

Prospective evaluation of urinary continence after laparoscopic radical prostatectomy using a validated questionnaire and daily pad use assessment: which definition is more relevant to the patient's perception of recovery?

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Introduction No standard definition for urinary continence after radical prostatectomy exists, and there are discrepancies in continence rates reported in the literature, as well as rates reported by physicians and patients. Therefore, we used two tools, a validated questionnaire and daily pad use, to identify the criteria that best reflects patients' perceptions of continence recovery.

Material and methods This is a prospective study of 74 patients who underwent nerve-sparing laparoscopic radical prostatectomy. Continence was assessed monthly for 3 months following catheter removal using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) and by recording the number of pads the patients used on a daily basis. According to daily pad use, patients were categorized as either dry (no-pads), socially continent (0–1 pad) or incontinent (≥ 2 pads).

Results Seventy-four patients were enrolled with a mean age of 64.3 (± 5.6) years. There were no significant differences in continence rates using scores from the International Consultation on Incontinence Questionnaire- Short Form (ICIQ-UI SF) or no-pad use (29.7% vs 32.4%, 45.9% vs 48.6% and 54.1% vs. 54.1%, at the 1-, 2- and 3-month follow-ups, respectively). However, the number of socially continent patients was significantly higher (59.5%, 70.3% and 81.1%, at the 1-, 2- and 3-month follow-ups, respectively [$p < 0.001$]).

Conclusions The totally dry definition better reflected patients' perceptions rather than the socially continent definition for the evaluation of continence recovery following laparoscopic radical prostatectomy. To avoid discrepancies, we recommend the use of a validated questionnaire as well as the no-pad definition to standardize the reporting of post radical prostatectomy continence rates.

Key Words: daily pads \leftrightarrow prostate cancer \leftrightarrow questionnaire \leftrightarrow radical prostatectomy \leftrightarrow urinary continence

INTRODUCTION

Prostate cancer is the second most commonly diagnosed cancer in men, with an estimated 1,276,106 new cases reported globally in 2018 [1]. While survival benefits and free surgical margins remain the

critical goals, the effect of a radical prostatectomy on a patient's quality of life remains an important issue. Post-prostatectomy urinary incontinence has been reported in 4% to 31% of patients, and has a considerable effect on physical activity, as well as social and psychological well-being [2, 3].

In comparison to open surgery, minimally invasive approaches such as laparoscopy and robotic-assisted laparoscopic radical prostatectomy offer a more rapid convalescence, less postoperative pain, shorter hospital stays, and better cosmetics of the surgical wound. However, these procedures offer no advantages in regard to urinary continence recovery [4, 5]. Patient preoperative clinical characteristics should be carefully considered to assess the risk of post-prostatectomy urinary incontinence. Ages greater than 75 years, a high body mass index (>30), poor overall health, a large prostate volume, and previous prostate surgery are all recognized risk factors [6, 7, 8]. Currently, no standard definition for continence exists. In some reports, continence is defined as 'no-pad' use, while others consider continence to include patients reporting the use of 1 pad per day, termed a 'safety-pad'. Several questionnaires, including the International Consultation on Incontinence Questionnaire- Short Form (ICIQ-UI SF), the Enlarged Prostate Cancer Index Composite and the Overactive Bladder questionnaire are considered reliable and useful tools for the evaluation of urinary function following radical prostatectomy [9, 10, 11]. The literature has addressed discrepancies between urinary continence rates assessed using physicians' interviews that enquire about daily pad use, as well as reports of the patients' perspectives [12, 13]. Therefore, our study aimed to identify the criteria that best reflect patients' perceptions of continence during the first 3 months following radical prostatectomy to avoid possible discrepancies in perceptions between patients and physicians and allow for better reporting of continence rates following radical prostatectomy.

MATERIAL AND METHODS

A total of 74 patients diagnosed with organ confined prostate cancer were assessed for eligibility to participate in the study. All patients required surgical intervention and provided written informed consent to participate and for their data to be published. The present study protocol was reviewed and approved by the Ethics Committee of the Faculty (IRB No. 00012098, FWA No. 00018699).

The inclusion criteria were patients with clinically localized prostate cancer who underwent nerve-sparing laparoscopic radical prostatectomy and had the ability to give fully informed consent. Exclusion criteria included patients with neurogenic bladders and urinary incontinence before surgery.

All patients underwent standard urological preoperative evaluations. This entailed taking medical histories and performing clinical examinations which

included a digital rectal examination, urine analysis and culture, and routine blood chemistry (including total prostate-specific antigen [PSA]). Trans-rectal ultrasound-guided core biopsies were performed on all patients, and further imaging studies (multiphasic computed tomography, multi-parametric magnetic resonance imaging, and radioisotope bone scans) were performed according to the clinical situation.

Urinary continence was assessed at 1, 2 and 3 months after catheter removal. The validated International Consultation on Incontinence Questionnaire- Short Form (ICIQ-UI SF) questionnaire was used for assessment at each follow-up session, after obtaining permission from the International Consultation on Incontinence (ICIQ) study group [12]. This questionnaire has been validated for multiple languages according to the International Conference on Incontinence grades of recommendation. The scoring system ranged from 0 to 21, with greater values indicating increased incontinence severity. Four continence categories were used: continent (0), mild incontinence (1–8), moderate incontinence (9–13), and severe incontinence (14–21). Each patient's questionnaire results were considered to be the patient's perceptions of urinary continence. To encourage our patients to comply and complete the questionnaire, we explained the benefit of this validated tool to evaluate their current continence status and to guide any further treatment options available, aiming to hasten recovery or improve continence. We also told our patients they could either complete it during the clinic-visit where they could discuss any unclear questions or take it home and bring it back on the next follow-up visit.

Continence was also assessed at the same follow-up session by directly interviewing the patients about the number of pads used per day. Three categories were defined: totally dry (no pad), socially continent (0–1 pad), and incontinent (≥ 2 pads).

Regarding postoperative rehabilitation, we counseled our patients about the current available data, drawn from the updated available guidelines and literature review, of the role of early postoperative pelvic floor muscle training in hastening (rather than increase rate) continence recovery. Half of our patients practiced pelvic floor muscle training at home after appropriate counseling from a specialized physiotherapist.

Statistical analysis

The Kolmogorov-Smirnov test was used to verify the normality of the distribution of variables. Comparisons between the three follow-up months for different categorical variables were assessed using the

Friedman test and Dunn's post hoc test for pairwise comparisons. Cochran's test was used to compare the follow-up months for two categorical variables and Dunn's test for pairwise comparisons. We compared the questionnaire scores with the total number of pads used per day using McNemar's chi-squared test. Significance was defined as $p \leq 0.05$. All data were analyzed using IBM SPSS software package version 20.0. (IBM Corp., Armonk, NY, USA).

RESULTS

1. Baseline and clinical data:

Seventy-four patients were included in the study. The average age was 64.3 (± 5.6) years with a mean hospital stay of 3.7 (± 1) days. Clinical data regarding patient preoperative PSAs, clinical tumor stages and Gleason scores of the biopsies are shown in Table 1.

2. Urinary continence assessments:

Results from the questionnaire scores showed that 22, 34 and 40 patients were continent (0 score) at the 1-, 2-, and 3-month follow-ups, respectively (Table 2). According to these results, there was a continence rate of 54.1% at the end of 3 months. Other degrees of post-prostatectomy urinary incontinence were classified based on the scores at different time points.

An analysis of each question (Table 3) showed a significant score decrease from the first month to the end of the third month.

According to the number of pads used per day (Table 4) 24, 36 and 40 patients were totally dry at the 1-, 2-, and 3-month follow-ups, respectively. In the socially

continent category, the total number of continent patients increased to 44, 52 and 60 patients by the end of the first, second and third months, respectively, giving continence rate of 81.1%. There was a significant decrease in the number of pads used per day from the first month to the end of the third month.

Table 2. Continence rates according to ICIQ-UI SF score

Score	1 month (n = 74)	2 months (n = 74)	3 months (n = 74)
Mean \pm SD =	7.4 \pm 6.2	4.6 \pm 5.0	3.3 \pm 4.2
p value between months	$p_1 < 0.001^*$	$p_2 < 0.001^*$	$p_3 = 0.012$
p value between months			
Continence categories			
Continent	22	34	40
Mild incontinence	21	18	26
Moderate incontinence	19	20	6
Severe incontinence	12	2	2
p value between months	$p_1 = 0.002^*$	$p_2 < 0.001^*$	$p_3 = 0.024^*$

ICIQ-UI SF – International Consultation on Incontinence Questionnaire-Short-Form questionnaire; p_1 – comparing between 1st month and 2nd month; p_2 – comparing between 1st month and 3rd month; p_3 – comparing between 2nd month and 3rd month; SD – standard deviation

Table 3. Comparison between the studied periods according to mean score for each question of ICIQ-UI SF

	1 month (n = 74)	2 months (n = 74)	3 months (n = 74)
How often do you leak urine?			
Mean \pm SD	2.1 \pm 1.6	1.3 \pm 1.5	1 \pm 1.3
p value	$p_1 = 0.002^*$	$p_2 < 0.001^*$	$p_3 = 0.100$
How much urine do you usually leak?			
Mean \pm SD	1.9 \pm 1.7	1.2 \pm 1.4	1 \pm 1.3
p value	$p_1 = 0.005^*$	$p_2 < 0.001^*$	$p_3 = 0.485$
Overall, how much does leaking urine interfere with your everyday life			
Mean \pm SD	3.4 \pm 3.4	2.1 \pm 2.5	1.3 \pm 1.9
p value	$p_1 = 0.001^*$	$p_2 < 0.001^*$	$p_3 = 0.009^*$

ICIQ-UI SF – International Consultation on Incontinence questionnaire-Short-Form questionnaire; p_1 – comparing between 1 month and 2 months; p_2 – comparing between 1 month and 3 months; p_3 – comparing between 2 months and 3 months; SD – standard deviation

Table 4. Comparison between the studied periods according to number of daily used pads

Daily used pads	1 month	2 months	3 months
0 pads	24	36	40
1 pad	20	16	20
>1 pad	30	22	14
P value	$p_1 = 0.026^*$	$p_2 < 0.001^*$	$p_3 = 0.143$

p_1 – comparing between 1st month and 2nd month; p_2 – comparing between 1st month and 3rd month; p_3 – comparing between 2nd month and 3rd month

Table 1. Demographic and clinical characteristics of patients

	No. (%)
Age (years)	
Mean \pm SD	64.3 \pm 5.6
Median (Min.–Max.)	65 (55–75)
PSA	
Mean \pm SD	16.1 \pm 10.9
Median (Min.–Max.)	11.7 (4.5–52.7)
Hospital stay (days)	
Mean \pm SD	3.7 \pm 1
Median (Min. – Max.)	3 (3–7)
Clinical T stage	
T1–T2a	33 (44.6%)
T2b	15 (20.3%)
T2c–T3	26 (35.1%)
Gleason Score of biopsy	
<7	6 (8.1%)
7	42 (56.8%)

No – number; PSA – prostate-specific antigen; SD – standard deviation; T – tumor stage

To investigate if there were discrepancies between the reported continence rates (Table 5), we compared the questionnaire scores with total pad use per day (no-pad/ 0–1 pad). Our analysis showed that social continence rates at the 1-, 2- and 3-month follow-ups were significantly higher (44, 52, 60, respectively [$p < 0.001$]) than the rates for totally dry patients or questionnaire scores. However, there was no significant difference in continence rates between no-pad use and questionnaire scores.

DISCUSSION

Radical prostatectomy is a commonly used curative treatment for prostate cancer with urinary incontinence and erectile dysfunction as major potential side effects. Post-prostatectomy urinary incontinence, however, has a greater impact on patient quality of life, indicating that an evaluation of different tools to best define and report the condition is needed.

According to Sacco et al. [14] and Borregales et al. [15], heterogeneity of methods and definitions in the literature are the primary reasons for discrepancies between reported continence rates, with trials using patient questionnaires for the evaluation of post-prostatectomy urinary incontinence reporting lower continence rates than those based on assessments of daily pad use [14, 15].

Lee et al. [12] investigated 66 patients to study the differences in perception of post robot-assisted laparoscopic radical prostatectomy urinary incontinence as acquired through doctor interviews of the number of daily pad use and by the patient-reported questionnaire using the International Consultation on Incontinence (ICIQ) questionnaire. They reported continence rates of 51.5% (34 patients) according to physicians. However, an analysis of the questionnaires of these patients revealed that only 5 (14.7%) patients reported that they never leaked during the 4 weeks of follow-up. According to the patient-reported questionnaire they found that only 14.7% were continent [12].

Holze et al. [13] conducted a comparison of various continence definitions using a prospective multicenter study and concluded that rates varied considerably depending on how continence was defined, with no-pad use rates of 44% at 3 months and 68% at 12 months following surgery and 71% and 90% for 0–1 pad over the same time periods, respectively.

Liss et al. [16] reported a study of 500 consecutive men who underwent robot assisted radical prostatectomy, aimed at evaluating the association of pad status and the patients' quality of life to determine whether safety and 1 pad status differed from no-pad status. Their results showed a significant difference in the quality of life between no-pad and 0-1 pad, concluding that continence should be strictly defined as no-pad use [16].

Borregales et al. [15] systematically reviewed several articles, where nine different definitions of continence were found with the most common being 'wearing no pads'. They concluded the no-pad definition to be optimal and the high-quality validation of the International Consultation on Incontinence questionnaire made it a reliable and excellent assessment tool of continence alone.

Our results showed no significant difference between the validated International Consultation on Incontinence Questionnaire- Short Form (ICIQ-UI SF) scores and totally dry (no-pad) definition, with urinary continence rates of 29.7% at the 1-month, 45.9% at the 2-month and 54.1% at the 3-month follow-ups versus 32.4%, 48.6% and 54.1%, respectively. However, these numbers vary significantly for the 0-1 pad definition, with continence rates of 59.5% at 1 month, 70.3% at 2 months and 81.1% at 3 months. These results indicate that the no-pad definition is better than the 0-1 pad definition for reporting post-radical prostatectomy continence rates that reflect the subjective sense of continence based on the questionnaire scores. Based on these results, to be better aligned with the patients' perceptions of continence, the treating physician should consider continence as no pad use (totally dry) and to use a validated questionnaire to help patients monitor their scores and possible improvements over the follow up period.

Table 5. Comparison of continence rates between the ICIQ-UI SF score and the daily used pads

	1 month			2 months			3 months		
	ICIQ	0-pad	0-1 pad	ICIQ	0-pad	0-1 pad	ICIQ	0-pad	0-1 pad
Continent	22	24	44	34	36	52	40	40	50
Incontinent	52	50	30	40	38	22	34	34	14
MCN _p		p_1 0.500	p_2 <0.001*		p_1 0.500	p_2 <0.001*		p_1 1.000	p_2 <0.001*

ICIQ-UI SF – International Consultation on Incontinence questionnaire- Short-Form questionnaire; p_1 – comparing between ICIQ UI SF score and 0-pads; p_2 ₀₁₅₀ comparing between ICIQ UI SF score and 0-1pad; MCN – McNemar test

CONCLUSIONS

The totally dry definition better reflected patients' perceptions rather than the socially continent definition for the evaluation of continence recovery following laparoscopic radical prostatectomy. To avoid discrepancies, we recommend the use of a validated questionnaire as well as the no-pad definition to standardize the reporting of post radical prostatectomy continence rates.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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CONSENT TO PARTICIPATE

All patients consented to participate in the study and to data publication after appropriate information through institutional consent.

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