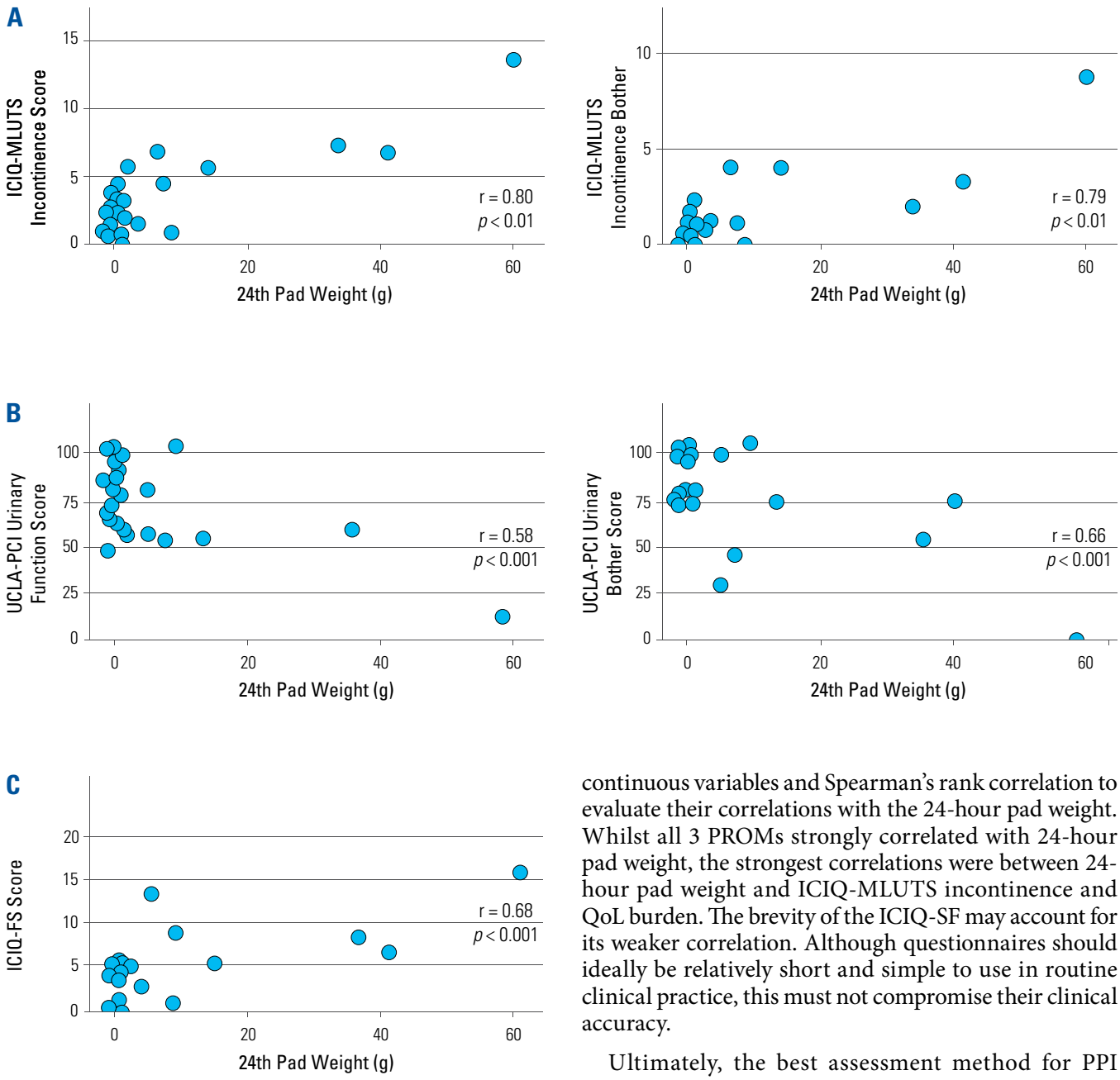
Our study focuses on the early postoperative period, as technical modifications, improvements in surgical technique, and the increasing use of robotic surgery have accelerated continence recovery[4,5,22,23]. Definitions of continence in the literature regarding the early postoperative period vary greatly. We defined continence as a 24-hour pad weight of ≤ 1g. According to this definition, 38% and 70% of our patients were continent at 3 and 6 weeks, respectively. Our study demonstrates that PROMs are reliable substitutes for the 24-hour pad weight test for PPI assessment in the early postoperative period.

The use of the daily pad number as a substitute for 24-hour pad weight remains controversial. Nitti et al.[24] reported a strong correlation between perceived pad use and the 24-hour pad weight. In our study, we found a moderate correlation between pad number and 24-hour pad weight at 3 weeks and 6 weeks postoperatively. This is in line with previous studies reporting that the pad number is not a reliable measure of incontinence[4,5,21]. Patients may change pads for a variety of reasons, including differing acceptable hygiene and pad wetness levels, convenience, and financial or physical access to pads. As previous studies did not evaluate pad number reliability specifically for PPI, our study serves to validate this finding in a post-prostatectomy population.

PROMs rely on the patients' own perceptions of their incontinence symptoms and their effect on QoL. Although many PROMs are used to assess incontinence, thus far, there is no universally accepted PROM. We assessed the correlation between 24-hour pad weight and both generic and condition-specific PROMs. Previous studies have attempted to define continence using such PROMs. Some have defined continence as an ICIQ-SF score equal to or less than the preoperative score[25]. Ito et al.[26] recently categorized ICIQ-MLUTS scores amongst men seeking treatment for bothersome lower urinary tract symptoms as mild to moderate (incontinence score of 16 to 25 and bother, ie, QoL burden, score of 22 to 80) and moderate to severe (incontinence score of ≥ 26 and bother score of ≥ 81) allowing LUTS to be expressed as categorical

FIGURE 1.

Scatter plot showing the correlation between 24-hour pad weight and (A) ICIQ-MLUTS incontinence score and bother (B) UCLA-PCI urinary function and bother (C) ICIQ-SF score at 6 weeks following RARP.
(r = Spearman's rank correlation coefficient, *P* = *P* value)



values. Whilst these banding ranges can provide an indication of an individual's LUTS severity relevant to a broader cohort, they do not provide a clear correlation with 24-hour pad weight. Moreover, as these PROMs are subjective measures of incontinence severity, it is difficult to determine a definitive cut-off score for continence. For this reason, we used the PROM scores as continuous variables and Spearman's rank correlation to evaluate their correlations with the 24-hour pad weight. Whilst all 3 PROMs strongly correlated with 24-hour pad weight, the strongest correlations were between 24-hour pad weight and ICIQ-MLUTS incontinence and QoL burden. The brevity of the ICIQ-SF may account for its weaker correlation. Although questionnaires should ideally be relatively short and simple to use in routine clinical practice, this must not compromise their clinical accuracy.

Ultimately, the best assessment method for PPI depends on the clinical context. PROMs can be used as a convenient and reliable substitute for 24-hour pad weight, particularly for routine PPI assessment. However, 24-hour pad weight remains important for situations when objective assessment is required, such as the decision to proceed to invasive therapy for PPI and monitoring of treatment response.

Our study has several limitations. We assumed that 24-hour pad weight is completely objective and did

not consider variables that may have affected it, such as activity level and fluid intake[6,27]. This is a small, single-surgeon series, which may introduce patient selection bias and may not be representative of the broader RARP population. A larger, multicentre study should be considered to confirm our findings. Furthermore, 6 weeks is a short follow-up period and correlation between 24-hour pad weight and PROMs may vary at greater follow-up intervals. However, our study focused on the early postoperative period because this is when incontinence is most significant. A large proportion of our cohort (70%) had reached continence by 6 weeks. Beyond 6 weeks, the proportion of incontinent men is small and we did not feel that it would be meaningful to compare PPI assessment methods when the range of PPI symptoms is not appreciable.

Conclusion

PROMs may be used as a substitute for the 24-hour pad weight test for PPI assessment in the early post-RARP period. ICIQ-SF and UCLA-PCI urinary function and QoL scores strongly correlate with 24-hour pad weight. However, the ICIQ-MLUTS incontinence and QoL scores provide the strongest correlation with PPI.

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