

A randomized clinical trial of suspension technique for improving early recovery of urinary continence after radical retropubic prostatectomy

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OBJECTIVE

To evaluate, in a prospective, single-blind, randomized trial, the safety and efficacy of a suspension technique for improving early recovery of continence after radical retropubic prostatectomy (RRP).

PATIENTS AND METHODS

We randomly assigned 60 men with clinically localized prostate cancer to RRP; 30 were treated with the suspension technique and the remaining 30 were not. All patients had RRP by the same surgeon followed by early catheter removal on the third day after RRP.

The primary outcome measures were the interval to recovery of continence, and the positive margin rates. The continence status was evaluated by a third party using validated questionnaires at baseline before RRP and at 4 and 7 days, and 2 weeks, 1, 3, 6 and 12 months after RRP.

RESULTS

The suspension technique resulted in significantly greater continence rates at 1, 3 and 6 months after RRP of 53% vs 20%, 73% vs 47% and 100% vs 83%. Kaplan-Meier curves also showed that patients in the suspension group had a significantly earlier recovery of continence than in the no-suspension group; the median (95% confidence interval) interval for recovery

was 31 (12–74) days in the suspension group and 90 (65–150) days in the no-suspension group (log rank test, $P=0.002$). The groups had no significant differences in their histological status.

CONCLUSIONS

The suspension technique had a significant effect on the earlier recovery of urinary continence within 6 months after RRP, without compromising the oncological outcome of RRP.

KEYWORDS

prostate cancer, prostatectomy, urinary continence, suspension technique, randomized trial

INTRODUCTION

Radical prostatectomy (RP) is commonly used to treat patients with clinically confined prostate cancer and a life-expectancy of ≥ 10 years [1]. Recently, many surgeons reported exceedingly low complication rates during and after retropubic RP (RRP) [2,3]. In the last decade, experienced surgeons have directed their efforts to decrease transfusion rates, decrease hospital stay, shorten the period of urinary catheterization, and improve continence and potency rates after RRP [4]. However, incontinence after RRP remains of great concern for most patients. Although urinary continence at ≥ 1 year after RRP is preserved in $>90\%$ of patients at most major medical centres [5–8], several studies have shown that the quality of life (QoL) is compromised by incontinence rates of

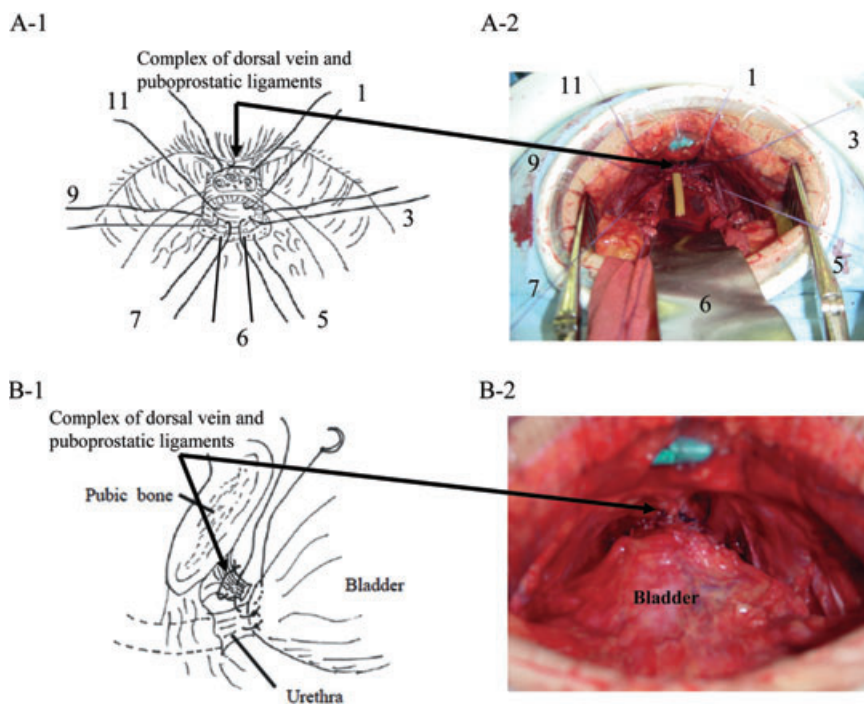
30–83% during the first 3 months after surgery [5,6]. This variation has been attributed to different definitions of continence, surgeon experience, and variations in surgical technique. The use of validated patient questionnaires has improved the standardization of the definition of continence and eliminated physician bias. In addition, a prospective randomized clinical trial needs to avoid the bias from surgeon experience and variations in surgical technique.

Several groups [9–11] suggested a prominent role for the puboprostatic ligaments in the maintenance of continence after RRP, as they support the urethra in maintaining its position in the pelvic floor. Some advocate placing a suture to attach the ligated dorsal vein to the pubic symphysis [12], while others preserve the puboprostatic ligaments before

apical resection [9–11]. We developed these procedures into a simple suspension technique of vesico-urethral anastomosis by placing two sutures that are anchored to the puboprostatic ligaments, preserving those anterior attachments to the pubic bone [13,14]. However, Katz *et al.* [15] recommended a wide resection of bladder neck and cutting the puboprostatic ligaments to decrease bladder neck and apical positive margins.

We conducted a prospective, randomized clinical trial to compare the efficacy in terms of earlier recovery of continence after RRP and the safety of using a suspension technique in RRP, with no suspension used in a control group, in men with clinically localized prostate cancer. In this trial, validated patient questionnaires were used to

FIG. 1. The suspension technique: A-1 and A-2, seven anastomotic sutures are placed through the mucosa of the urethra. B-1 and B-2, two sutures at the 1 and 11 o'clock positions were anchored to the ligated complex, including both the dorsal vein and the puboprostatic ligaments, to suspend the vesico-urethral anastomosis (lateral view).



evaluate continence by a third party, and a recent series of 60 consecutive patients who had RRP by the same surgeon was analysed.

PATIENTS AND METHODS

This study was a prospective, single-blind, randomized clinical trial of a suspension technique during RRP for localized prostate cancer. The study protocol was approved by the Kurume University School of Medicine ethics committee, and the study was conducted in accordance with the declaration of Helsinki. Patients with a clinical stage of T1 or T2 prostate cancer who were considered for RRP were recruited to participate in this clinical trial at Kurume University Hospital from July 2005 to February 2006. All patients provided written informed consent. Patients were excluded if they had: previous TURP, suprapubic prostatectomy, or local radiotherapy or hormonal therapy; insulin-dependent diabetics (to avoid the possibility that diabetic neuropathy affects the continence); or a history of neurological disease.

Eligible patients were randomized equally into the two groups, having RRP with or without the suspension technique. Randomization was by a blocked stratified procedure, where each block consisted of two treatment assignments with two strata, two age groups (<65, ≥65 years), and two groups with different baseline clinical stages (T1, T2). Before RRP, each patient had a standard evaluation, including taking a careful history, a DRE, TRUS, serum PSA determination, routine blood tests, transrectal biopsies under TRUS guidance, a chest X-ray, pelvic CT, MRI and a radioisotope bone scan. Clinical stages were determined according to the 2002 TNM classification. All participants were unaware of whether they had a suspension procedure or not. Double-blinding was deemed unnecessary because the investigator (who also performed the RRP) had no influence in determining the key evaluation factor, the assessment of continence.

All RRP was done the same surgeon (M.N.) who used a modification of both the anatomical technique described by Walsh and the 'bunching' technique described by Myers, with an attempt at bilateral nerve-sparing

whenever feasible [16,17]. All patients also had a limited pelvic lymphadenectomy. The pelvic lymph nodes were submitted for permanent section, with no frozen-section analysis. The neurovascular bundles were preserved unilaterally or bilaterally, depending on the patient's wishes, and the potency status before RRP, favourable Gleason scores, clinical stage and intraoperative assessment of the gland were recorded. The suspension technique was done as reported previously [13,14]; briefly, the puboprostatic ligaments that attach the prostate to the symphysis pubis were not divided before apical resection and were included in the bunching complex. After the ligating the complex, including both the dorsal vein complex and the puboprostatic ligaments, this complex was sharply divided anteriorly from the prostate with a safe distance (1–2 mm), and the urethra was defined and divided. After the apical dissection was completed and the anterolateral pedicles were controlled, Denonvilliers' fascia was incised and seminal vesicles were released as the dissection progressed laterally, to liberate the base of the prostate. After removing the prostate, the bladder neck was reconstructed by completely everting the mucosa and sutured outward with a running 4-0 absorbable suture around the edge. The bladder neck was narrowed to ≈1 cm, for convenient passage of a 20 F catheter. Anastomotic sutures of 3-0 absorbable polyglactin were placed at the 1, 3, 5, 6, 7, 9 and 11 o'clock positions through the full thickness of the urethra, including the mucosa and muscularis of the bladder neck, ensuring mucosa-to-mucosa anastomosis. The sutures at the 1 and 11 o'clock positions were anchored to the ligated complex including both the dorsal vein complex and the puboprostatic ligaments, to suspend the vesico-urethral anastomosis (suspension technique). The difference between the suspension and no-suspension techniques was only the placing of two sutures into the ligated complex (Fig. 1). During the procedure, a portable head-light (PeriLux LED, Hodies, Australia) was used to improve illumination of the surgical field and magnifying loupes (×2.5) were used to allow better visualization of anatomical details. Blood loss was measured by weighing all blood in the gauze and from a suction device during surgery, and the time from skin incision to closure of the wound was defined as the surgical duration. The retropubic space and vesico-urethral anastomosis were drained with a closed suction device at the end of the procedure.

The drain was removed on the next day after RRP if the drain volume was <100 mL. The gravity cystogram was routinely done on the second day after RRP. In brief, the bladder was filled with 150–200 mL of contrast medium until the patient reported a sense of fullness and discomfort. Several films of the bladder and vesico-urethral junction were taken in anteroposterior, lateral and oblique projections. Films were also obtained after manipulating the urethral catheter and after emptying the bladder, in an attempt to detect potential extravasation. The urethral catheter was removed 3 days after RRP if there was no or only minimal extravasation on the cystogram [13]. If there was significant extravasation was on the initial cystogram, the urethral catheter was retained and a second cystogram for deciding catheter removal was taken 3–5 days after the initial cystogram in the hospital. Patients were usually discharged from the hospital 7 days after RRP, as defined in the clinical pathway.

For the histopathological examination, the RRP specimens were processed with sections cut at 3-mm intervals, as previously reported [16]. The specimens were delivered fresh, then weighed, measured and grossly inspected. The outer surface of the gland was thoroughly inked with different colours to maintain the orientation of the specimen. The prostate base and apex were defined as the proximal third and distal 5 mm portions of the prostate, respectively. An entire apical block of the prostate, including apical and urethral margins, was removed by a single transverse section perpendicular to the urethra and 5 mm in greatest vertical dissection at the midline. This tissue block then was serially sectioned at 3-mm intervals in parasagittal planes that were perpendicular to the initial transverse incision and parallel to the distal segment of the urethra. The specimen was pathologically classified according to the 2002 TNM system and the following definitions were used to determine the pathological status of the primary tumour: (i) organ-confined disease, tumour confined to the prostate; (ii) positive surgical margins (PSMs), indicated as any cancer in contact with the inked surface of the prostate; (iii) extraprostatic extension, tumour that penetrated through the prostate capsule reaching the inked margins; (iv) seminal vesicle invasion, any invasion of the seminal vesicle wall by tumour cells; and (v) nodal disease, presence of prostate cancer lymph node metastases.

Patients were interviewed by a research nurse using a Japanese version [17] of the University of California, Los Angeles, Prostate Cancer Symptom Index at baseline, and at 4 and 7 days, and 2 weeks, 1, 3, 6 and 12 months after RRP. The Japanese version questionnaire was validated in Japan to be as useful as the original version [18]. Patient responses to these survey items were collected by a data manager at our institution, and who was independent of the operating surgeon. The definition of continence was based on patient responses to three questionnaire items, selected to reflect the range of incontinence severity: (i) Over the past 4 weeks, how often have you leaked urine?; (ii) Which of the following best describes your urinary control during the last 4 weeks?; and (iii) How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks ('4 weeks' in the three items was modified to '24 h' during 1 month after RRP). Continence was defined as the answer of 'Not at all' to (i), 'Total control' to (ii) and 'No pad' to (iii), respectively, and the day on which continence was recovered was recorded.

The sample size was chosen to detect a difference of >30 days in the time to recovery of continence after RRP between suspension and no suspension, with a SD of 40 days, 80% power and the $\alpha = 0.05$ significance level. The sample size was estimated based on the previous clinical trial [13,14]. These calculations and values required the enrolment of 50 men, and this was increased to a target enrolment of 60 to account for a potential discontinuation rate of up to 20%. Data were entered into a computer database with a security system by one research nurse, and then analysed using commercial software. The differences in the mean values among the various groups were assessed using the chi-square test or one-way ANOVA. The primary outcome of interest was the interval before the return of urinary continence after RRP, and the association of this outcome variable with the surgical technique of suspension was assessed using Kaplan-Meier plots, with the log-rank statistic to test for differences in the curves. To minimize and control for selection bias we constructed a Cox proportional hazards model for the interval to continence. Variables considered for this model included surgical technique (suspension or no suspension), age at surgery, body mass index (BMI), baseline PSA level, clinical tumour stage, intraoperative blood loss and duration of

surgery, prostate volume, Gleason score, seminal vesicle invasion, PSMs and pathological stage. Test results were considered significant at $P < 0.05$.

RESULTS

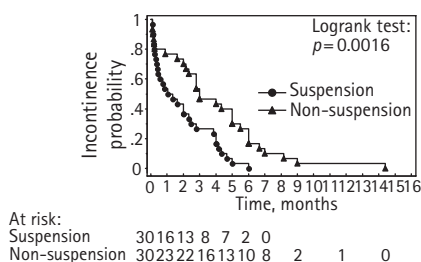
In all, 71 patients were scheduled to undergo open RRP for clinically localized prostate cancer at our institution from July 2005 to February 2006. Of the 71 patients who were screened for eligibility, 60 satisfied all eligibility criteria and agreed to participate in the trial, and were randomized to receive the suspension technique (30) or no suspension (30) during RRP. All of the randomized patients completed the study. There was no significant difference between the groups in the preoperative baseline demographics or the clinical characteristics of the patients. In addition, there was no significant difference in prostate volume, surgical duration and blood loss between the groups (Table 1). No patients had symptoms of urinary incontinence before RRP.

There were no complications during RRP in either group of patients. The median catheterization time was similar in both groups. The rate of urinary retention after catheter removal was 13% (four of 30) and 3% (one of 30) in the suspension and the no-suspension groups, respectively. Those patients with urinary retention were treated with simple catheter replacement for 1 or 2 days. There was no patient with urinary retention after hospital discharge (>7 days). In the median follow-up of 14.2 (12–19) months, no clinical signs of pelvic abscess, urethral stricture or urinoma developed in any patient.

The two groups had no significant differences in their pathological status; in the suspension group, PSM were detected in none and 40% of patients with pT2 and pT3, respectively. In the no-suspension group, PSM were found in 3% and 33%, respectively (Table 2). There was no significant difference between the groups in the frequency of PSMs.

The continence rates at the various follow-up times are shown in (Table 3). The suspension technique resulted in significantly greater continence rates at 1, 3 and 6 months after RRP, although the rates at 12 months were not significantly affected. Kaplan-Meier curves show that the patients in the

FIG. 2. Kaplan-Meier curves showing that the patients in the suspension group had a significantly earlier return of continence than in the no-suspension group (log-rank test, $P=0.002$). The median (95% CI) time to recovery in the suspension group was 31 (12–74) days and in the no-suspension group was 90 (65–150) days.



suspension group had a significantly earlier return of continence than those in the no-suspension group (log-rank test, $P=0.002$; Fig. 2). The median (95% CI) interval to recovery of continence in the suspension group was 31 (12–74) days and in the no-suspension group was 90 (65–150) days. A Cox proportional hazards regression analysis was used to determine risk factors for incontinence after RRP (Table 4). In both the univariable and multivariable analysis, no suspension technique ($P=0.005$) and age at surgery ($P=0.035$) were the only significant risk factors for the recovery of continence after RRP. Other factors, including BMI, PSA level, clinical stage, intraoperative blood loss, duration of surgery, prostate weight, Gleason score, seminal vesicle invasion, PSM and pathological stage were insignificant.

DISCUSSION

In the present randomized trial, the suspension technique led to a significantly earlier recovery of continence than in the controls, with median intervals of 31 and 90 days. The suspension technique also resulted in significantly greater continence rates at 1, 3 and 6 months after RRP of 53% vs 20%, 73% vs 47% and 100% vs 83%, although the rate at 12 months were not significantly different. These results are considered reliable, as they were obtained in a randomized and prospective trial, with all RRP by the same surgeon. This differs from other published studies in which the surgical technique and the patient outcome were usually evaluated retrospectively, and the procedures were often performed by different surgeons from the same institution [2]. Comparative evaluations, ideally by the same

TABLE 1 Clinical data of the 60 men with localized prostate cancer (30 in each group)

Characteristic mean (SD), median (range) or n (%)	Suspension	No suspension
Age, years	66.9 (6.5)	66.6 (5.3)
BMI, kg/m ²	69 (52–76)	68 (50–75)
	22.7 (2.3)	23.4 (2.4)
	22.7 (16.6–26.1)	23.4 (16.6–29.7)
Clinical T stage		
T1c	13 (43)	14 (47)
T2a	13 (43)	12 (40)
T2b	4 (13)	4 (13)
PSA level before RRP, ng/mL		
	10.6 (6.2)	10.6 (5.8)
	8.9 (4.1–26.0)	8.8 (3.1–26.5)
Intraoperative blood loss, mL		
	429 (223)	517 (354)
	360 (105–1020)	440 (85–1517)
Operative duration, min		
	158 (25)	161 (36)
	154 (120–225)	157 (110–260)
Removal of catheter, days		
	3.1 (0.3)	3.7 (3.2)
	3 (3–4)	3 (3–20)
Prostate weight, g		
	28.8 (9.4)	34.0 (18.6)
	26.5 (17.4–49.8)	30.2 (11.5–106.6)

Variable	Number with PSM/total (PSM rate, %)	
	Suspension	No suspension
Pathological stage		
pT2a	0/7 (0)	0/14 (0)
pT2b	0/4 (0)	0/4 (0)
pT2c	0/5 (0)	1/4 (3)
pT3a	10/13 (37)	5/6 (17)
pT3b	2/2 (7)	2/2 (7)
PSM rates		
In pT2	0	33
In pT3	40	33

TABLE 2 Positive surgical margin rate according to pathological stage

Time after RRP	N continent/n available (rate, %)		P (chi-square)
	Suspension	No suspension	
4 days	3/24 (13)	2 (8)	0.669
1 week	7/30 (23)	5 (18)	0.561
2 weeks	11/30 (37)	5 (17)	0.093
1 month	16/30 (53)	6 (20)	0.029
3 months	22/30 (73)	14 (47)	0.034
6 months	30/30 (100)	25 (83)	0.020
12 months	30/30 (100)	29 (97)	0.313

TABLE 3 Continence rates in 60 men after RRP

surgeon with the same skill, are needed to determine whether the suspension technique provides equal or better outcomes than the no-suspension technique. More experience and more subtle changes in skill might have contributed to the improved outcomes. Another reason is that physician-based assessments of urinary continence and patient-reported outcomes differ. Litwin *et al.* [18] assessed urinary continence in men with prostate cancer using the University of California Los Angeles Prostate Cancer Symptom Index, and identified a significant difference in the physician and patient assessments of urinary QoL (21% vs 97%).

The possible mechanisms of urinary incontinence after RP include damage to the pelvic floor and urethral sphincter, damage to pelvic floor innervation, and loss of anterior urethral support. Various surgical techniques, including bladder neck preservation [11,19], intussusception of the bladder neck [20], puboprostatic ligament-sparing [10] and suspension of the vesico-urethral anastomosis [12–14] have been used to improve the early return of continence after RRP. Conflicting reports were published about the effect of bladder neck preservation on continence after RRP.

Selli *et al.* [19] and Deliveliotis *et al.* [11] found that preserving the bladder neck offered an earlier return of continence after RRP, but Poon *et al.* [21] did not. These reports were not randomized trials, and the surgeons were not the same, except in the report of Selli *et al.* In a randomized trial in which the surgeon, pathologist and interviewer were the same throughout, Srougi *et al.* [22] concluded that bladder neck preservation during RRP does not improve urinary continence, and that it might compromise cancer control. Walsh and Marschke [20] did not address bladder neck preservation; their technique instead used intussusception of the bladder neck with Lambert sutures, to prevent the bladder neck from pulling open as the bladder fills. They reported that 82% of the 54 men were continent at 3 months after RRP with intussusception of the bladder neck, vs 54% of 64 men who had RRP without intussusception, but that study was limited because their significantly greater continence rate at 3 months was compared with their previous report. If injuries to the bladder neck, the puboprostatic ligament and urethral sphincter are minimal, the continence mechanism will recover gradually. Therefore, a

Analysis	Hazard ratio (95% CI)	P
Univariable		
Age at surgery (continuous)	1.055 (1.008–1.104)	0.021
BMI (continuous)	1.037 (0.922–1.166)	0.548
Serum PSA (continuous)	1.019 (0.973–1.066)	0.425
Clinical stage (T2/T1c)	1.079 (0.631–1.845)	0.780
Suspension (no/yes)	2.347 (1.342–4.098)	0.003
Blood loss (continuous)	1.000 (0.999–1.001)	0.692
Duration of surgery (continuous)	1.007 (0.998–1.015)	0.145
Prostate weight (continuous)	1.007 (0.984–1.030)	0.576
Gleason score (continuous)	1.057 (0.735–1.520)	0.765
Seminal vesicle invasion (yes/no)	1.883 (0.584–6.061)	0.290
PSM (yes/no)	1.096 (0.636–1.879)	0.741
Pathological stage (pT3/pT2)	1.244 (0.732–2.114)	0.421
Multivariable		
Suspension (no/yes)	2.337 (1.282–3.906)	0.005
Age at surgery (continuous)	1.049 (1.003–1.096)	0.035

TABLE 4
Cox proportional hazards
analysis of risk factors for
incontinence after RRP

combination of anterior urethral support, e.g. the suspension technique, and puboprostatic ligament-sparing seems a promising concept in establishing the early recovery of continence after RRP. However, the previously described suspension technique was more concerned with only anterior support of the urethra by anchoring the anastomosis to the pubic bone [12]. Puboprostatic ligaments support the strained external urethral sphincter and preserve the urethra in its normal place in the pelvic floor. Therefore, their anatomical and morphological stability seems to be important in postoperative continence. Lowe [10] reported that preserving the anterior urethral ligamentous attachments was recommended for earlier recovery of continence after RRP, with high continence rates (49% at 1 month and 80.4% at 3 months) after surgery. The premise that suspension is effective could be based on the pubo-urethral continuity of the puboprostatic ligaments. We used both puboprostatic ligament-sparing and suspension techniques in the suspension group.

In the present study, factors such as age, BMI, preoperative PSA level, clinical stage, intraoperative blood loss, duration of surgery, prostate weight, Gleason score, pathological stage, PSMs and surgical technique, all mentioned in previous studies as affecting the continence status after RRP, were analysed using Cox proportional hazards regression models. In both the univariable and multivariable analysis, not using the suspension technique and age at surgery were

the only significant risk factors for the recovery of continence after RRP. Eastham *et al.* [23] reported similar results; they found that the risk of urinary incontinence after RRP is related to age and sensitive to the surgical technique used.

Complete removal of the cancer remains the goal of RRP; modifications to the surgical technique of RRP must not compromise the pathological outcome. Most investigators agree that the prostate apex is the most frequent site of PSM after RP. The PSM rate in pT2 prostate cancer for open RP is 2.7–14%, with a decreasing trend during the last decade [15]. In the present study, the pT2 PSM rates were 0% for the suspension group and 3% for the no-suspension group.

The present study has some limitations; there were relatively few patients and the study was conducted in one institution, although it was a prospective and randomized trial. Clinical trials with more patients at several institutions are necessary to confirm the effect of the suspension technique on the early recovery of continence and the oncological outcome after RRP.

The earlier recovery of continence has a clear and positive effect on the patient's QoL, as urinary incontinence is the symptom that bothers most patients after RRP, and undermines their conviction of having chosen this form of treatment. The present prospective randomized study shows that the suspension technique had a significant effect

on the earlier recovery of urinary continence within 1–6 months after RRP, without hindering the oncological outcome. This technique could be used in laparoscopic and/or robotic RP, and could result in earlier continence after surgery.

CONFLICT OF INTEREST

None declared.

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Abbreviations: (R)RP, (retropubic) radical prostatectomy; BMI, body mass index; PSM, positive surgical margin; QoL, quality of life.