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ORIGINAL RESEARCH

A Contemporary Series on Retropubic Radical Prostatectomy and an Analysis of Factors Influencing Biochemical Recurrence-Free Survival

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ABSTRACT

This study investigates outcomes and identifies factors influencing biochemical recurrence and biochemical recurrence-free survival (BRFS) rates in patients undergoing retropubic radical prostatectomy (RRP) at a tertiary university hospital over 10 years. Data of patients who underwent RRP between 2012 and 2022 were analyzed retrospectively. Variables included demographic information, preoperative prostate-specific antigen (PSA) levels, prostate volume, PSA density, operative details, histopathological findings, and postoperative follow-up data. Patients without at least three years of regular follow-up were excluded from the study. The Cox regression analyses were performed to determine the independent risk factors for BRFS. Survival analysis was performed using Kaplan-Meier and the log-rank test. The final analysis included 115 patients. The median follow-up duration was 77.2 months (range: 36.3–153.6), and the median BRFS was 47.3 months (range: 0–153.6). The 3-year BRFS rate was 61.8%. Positive surgical margins were identified as a significant predictor of BRFS (HR: 2.388, p=0.004), while higher PSA density and the ISUP grade groups also showed associations with recurrence risk (p= 0.033 and 0.048, respectively). Survival analyses confirmed shorter BRFS in patients with positive surgical margins (p=0.000). This study highlights the effectiveness of RRP in the surgical management of localized PCA. Surgical margin status emerged as the primary predictor of BRFS. PSA density may be a promising parameter in predicting biochemical recurrence, but further studies are needed.

Keywords: Retropubic radical prostatectomy. Prostate cancer. Biochemical recurrence-free survival.

Retropubik Radikal Prostatektomi Üzerine Çağdaş Bir Seri ve Biyokimyasal Nükssüz Sağkalımı Etkileyen Faktörlerin Analizi

ÖZET

Bu çalışmanın amacı üçüncü basamak sağlık hizmeti veren bir üniversite hastanesinde son 10 yılda yapılan retropubik radikal prostatektomi (RRP) ameliyatlarının sonuçlarını değerlendirmek ve cerrahi tedavi alan hastalarda biyokimyasal nüksüz sağkalımı (BNS) etkileyen faktörleri belirlemektir. Bu çalışma için kliniğimizde 2012-2022 yılları arasında RRP geçiren hastaların verilerini retrospektif olarak analiz edildi. İncelenen veriler arasında; hastaların demografik bilgileri, preoperatif prostat spesifik antijen (PSA) düzeyi, prostat hacmi, PSA dansitesi, operatif veriler, histopatolojik sonuçlar ve postoperatif takip bilgileri mevcuttu. En az üç yıllık düzenli takibi olmayan hastalar çalışma dışı bırakıldı. BNS üzerine etki eden faktörleri belirlemek için Cox regresyon analizi uygulandı. Sağkalım analizi log-rank testi uygulanarak Kaplan-Meier grafi ile verildi. Analize 115 hasta dahil edildi. Medyan takip süresi 77,2 ay (36,3–153,6) ve medyan BNS 47,3 aydı (0–153,6). 3 yıllık BNS oranı 61.8%' olarak bulundu. Cerrahi sınır pozitifliği BNS etkileyen önemli bir faktör olarak tespit edildi (HR: 2.388, p=0.004). Ayrıca yüksek PSA dansitesi ve yüksek ISUP derece grup varlığı biyokimyasal rekürrens ile ilişkili bulunmuştur (p sırasıyla = 0,033 ve 0,048). Sağkalım analizi cerrahi sınırı pozitif olan hastaların daha kısa BNS süresine sahip olduklarını göstermiştir. (p=0.000). Bu çalışa RRP' nin lokalize prostat kanseri tedavisindeki yerini vurgulamıştır. Cerrahi sınır durumu BNS' yi öngörmede anlamlı bir parametredir. PSA dansitesi biyokimyasal rekürrensi öngörmede umut vaat eden bir parametredir; ancak bu konuda daha ileri çalışmalara gereksinim vardır.

Anahtar Kelimeler: Retropubik radikal prostatektomi. Prostat kanseri. Biyokimyasal nükssüz sağkalım.

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Prostate cancer (PCA), which has an age-standardized incidence rate of 29.4 per 100,000, ranks as the second most frequently diagnosed cancer globally, following breast cancer[1]. Considering only the male population, PCA ranks as the second most commonly diagnosed cancer after lung cancer[1]. Definitive treatment options for localized PCA include surgery (radical prostatectomy) and external beam radiation therapy[2]. Radical prostatectomy involves the excision of the whole prostatic gland with the prostate capsule, the distal segments of the bilateral vas deferens, and the

seminal vesicles. The procedure is subsequently followed by vesicourethral anastomosis. The application of radical prostatectomy dates back to 1905 when Hugh Hampton Young introduced the perineal approach[3]. Later, in 1948, Milin described the extraperitoneal radical prostatectomy using an abdominal infra umbilical incision[4]. In 1979, Walsh developed a technique for managing the dorsal venous complex, significantly reducing intraoperative blood loss and enhancing procedural safety[5]. Furthermore, Walsh introduced the concept of nerve-sparing radical prostatectomy[6]. The nerve-sparing retropubic radical prostatectomy (RRP) became the standard surgical procedure for prostate cancer treatment for many years. While laparoscopic radical prostatectomy (LRP) and robot-assisted radical prostatectomy (RARP) are now widely utilized, open RRP continues to hold its place in the management of PCA treatment[7].

Systematic reviews have demonstrated that laparoscopic and robot-assisted radical prostatectomy do not provide superior oncological outcomes compared to RRP[8,9]. Although LRP and RARP offer advantages in terms of complication rates and length of hospital stay, some LRP series have reported higher incidences of anastomotic leakage, organ injury, and ileus than RRP[2,8,9]. Furthermore, the significantly greater cost-effectiveness of RRP and its ability to be performed with fewer technological instruments compared to the other two methods represent a critical advantage in favor of RRP[7].

This study aims to present the outcomes of a 10-year RRP series conducted at a university hospital delivering tertiary healthcare services and to identify factors influencing biochemical recurrence-free survival (BRFS) in these patients.

Material and Method

In this study, we retrospectively analyzed the data of 125 patients who underwent RRP for prostate cancer in our clinic between January 1, 2012, and January 1, 2022. The analyzed parameters included patient demographic data (age, weight), preoperative prostate-specific antigen (PSA) levels, prostate volume, PSA density, American Society of Anesthesiologists (ASA) scores, postoperative complications, preoperative and postoperative hematocrit level, estimated blood loss, operation time, length of hospital stay, Gleason scores and International Society of Urological Pathology (ISUP) grade group of the radical prostatectomy specimens, presence of perineural invasion (PNI), presence of lymphovascular invasion (LVI), lymph node status, surgical margin status, postoperative PSA follow-up results, bladder neck contracture rate, last follow-up date, the date of biochemical recurrence (BCR), 3-year BRFS status, BRFS time. PSA density was determined by dividing the PSA level by the prostate volume. Estimated blood loss was calculated using the formula: the difference between the preoperative and postoperative hematocrit values was divided by the preoperative hematocrit, and the result was multiplied by the total blood volume. Total blood volume was calculated by multiplying the body weight by 70 ml/kg. Postoperative complications were classified according to the Clavien-Dindo classification system[10]. Patients who underwent radical prostatectomy surgery out of abdominal RRP technique and those with less than three years of follow-up were excluded from the study. As our department serves as a training clinic for urology, residents also participated in these surgeries.

Surgical Procedure

Following field preparation and sterilization in the supine position under general anesthesia, a sub-umbilical midline incision was made, traversing the skin, subcutaneous tissue, and fasciae, and finally reached the peritoneum. The endopelvic fascia was incised to expose the prostate capsule. The puboprostatic ligament and dorsal venous complex were ligated and transected using a 1/0 Vicryl suture. Subsequently, the urethra was incised at the prostate apex, rotated 180 degrees, and the foley catheter was clamped and cut distal to the external urethral opening. The lateral pedicles were then dissected using both blunt and sharp dissection techniques. The bladder neck was dissected and preserved, allowing the prostate base to be separated through a combination of blunt and sharp dissection. Posteriorly, the vas deferens were bilaterally ligated and transected at the level of the seminal vesicles, which were subsequently dissected. The Denonvilliers fascia was identified, enabling the separation of the prostate from the rectum. After removing the radical prostatectomy specimen from the surgical site, meticulous hemostasis was achieved. A 20F Foley catheter was then inserted before vesicourethral anastomosis. The anastomosis of the bladder neck to the urethra was performed using six 2/0 Vicryl sutures corresponding to 1, 3, 6, 9, 11, and 12 o'clock. A drain was placed in the surgical site, and the surgical layers were closed in alignment with the anatomical planes.

Ethics Statement

The study protocol was approved by the Clinical Research Ethics Committee of Zonguldak Bülent Ecevit University (approval number: 2024/20) and complied with the tenets of the Helsinki Declaration.

Biostatistical Analysis

Categorical variables were compared using the chi-square test, continuity correction, and Fisher's exact test. Shapiro–Wilk and Kolmogorov–Smirnov tests were performed to evaluate the normality of continuous data. The Mann–Whitney U and Kruskal–Wallis test was used for nonnormally distributed variables. Continuous data are expressed as the median and minimum-maximum values. The Cox regression analyses were performed to determine the independent risk factors for BRFS. Survival analysis was performed using Kaplan-Meier and the log-rank test. $P<0.05$ was considered to indicate a statistically significant result. SPSS software (IBM SPSS Statistics for Windows, version 25.0; IBM Corp) was used for the analyses.

Results

After applying exclusion criteria, 115 patients were included in the final analysis. The median age of the patients was 64.5 years (range: 47.5–75.3), with a median body weight of 78.5 kg (range: 55–106). The median prostate volume was 41 ml (range: 20–120), the preoperative PSA level was 8.9 ng/ml (range: 3.1–27.5), and the PSA density was calculated as 0.21 ng/ml^2 (range: 0.09–1.17). The median duration of the surgeries was 175 minutes (range: 115–230), and the median estimated blood loss was calculated as 742 ml (range: 525–1375). The median length of hospital stay was 5 days (range: 3–9), with most postoperative complications being minor (13% vs. 2.7%). During clinical follow-up, one patient presenting with acute chest pain was diagnosed with acute myocardial infarction following cardiac evaluation and underwent percutaneous transluminal coronary angioplasty performed by the cardiology team. Another patient developed a hematoma at the incision site, necessitating re-exploration and hemostasis under general anesthesia. Additionally, one case of bowel evisceration at the surgical wound site required surgical repair under general anesthesia. During long-term follow-up, bladder neck contracture was observed in 10 patients (8.7%). (Table I)

The evaluation of RRP specimens revealed that most patients (57.4%) were classified as ISUP grade group 1 (Gleason 3+3). Of the patients, 93 (80.8%) were staged as pT2, while 19.2% were pT3. PNI positivity was observed in 64 patients (55.7%), and LVI positivity was noted in 6 (5.2%). Extended pelvic lymph node dissection (including external iliac, internal iliac, and obturator zones) was performed in 21 patients (18.3%), with malignant lymph nodes identified in only one case. Positive surgical margins were identified in 42 patients (36.5%). The median follow-up duration was 77.2 months (range: 36.3–153.6), and the median BRFS was 47.3 months (range: 0–153.6). (Table I)

Table I: The Clinicopathological characteristics of the entire patients.

Age (median, min&max; years)			64.5 (47.5-75.3)
Body Weight (median, min&max; kg)			78.5 (55-106)
Prostate Volume (median, min&max; ml)			41 (20-120)
Preop PSA Level (median, min&max; ng/ml)			8.9 (3.1-27.5)
PSA Density (median, min&max; ng/ml^2)			0.21 (0.09-1.17)
Estimated Blood Loss (median, min&max; ml)			742 (525-1375)
Operation Time (median, min&max; min)			175 (115-230)
Length of hospital stay (median, min&max; days)			5 (3-9)
Follow-up duration (median, min&max; months)			77.2 (36.3-153.6)
Biochemical recurrence-free survival (median, min&max; months)			47.3 (0–153.6)
Postoperative Complication			15 (13%)
Minor (I—II) (*n*, %)			3 (2.7%)
Major (≥ III) (*n*, %)			1 (0.9%)
(IIIa) Percutaneous transluminal coronary angioplasty			1 (0.9%)
(IIIb) Surgical intervention due to hematoma			1 (0.9%)
(IIIb) Surgical intervention due to bowel evisceration			1 (0.9%)
Bladder neck contracture *(n,%)*			10 (8.7%)
ISUP Grade Group	*1*	*3+3 (n,%)*	66 (57.4%)
	2	*3+4 (n,%)*	26 (22.6%)
	3	*4+3 (n,%)*	14 (12.2%)
	4	*4+4 (n,%)*	3 (2.6%)
	5	*>4+4 (n,%)*	6 (5.2%)
pT	*T2a*	*(n,%)*	27 (23.5%)
	T2b	*(n,%)*	14 (12.2%)
	T2c	*(n,%)*	52 (45.1%)
	T3a	*(n,%)*	14 (12.2%)
	T3b	*(n,%)*	8 (7%)
PNI	*Negative*	*(n,%)*	51 (44.3%)
	Positive	*(n,%)*	64 (55.7%)
LVI	*Negative*	*(n,%)*	109 (94.8%)
	Positive	*(n,%)*	6 (5.2%)
Lymph Node	*Nx*	*(n,%)*	94 (81.7%)
	N0	*(n,%)*	20 (17.4%)
	N1.	*(n,%)*	1 (0.9%)
Surgical Margin	*Negative*	*(n,%)*	73 (63.5%)
	Positive	*(n,%)*	42 (36.5%)

min: Minimum, max: Maximum. kg: Kilogram, Preop: Preoperative,
PSA: prostate-specific antigen, ng: Nanogram, ml: Milliliter,
ISUP: International Society of Urological Pathology, min: minutes
pT: pathological T stage, PNI: Perineural invasion,
LVI: Lymphovascular invasion

At the end of the third-year follow-up status, the patients were categorized into two groups based on the presence of BCR. The 3-year BRFS rate was 61.8%. Group 1 (n=71) included patients without BCR, while Group 2 (n=44) included those with BCR. The comparison between these groups indicated that patients with BCR had a higher incidence of positive surgical margins (54.5% vs. 25.4%, p= 0.003), significantly elevated PSA density (0.38 vs. 0.15, p=0.033), and a significantly greater proportion of patients with higher ISUP grade groups (p=0.048). (Table II)

Table II: Comparative analysis of clinicopathological characteristics of the groups

			Group 1 (n=71)	Group 2 (n=44)	p-value
Age (median, min&max; years)			64.6 (51.9-75.3)	63.9 (47.5-71.9)	0.629
Body weight (median, min&max; kg)			77 (67-102)	87.5 (65-105)	0.388
Prostate volume (median, min&max; ml)			45 (20-120)	36 (25-62)	0,247
Preop PSA level (median, min&max; ng/ml)			8.1 (3.1-27.3)	9.3 (4.1-27.5)	0.629
PSA density (median, min&max; ng/ml^2)			0.15 (0.11-1.16)	0.38 (0.09-1.17)	**0.033**
ISUP Grade Group	*1*	*(n,%)*	47 (66.2%)	19 (43.2%)	**0.048**
	2,3	*(n,%)*	19 (26.8%)	21 (47.7%)	
	4,5	*(n,%)*	5 (7%)	4 (9.1%)	
pT	*pT2*	*(n,%)*	58 (81.7%)	35 (79.5%)	0.968(cc)
	pT3	*(n,%)*	13 (18.3%)	9 (20.5%)	
PNI	*Negative*	*(n,%)*	34 (47.9%)	17 (38.6%)	0.437(cc)
	Positive	*(n,%)*	37 (52.1%)	27 (61.4%)	
LVI	*Negative*	*(n,%)*	69 (97.2%)	40 (90.9%)	0.201(fe)
	Positive	*(n,%)*	2 (2.8%)	4 (9.1%)	
Surgical Margin	*Negative*	*(n,%)*	53 (74.6%)	20 (45.5%)	**0.003**cc
	Positive	*(n,%)*	18 (25.4%)	24 (54.5%)	

min: Minimum, max: Maximum. kg: Kilogram, Preop: Preoperative, PSA: prostate-specific antigen, ng: Nanogram, ml: Milliliter, ISUP: International Society of Urological Pathology, pT: pathological T stage, PNI: Perineural invasion, LVI: Lymphovascular invasion

Cox regression analysis performed to identify parameters influencing BRFS indicated that only positive surgical margins had a significant impact (HR: 2.388, p=0.004 CI: 1.319-4.322). (Table III) Survival analysis further demonstrated that patients with positive surgical margins had a statistically significantly shorter BRFS (the log-rank test, p=0.000). (Figure 1)

Table III: Cox regression analysis for predictors of biochemical recurrence free survival.

Factor		Cox regression Analysis			
				%95 CI	
		OR	p-value	Lower	Upper
Preop. PSA level	*(ng/ml)*	1.007	0.687	0.973	1.043
Age	*years*	0.961	0.142	0.910	1.014
ISUP Grade Group	*1*		0.853		
	2, 3	1.850	0.074	0.943	3.629
	4, 5	1.685	0.433	0.457	6.208
pT	pT2 (R) vs pT3	0.981	0.965	0.422	2.281
PNI	*Negative (R) vs positive*	0.836	0.601	0.428	1.635
LVI	*Negative (R) vs positive*	1.243	0.692	0.424	3.645
Surgical Margin	*Negative (R) vs positive*	**2.388**	**0.004**	**1.319**	**4.322**

OR: Odss ratio, Preop: Preoperative, PSA: Prostate-specific antigen, ng: Nanogram, ml: Milliliter, R: Reference category,
ISUP: International Society of Urological Pathology, pT: Pathological T stage, PNI: Perineural invasion,
LVI: Lymphovascular invasion.

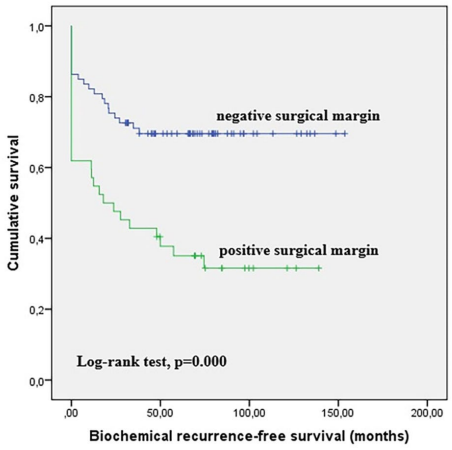

Figure 1:
Kaplan-Meier survival curves according to surgical margin status

Patients were classified into three groups to assess the impact of positive apical surgical margins on BRFS: negative surgical margins, positive margins confined to the apex, and positive margins outside the apex. The BRFS of patients with positive apical surgical margins did not differ significantly from those with positive margins outside the apex (p=540, median BRFS 23.7 [0-84.5] vs. 18 [0-139] respectively). However, the BRFS of patients with positive apical surgical margins was significantly shorter than those with negative surgical margins (p=0.033, median BRFS 23.7 [0-84.5] vs. 56.3 [0-153.6] respectively).

Discussion and Conclusion

This study found that RRP is an effective treatment for PCA, and a positive surgical margin is the most influential factor in BRFS. Furthermore, we observed that patients with BCR tended to have higher PSA density and ISUP grade group. A high-volume study with long-term follow-up of patients with localized prostate cancer identified positive surgical margins, pT3b staging, and pT3a combined with an ISUP grade group >2 as factors associated with a high risk of BCR[11]. In our study, positive surgical margins were the only factor found to be significant. The relatively low number of patients with pT3b (n:8. 7%) and pT3a combined with an ISUP grade group >2 (n:3, 2.6%) in the entire cohort may explain why these two factors did not achieve statistical significance in our analysis. Although the number of pT3 patients in our study was limited, the relatively higher proportion of patients with higher ISUP grade groups among those who developed BCR within three years is consistent with findings reported in the literature[12].

In a review conducted by Ho MD et al. on the stratification of prostate cancer, PSA density was suggested to be associated with high-grade disease[13]. Similarly, Sasaki et al. found that patients with a familial history of prostate cancer exhibited higher PSA density and that these individuals demonstrated poorer clinicopathological outcomes and an association with disease progression following radical prostatectomy[14]. These findings align with our cohort results, where patients defined as BCR within three years exhibited higher PSA density. Furthermore, Greco et al. suggested that PSA density could predict biochemical and local failure in radiotherapy patients[15]. When evaluated alongside these findings and other studies, PSA density emerges as an essential biomarker indicative of tumor burden. However, there is a need for well-designed, advanced studies to investigate this subject further.

A long-standing debate persists regarding which surgical approach, RARP, LRP, or RRP, is superior for the treatment of patients diagnosed with localized PCA. Urology associations have not endorsed any method superior to the others[2,16]. The consensus is that all three approaches demonstrate comparable effectiveness regarding oncological outcomes[2,9,17–20]. Systematic reviews and meta-analyses have indicated that RARP offers advantages in reduced blood loss, lower transfusion requirements, shorter hospital stays, and fewer complications[17,20,21]. Wang et al. reported that RARP results in lower rates of positive surgical margins and BCR compared to RRP[21]. Similarly, Ramsay et al. reviewed studies comparing RARP and LRP and found no significant differences in BCR rates, although they highlighted the superiority of RARP in reducing positive surgical margins[17]. Haglind et al. found no significant differences between RARP and RRP regarding incontinence or positive surgical margins in a prospective, controlled, non-randomized study. Still, they noted that erectile dysfunction outcomes were modestly better in RARP patients[22]. In contrast, Du et al. argued that RARP is superior to both LRP and RRP in terms of nerve-sparing, erectile function, and urinary continence outcomes in a systematic review and meta-analysis[23].

An often-overlooked issue in RARP studies is cost-effectiveness. RARP imposes a substantial financial burden on patients and healthcare systems, with reports suggesting that centers performing RARP must maintain a high annual case volume of approximately 150 to mitigate these costs. LRP, another minimally invasive approach, is less expensive than RARP and has been shown to offer benefits such as reduced blood loss and shorter hospital stays compared to RRP[17]. However, its extended learning curve and reports from particular series indicating disadvantages compared to RRP, such as higher rates of anastomotic leakage, organ injury, and ileus, represent notable disadvantages for LRP[2,17]. Additionally, the fact that surgeons performing RARP and LRP are often more experienced and operate in higher-volume settings compared to those performing RRP raise concerns that functional, and some oncological outcomes may be influenced by surgical experience rather than solely by the surgical method itself[20]. Furthermore, it has been observed that the RRP series typically involve a more significant number of surgeons per study and have longer follow-up durations[20]. Based on this information, RRP remains positioned in treating localized prostate cancer due to its comparable oncological and functional outcomes, relatively shorter learning curve, and cost-effectiveness[9,24].

Our findings regarding estimated blood loss, operative time, and length of hospital stay are consistent with the literature[17,18,25]. Prudhomme et al. presented the case series of a single experienced surgeon, noting that the estimated blood loss was nearly as low as in the RARP series[26]. This low blood loss may be attributed to the surgeon's experience. Our estimated blood loss result is comparable to that reported in other studies[18,25]. However, our surgical margin positivity rate was somewhat higher than those described in the literature. Notably, these studies primarily reported the outcomes of a single experienced surgeon[18,25,26]. Given that our center is a teaching hospital that trains urology residents and allows them to perform RRP, we suggest that this factor contributes to our study's higher surgical margin positivity rate. Grabbert et al. conducted their study in a tertiary health care center and did not specify the operations were exclusively performed by a single experienced surgeon. Their study reported a surgical margin positivity rate of 29%[27]. Consequently, our surgical margin positivity rate is within an acceptable range based on teaching hospitals that train residents.

Previous studies have reported that positive apical surgical margins are not associated with poor prognostic outcomes compared to positive surgical margins outside the apex[28]. Some of these studies have even suggested that patients with positive apical surgical margins exhibit BRFS durations comparable to those with negative surgical margins[29]. In contrast, our study demonstrated that patients with positive apical surgical margins experienced BCR significantly earlier than those with negative surgical margins. Furthermore, there was no significant difference in BRFS between patients with positive apical surgical margins and those with positive margins outside the apex. Consistent with our findings, Pettus et al. reported that positive apical surgical margins do not indicate a better prognosis than positive margins outside the apex and that such patients experience BCR more frequently than those with negative surgical margins[30]. To resolve this dilemma., there is a need for well-designed, high-quality studies.

The primary limitation of our study is the retrospective nature of the study. The secondary one is the lack of post-RRP functionality data (urinary incontinence and erectile dysfunction rates), a limitation stemming from the challenges inherent in standard data collection processes due to the study's retrospective design. Additionally, our study primarily focuses on the oncological outcomes of RRP. Given the low overall and PCA-specific mortality rates, data on overall and cancer-specific survival could not be presented. Nonetheless, due to the growing preference for minimally invasive surgical techniques and the decreasing volume of recent publications on RRP, our study seeks to contribute to the reappraisal of this surgical approach by presenting a contemporary series on RRP.

This study highlights the effectiveness of RRP in the surgical management of localized PCA. Positive surgical margins emerged as the primary predictor of BRFS. PSA density may be a promising parameter in predicting BCR, but further studies are needed. Although minimally invasive techniques are gaining prominence, RRP is a viable alternative, especially in settings with limited resources. A positive apical surgical margin is not associated with a better prognosis.

Ethics Committee Approval Information:
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