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ARTICLE

Role of sparing of puboprostatic ligaments on continence recovery after radical prostatectomy: a randomized controlled trial

Akram Assem[a], Tamer Abou Youssif[a], Seif M. Hamdy[a], Ahmad M. Beltagy[a] and Ali Serdar Gozen[b]

[a]Department of Urology, Faculty of Medicine, Alexandria University, Alexandria, Egypt; [b]SLK-Kliniken Urology Department, Heidelberg University, Heilbronn, Germany

ABSTRACT

Objective: Sparing of puboprostatic ligaments (PPLs) during radical prostatectomy was introduced as a technique to improve urinary continence. This study aims to study the effect of sparing of PPLs during laparoscopic radical prostatectomy in terms of continence during the first 3 months.

Methods: A total of 74 patients, diagnosed with clinically localized prostate cancer, were randomly assigned to two equal groups; PPLs division and sparing during LRP. Based on the number of daily used pads, both groups completed 3 months follow-up to assess continence recovery. The effects of age, preoperative total prostate-specific antigen (PSA) and clinical tumor stage on continence recovery were also studied. The study was registered and approved by the Ethics Committee of Alexandria University-Faculty of Medicine (Protocol No. 0201074).

Results: Seventy-four patients were enrolled, with a mean age of 63.8 years. Baseline characteristics were comparable, except significantly higher mean PSA in the division group. Sixty patients were continent (0–1 pad/day) at 3 months follow-up. Continence was significantly better in the sparing than division group at 1 week after catheter removal (67.6% vs 40.5%, $p = 0.01$), at 1 month (73% vs 45.9%, $p = 0.009$) and 2 months (89.2% vs 51.4%, $p = 0.0001$). At 3 months follow-up, there was no significant difference between both groups (83.3% vs 78.4% for sparing and division groups, respectively; $p = 0.28$). Moreover, continence was significantly improved at 3 months compared to 1 week in both groups.

Conclusion: Sparing of puboprostatic ligaments during radical prostatectomy significantly improves postoperative early recovery of urinary continence.

Abbreviations: CT: Cross-sectional imaging; cT: Clinical tumor stage; DRE: Digital rectal examination; LRP: Laparoscopic radical prostatectomy; mpMRI: Multiparametric magnetic resonance imaging; RP: Radical prostatectomy; PPI: Post prostatectomy incontinence; PPLs: Puboprostatic ligaments; PSA: Prostate specific antigen; UC: Urinary continence

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Introduction

Prostate cancer (PCa) is the second most commonly diagnosed cancer in men, with an estimated 1,276,106 new cases reported worldwide in 2018 [1]. While survival benefit and free surgical margins remain critical goals, the impact of radical prostatectomy (RP) on the patient's quality-of-life (QoL) remains an important issue [2]. Post-prostatectomy incontinence (PPI) has been reported in 4–31% of patients, according to the Surveillance, Epidemiology, and End Results (SEER) database, with a large impact on psychological well-being, regardless of oncologic and sexual outcome [2,3]. Laparoscopic radical prostatectomy (LRP) has been established as a valid therapeutic option for the management of PCa [4,5]. In 1997, Schuessler et al. [4] carried out LRP to apply the advantages of laparoscopy to the open technique. Such effort was continued by Guillonneau and Vallancien [5] to improve the operative results. Compared to open surgery, LRP offers more rapid convalescence, less postoperative pain, shorter hospital stay and superior cosmoses [6].

Several studies assessed the potential preoperative predictors of urinary continence (UC) recovery after RP. According to the literature, two main anatomical components are responsible for male UC: the sphincteric and the supportive system [7]. The sphincteric mechanism includes the rhabdosphincter, assisted by the internal sphincter at the bladder neck [7]. Sparing the supportive system, including the endopelvic fascia, the Denonvilliers fascia, the puboprostatic ligaments (PPLs), the levator ani muscles and the arcus tendinous fascia may help in achieving the UC in patients after RP [8–10].

The PPLs are bands of fibrous tissue, originating from the endopelvic fascia and forming a whole tissue sheath lying on the anterior surface of the prostate and going from the pubis to the anterior smooth muscle layer of the bladder neck, the so-called anterior detrusor apron [8,9]. Given this anatomical continuity, it has been claimed in the literature as a potential

CONTACT Ahmad M. Beltagy a_abdelkhalek11@alexmed.edu.eg Faculty of Medicine, Alexandria University, Azarita Medical Campus, Champollion st, 21517, Alexandria, Egypt

improvement of continence recovery associated with the sparing of the PPLs [8–10].

The effect of sparing of the PPLs during extra-peritoneal LRP on postoperative early continence was reported firstly in the literature by Stolzenburg et al. [9]. They observed a significant reduction in continence recovery in PPLs sparing patients [9].

In this randomized controlled trial, we compared patients with and without PPLs sparing during LRP in terms of UC recovery at 1 week and monthly till 3 months. We also studied the clinical factors of age, preoperative total PSA and clinical tumor (cT) stage on UC recovery at 3 months.

Materials and methods

Study population

Between October 2017 and August 2019, a total of 77 patients diagnosed with PCa were assessed for eligibility to enter the study. All patients requested surgical intervention and provided informed written consent; the study was approved by the Faculty ethical committee. Three patients were excluded for different reasons, so 74 patients were included in the study (Figure 1). Inclusion criteria were patients aged $\leq$75 years, body mass index $<$30, clinically localized PCa in whom nerve-sparing LRP was performed and the ability to give fully informed consent. Exclusion criteria were patients with neurogenic bladder and urinary incontinence before surgery.

All patients were subjected to the standard urologic preoperative evaluation, including history taking, clinical examination including digital rectal examination, urine analysis (and culture) and routine blood chemistry including total PSA. Transrectal ultrasound guided core biopsy was applied to all patients and imaging studies (multiphasic CT, mpMRI, radioisotope bone scan) were performed according to the clinical situation.

Study design

Patients were randomly assigned to one of two groups: PPLs division ($n = 37$) or PPLs sparing ($n = 37$). Randomization was carried out using computer-generated simple random tables in a 1:1 ratio. Sample size was determined of a minimum 60 patients (30 per group) in detecting an assumed average

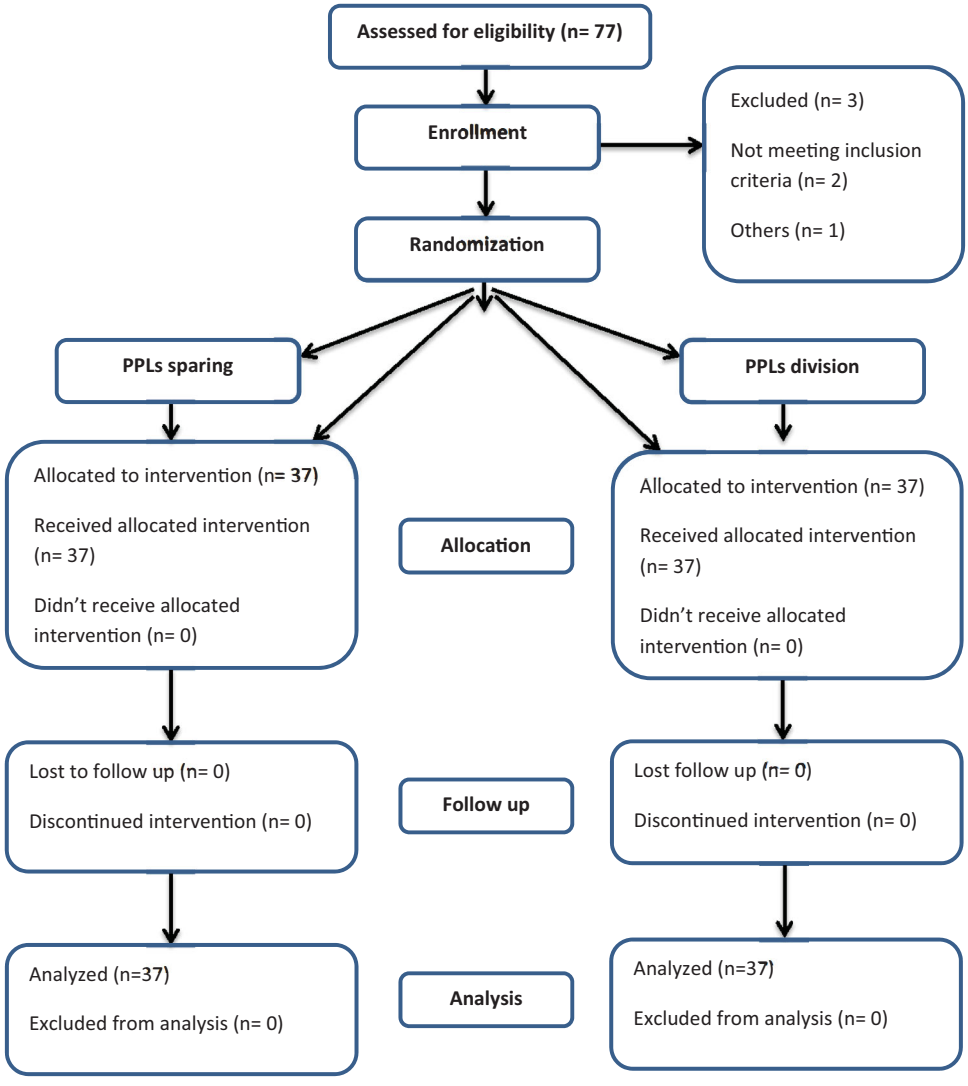

Figure 1. CONSORT flowchart.

Table 1. Baseline characteristics of patients of both groups.

	PPLs division ($n = 37$)	PPLs sparing ($n = 37$)	Total	p-value
Age (years)				
Range	57–75	55–72	55–75	
Mean	65.73	62.86	63.8	0.063
SD	5.51	5.31	5.7	
PSA (ng/ml)				
Range	4.50–52.70	5.20–33.00	4.50–52.70	
Mean	19.21	13.06	16.14	**0.015***
SD	13.09	7.22	10.94	
Gleason score, *n* (%)				
<7	4 (10.8)	2 (5.4)	6 (8.1)	
7	17 (45.9)	25 (67.6)	42 (56.8)	0.230
>7	16 (43.2)	10 (27.0)	26 (35.1)	
cT Stage *n* (%)				
T1–T2a	13 (35.1)	20 (54.1)	33 (44.6)	
T2b	8 (21.6)	7 (18.9)	15 (20.3)	0.230
T2c–T3	16 (43.2)	10 (27.0)	26 (35.1)	

*statistically significant ($p<0.0$ 5).

proportional difference in UC outcome. This sample size provided a statistical power of 80%, taking into consideration a 95% confidence level. For all patients, a 3-month follow-up was completed. The study was registered and approved by the Ethics Committee of Alexandria University-Faculty of Medicine (protocol No. 0201074).

Procedure

Nerve-sparing LRP was performed in all cases. The extraperitoneal approach used an open access technique through a peri-umbilical incision, followed by space creation using a space-maker balloon. The first trocar was inserted peri-umbilical and four working trocars were placed (12 mm optic port, 2×10 mm medial, 2×5 mm lateral ports). When indicated, lymphadenectomy was performed according to Briganti score. In the PPLs division group, transection of the Santorini plexus and PPLs was done. In the PPLs sparing group, the endopelvic fascia was minimally incised, creating a window to facilitating the ligation of the Santorini plexus with a 3/0 V-loc™ stitch, without involvement of the PPLs. The ligaments were then identified and cleaned of any overlapping fatty tissue. The needle was then used and passed under the ligaments and over the Santorini plexus from right to left. The needle was guided from left to right in the plane below the dorsal venous complex and above the anterior urethral wall. The prostate is then dissected leaving intact PPLs. Posterior reconstruction (Rocco's stitch) was performed in all cases. After completing the prostatectomy, a 16 Fr Foley catheter was placed and urethro-vesical anastomosis was performed with two running 3/0 V-loc™ sutures with VanVelthoven [11] technique.

Continence assessment

In both groups, preoperative parameters together with intraoperative data were recorded. On the 10th post-operative day, an X-ray retrograde cystogram was performed to exclude anastomotic leakage followed by catheter removal. Patients were assessed for UC recovery at 1 week, 1, 2 and 3 months by asking the patients about the total number of daily used pads. Based on the scale introduced by Ficarra et al. [12], patients were classified into three categories; completely dry with no pad use (C0), socially continent using a single safety pad (C1) or incontinent using $\geq$2 pads (C2). To assess overall continence, patients were considered continent if using maximum 1 pad/day or incontinent if more than 1 pad/day. We differentiated between no pad and single pad use for better reporting of continence compared to previous study by Stolzenberg et al. [10].

Statistical analysis

Results are given as mean and standard deviation plus or minus SD. Statistical analysis was performed using the software package SPSS 20.0 (SPSS Inc, Chicago, IL). Student t, χ^2 and Fisher exact tests were used when appropriate. A p-value < 0.05 was considered significant.

Results

Baseline characteristics and intraoperative data

Table 1 provides a summary of baseline characteristics of both groups. There was no significant difference between the two groups regarding the studied parameters, except mean PSA was significantly higher in the PPLs division group ($p = 0.015$).

Regarding the surgical approach, 68 patients underwent extra-peritoneal LRP compared to six patients of the trans-peritoneal approach. There was no significant difference between the two studied groups as regards mean operative time (186.22 mins in division, 194.32 mins in sparing, $p = 0.582$) or the mean estimated blood loss (73.89 ml in division, 99.44 ml in sparing, $p = 0.145$).

Urinary continence outcomes

The number of daily used pads was significantly lower in the PPLs sparing than division group during follow-up (with a p-value of 0.023 at 1 week, 0.0029 at 1 month, 0.0001 at 2 months and 0.0269 at 3 months). Moreover in both groups, the total number of daily pads declined significantly at 1, 2

and 3 months compared to 1 week following catheter removal (Figure 2).

Regarding Ficarra et al.'s [12] scale, there was a significant difference between both groups during follow-up (Table 2). The analysis showed a significant improvement in the scale categories from C2 to C1 or C0 comparing 1 week to the following 3 months in the sparing group, but from the 2nd month in the division group.

When considering a maximum 1 pad/day as continent, as mentioned by Stolzenberg et al.'s [10] clinical study, 60 patients (76.66%) were continent at 3 months. UC was significantly better in the sparing than division group at 1 week (67.6% vs 40.5%, $p = 0.01$), at 1 month (73% vs 45.9%, $p = 0.009$) and at 2 months (89.2% vs 51.4%, $p = 0.0001$). However, at 3 months, there was no statistically significant difference between the groups (83.3% vs 78.4% for sparing and division groups, respectively; $p = 0.28$). Moreover, continence was significantly improved at 3 months compared to 1 week in both groups.

There was no statistically significant difference between continent and incontinent patients at 3 months regarding age, preoperative PSA or cT stage (Table 3).

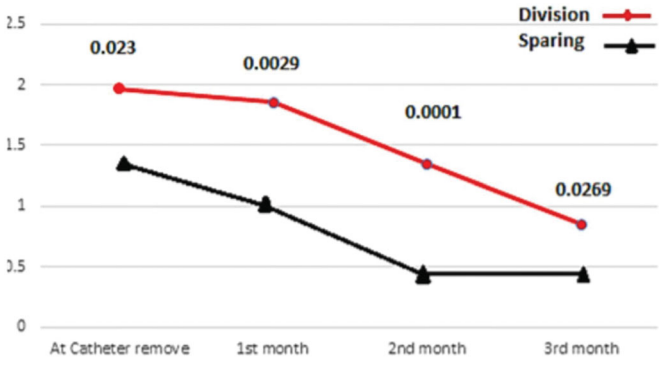

Figure 2. Continence assessment according to the mean number of daily pads.

Table 2. Comparison between both groups according to Ficarra scale.

	1 week		1 month		2 months		3 months	
Ficcara scale	*n*	%	*n*	%	*n*	%	*n*	%
Division group								
C0	6	16.2	6	16.2	13	35.1	15	40.5
C1	9	24.3	11	29.7	6	16.2	14	37.8
C2	22	59.5	20	54.1	18	48.6	8	21.6
p1			0.369		**0.028***		**0.017***	
Sparing group								
C0	12	32.4	18	48.6	23	62.2	25	67.6
C1	13	35.1	9	24.3	10	27.0	6	16.2
C2	12	32.4	10	27.0	4	10.8	6	16.2
p1			**0.013***		**0.001***		**0.001***	
p2	**0.012***		**0.002***		**0.001***		**0.001***	

p1, comparison between 1 week and other times of follow-up; p2, comparison between the division and sparing groups.
*statistically significant ($p < 0.05$).

Discussion

The effect of PPLs sparing during RP on early continence has been reported in the literature. We prospectively randomized 74 patients to study the potential benefit of PPLs sparing during LRP by conducting a follow-up schedule to assess continence. In 1945, Young [13] first suggested these ligaments support the bladder neck and promote UC after perineal RP. Steiner [14] published a detailed anatomic study of PPLs, described as a pyramid-shaped structure as part of suspensory mechanism attaches the membranous urethra to the pubic bone. He concluded that careful apical dissection during RP may help in preserving UC, as we found in our results [14].

Poore et al. [15] published the data of 43 men, in whom retropubic RP was performed (standard apical dissection in 25, PPLs sparing technique in 18). The median time until UC was significantly shorter for the sparing group than for the standard method (6.5 and 12 weeks, respectively). However, the overall continence rate at 1-year follow-up for the two groups was similar (100% and 94%, respectively).

In 2006, Stolzenburg et al. [9] first reported in the literature the effect of PPLs sparing during 100 cases of extraperitoneal LRP on UC recovery. They considered a maximum 1 pad/day as continent and reported 12 continent patients in the sparing group, compared to six in the non-sparing group at 2 weeks and reached 38 patients in the sparing group compared to 24 in the non-sparing group by 3 months [9]. However, in our study, because of the schedule of assessment, we found this significant superiority starting from one week, 1 and 2 months postoperatively. In our study, when considering a maximum 1 pad/day as continent, UC was significantly better in PPLs in the sparing group at 1 week, 1 and 2 months, but not at 3 months (because two patients in the sparing group reported additional one pad use). However, when considering no-pad use as a more strict definition for continence, the number of totally dry patients was significantly higher in the sparing group at 3 months (67.6% vs 40.5%, respectively). Such findings were established because we compared both groups considering categories described by Ficcara et al. [12] to differentiate between totally dry (C0) and socially continent (C1) patients.

Table 3. Comparison between continent and incontinent patients regarding age, PSA and clinical tumor stage.

Parameter		Continent ($n = 60$) *n* (%)	Incontinent ($n = 14$) *n* (%)	*p*-value
Age	<65	28 (46.7%)	7 (50%)	0.969
	65–<70	19 (31.7%)	4 (28/6%)	
	70–<75	13 (21.7%)	3 (21.4%)	
PSA (ng/mL)	<10	18 (18%)	4 (28.6%)	0.981
	10–20	24 (40%)	6 (42.9%)	
	>20	18 (30%)	4 (28.6%)	
Clinical T stage	T1–T2a	26 (34.3%)	7 (50 %)	0.392
	T2b	14 (23.3%)	1 (7.1 %)	
	T2c–T3	20 (33.3%)	6 (42.9%)	

Asimakopoulos et al. [10] described a technique aimed at better sparing of the pubovesical complex (including the PPLs) by the identification of an avascular dissection plane between the anterior detrusor apron and prostate. They reported data of 24 patients demonstrating an 80% rate of complete UC at the time of catheter removal, increased to 100% 1 month later [11]. However, in comparison to our study, a control group was not available.

Another study by Kaggwa and Galukande [16] included 24 men with clinically localized prostate cancer who underwent open RP using PPLs sparing technique. They reported a continence recovery rate of 19/24 (79%) at 3 months of totally dry cases, compared to 25/37 (67.6%) of our results [16]. However, their study limitations include being a retrospective analysis, with a smaller number of patients, no comparative group and no earlier follow-up before 3 months.

Regarding age, we found no significant correlation with continence rates after 3 months. Mandel et al. [17] analyzed data from a cohort of 8,295 patients submitted to RP, showing that 1-year continence rates stratified for age groups of <65, $\geq 65-<70$ and $\geq 70-<75$ years were 93.2%, 90.8% and 86.0%, respectively. In our analysis, 3-month continence rates stratified for age groups of <65, $\geq 65-<70$ and ≥ 70 years were 80%, 82.6% and 81.25%, respectively. We also found no correlation between UC and preoperative PSA and cT stage at 3 months follow-up.

The strengths of our study include it being prospective randomized, all cases being operated on by a single experienced surgeon, with a well established follow-up starting from 1 week after catheter removal and the differentiation between totally dry and socially continent definitions of continence. However, it is limited by a relatively small group of patients and use of daily pads as a single tool of continence assessment.

Conclusion

Sparing of puboprostatic ligaments during radical prostatectomy significantly improves postoperative early recovery of urinary continence. Based on the current study, we recommend sparing of these ligaments during dissection and early continence assessment with patients counseling of improving continence rates over the following 3 months after catheter removal.

Ethical approval

Approved by the Ethics committee of Faculty of Medicine, Alexandria University, Egypt. (IRB No. 00012098, FWA No. 00018699, protocol No. 0201074).

Informed consent

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

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Tamer Abou Youssif http://orcid.org/0000-0003-1086-4980
Ahmad M. Beltagy http://orcid.org/0000-0001-5178-2733

Data availability statement

Data collection was done in our center and protected by patient confidentiality.

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