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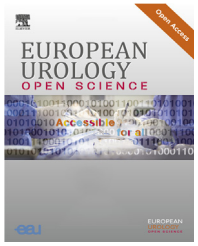

European Association of Urology

Prostate Cancer

Long-term Outcomes and Patient Satisfaction Following Salvage Robot-assisted Radical Prostatectomy: A Modern Perspective

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Article info

Article history:
Accepted November 29, 2023

Associate Editor:
Roderick van den Bergh

Keywords:
Prostate cancer
Prostatectomy
Prostate-specific antigen
Robotic surgical procedures
Salvage therapy

Abstract

Background and objective: Approximately two-thirds of men who undergo primary treatment for prostate cancer (PC) will experience biochemical recurrence (BCR). Salvage robot-assisted radical prostatectomy (sRARP) offers curative treatment in this disease setting and men who choose this option may avoid palliative androgen deprivation therapy (ADT). The purpose of this study was to describe long-term outcomes and patient feedback following sRARP.
Methods: We reviewed data for consecutive men with biopsy-proven localized BCR who underwent sRARP and pelvic lymph node dissection at a single tertiary referral center between 2004 and 2021. Perioperative data, Clavien-Dindo complications, and functional outcomes were recorded. The Kaplan-Meier method was used to estimate prostate-specific antigen–free (≥0.2 ng/ml) survival (PSAFS) and metastasis-free survival (MFS). Three Likert-type items (score 1-5) from the validated Surgical Satisfaction Questionnaire-8 were distributed to patients postoperatively.
Key findings and limitations: We included 78 men, of whom 72 (92%) had undergone primary radiotherapy and six (8%) had received primary prostate ablation. Median follow-up was 10.1 yr (interquartile range 5.8–12.4). Final pathology identified ≥pT3N0M0 in 35 patients (45%) and positive margins in 23 (29%). The overall complication rate was 50%. Of the 26 (33%) major (grade ≥III) complications, anastomotic stricture (32%) was most common. The estimated 3-, 5-, and 10-yr survival rates were 85.6% and 80.2%, 83.5% for PSAFS (n = 11), and 74.1%, 83.5%, and 70.5% for MFS (n = 23), respectively. At last follow-up, postoperative ADT had been administered to 17 patients (22%), and 39 men (50%) remained alive a decade after sRARP. Continence and potency were maintained in 33/62 (53%) and 1/16 (6%) patients, respectively. Thirty-five respondents (45%) reported median questionnaire scores (≥4) in favor of sRARP. Limitations include the small single-center series and a single query point for patient feedback.

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https://doi.org/10.1016/j.euros.2023.11.011

Conclusions and clinical implications: Long-term outcomes of sRARP suggest that the technical challenges and morbidity of the procedure are qualified by patient feedback and the opportunity to evade the morbidity and mortality of biochemically recurrent PC.

Patient summary: We reviewed the cancer outcomes and side effects of robot-assisted surgical removal of the prostate after treatment failure with radiation or ablation for prostate cancer. We found that this type of treatment has substantial risks and long-term side effects, but the surgery provides an opportunity to cure prostate cancer and/or avoid the consequences of indefinite hormonal treatment. Overall, most men who underwent this surgery were not disappointed with their decision despite the higher risks and consequences.

1. Introduction

Prostate cancer (PC) remains the most common noncutaneous solid-organ malignancy and the second leading cause of cancer-related death in the USA [1]. Approximately one-third of men with localized PC will undergo radiation treatment with curative intent [2]; however, up to 60% of these patients will experience biochemical recurrence (BCR) within 5–10 years [3,4]. Management of BCR has historically been dependent on androgen deprivation therapy (ADT). However, the most recent guideline amendments advocate for observation or clinical trial enrollment for these patients given the nuanced and multidisciplinary effort required for management [5]. Alternatively, biopsy-confirmed localized recurrence can be managed with salvage radiation, ablation, or radical prostatectomy. A systematic review of salvage radical prostatectomy (sRP) suggests that better techniques, patient selection, and minimally invasive surgery have led to better cancer control and lower morbidity [6]. Furthermore, modern approaches, specifically salvage robot-assisted radical prostatectomy (sRARP), have the potential to further modify the risk/benefit ratio [7].

Despite the prospect of cure and possible avoidance of ADT, sRARP remains underutilized [8]. Although sRARP may decrease the risk of anastomotic strictures and improve continence in comparison to open sRP, the risk of significant adverse events is not eliminated [9]. Such concerns highlight the importance of shared decision-making and of postoperative health-related quality of life. Patient satisfaction with primary radical prostatectomy has been favorable [10], but there is a paucity of data to shed light on the choice to pursue sRARP.

Given the rate of nonsurgical primary treatment and the future rise of focal therapy for PC [11], the need for definitive salvage surgery such as sRARP is likely to intensify. Therefore, our aim was to present predictors of oncologic and functional outcomes after sRARP. Balancing of these outcomes will better inform patient discussions before undertaking a technically challenging and undoubtedly morbid procedure. We used a validated instrument to explore concordance between the complex decision to pursue sRARP and postoperative patient sentiment.

2. Patients and methods

We reviewed an institutional review board–approved (approval #00149) prospective database of consecutive men who underwent sRARP between 2004 and 2021. All patients experienced BCR following nonsurgical primary treatment (primary radiation or ablative therapy), which was defined using the Phoenix criterion of 2 ng/ml above the nadir prostate-specific antigen (PSA) level. A biopsy was performed to confirm histopathologic diagnosis of localized recurrence. Metastatic evaluation included a technetium-99 bone scan and computed tomography of the abdomen/pelvis, and/or prostate-specific membrane antigen positron emission tomography (PSMA/PET), starting in 2020. In 2010, multiparametric magnetic resonance imaging was used for preoperative staging. Patients with localized recurrence and an estimated life expectancy of >5 yr were eligible for surgery. Shared decision-making in a multidisciplinary clinic was required before sRARP.

Transperitoneal sRARP was performed via a posterior approach by eight experienced fellowship-trained surgeons. A posterior Rocco suture reconstruction and urethral suspension were used to augment the vesicourethral anastomosis [12]. Extended bilateral pelvic lymph-node dissection (eBPLND) was planned for all patients. Nerve-sparing was generally not performed. A fluoroscopic cystogram was obtained 2 weeks postoperatively and weekly thereafter until radiographic evidence of a healed anastomosis.

Oncologic outcomes included PSA-free survival (PSAFS), metastasis-free survival (MFS), and overall survival (OS). PSAFS was defined as the time from surgery until post-sRARP PSA $\geq$0.2 ng/ml and excluded patients with PSA persistence. PSA persistence was defined as postoperative PSA that remained >0.2 ng/ml relative to the preoperative value. MFS was defined as time to local or distant recurrence, whichever occurred first. OS was defined as the time from surgery to death from any cause. Patients were censored at the last known visit date if they were lost to follow-up or did not experience events of interest during the study period.

Functional outcomes were assessed at baseline and postoperatively. Continence was defined as no pad use or use of a security liner. Potency was defined as an erection sufficient for penetration with or without the aid of a phosphodiesterase-5 inhibitor. Perioperative outcomes included Clavien-Dindo minor (grade $\leq$II) and major (grade $\geq$III) complications [13] recorded for the duration of follow-up. A modified version of the validated Surgical Satisfaction Questionnaire-8 (SSQ-8) [14] was used to analyze patient feedback. Patients were contacted >1 yr after their surgery and asked three of the eight original SSQ-8 questions. The follow-up period was defined as the time from sRARP until the date of the last follow-up or death.

Categorical data are reported as the frequency and proportion. Continuous variables were non-normally distributed and results are reported as the median and interquartile range (IQR). Estimates for PSAFS, OS, and MFS were calculated using the Kaplan-Meier method. Cox proportional-hazards regression was used to identify factors associated with PSAFS and MFS. Factors with a p value of <0.05 on univariable analysis were included in the multivariable analysis. Statistical significance was set at $p < 0.05$. Data management and statistical analyses were conducted using SAS v9.4 (SAS Institute Inc., Cary, NC, USA) and R v4.3.0 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

A total of 78 men with median PSA of 3.7 ng/ml (IQR 2.4–5.8) underwent sRARP at a median of 67.6 months (IQR 43.6–96.3) after nonsurgical primary treatment. Seventy-two patients (92.3%) had primary radiotherapy, of whom 16 (22%) had concurrent ADT, five (6%) had cryotherapy, three (60%) of whom had concurrent ADT, and one (1%) had high-intensity focused ultrasound. Biopsy-proven Gleason ≥8 localized recurrence was found in 24 patients (31%), and 19 (24%) had preoperative PSA >6 ng/ml (Table 1).

Perioperative and pathologic data are shown in Supplementary Table 1. eBPLND was deferred in nine patients (12%) because of a hostile surgical field and concerns regarding possible vascular injury. ≥pT3 disease was found in 35 patients (45%), 13 (37%) of whom also had positive surgical margins. Gleason 8–10 disease was identified in 18 men (23%), and five patients (6%) had positive lymph nodes.

Overall, 57 complications occurred in 39 patients (50%). Nine patients (12%) experienced multiple complications (Table 2). Major complications occurred for 26 patients (33%). The most common minor and major complications were anastomotic leak (33.3%) and bladder neck contracture (31.5%), respectively. Continence and potency were maintained in 33/62 (53%) and 1/16 (6%) patients who reported continence and potency at baseline, respectively. Secondary procedures to treat incontinence were performed for 15 men (19%).

Over median follow-up of 10.1 years (IQR 5.8–12.4), postoperative PSA progression to ≥0.2 ng/ml occurred for 11 of 57 evaluable men (19%) in the PSAFS analysis (Figure 1A). Twenty-one patients (27%) were censored, 20 because of PSA persistence and 1 because of inadequate postoperative PSA data. At last follow-up, 17/78 patients (22%) had documented administration of ADT. Of the 11 men with PSA progression, seven (64%) received ADT ± taxane chemotherapy ± radiation; the remaining four were managed with PSA monitoring. Another 10/20 men (50%) whose immediate postoperative PSA was >0.2 ng/ml were given palliative ADT (Supplementary Fig. 1). The estimated 3-, 5-, and 10-yr PSAFS rates were 85.6%, 83.5%, and 83.5%, respectively. On univariable analysis, preoperative Gleason 8–10 disease (hazard ratio [HR] 5.9, 95% confidence interval [CI] 1.7–20.3; $p = 0.005$), postoperative Gleason 8–10 disease (HR 11.4, 95% CI 2.2–59.1; $p = 0.004$), and positive surgical margins (HR 5.3, 95% CI 1.3–21.2; $p = 0.019$) were associated with risk of postoperative PSA progression to ≥0.2 ng/ml (Table 3). Metastatic disease occurred in 23 patients (29%). Extracapsular extension (HR 2.4, 95% CI 1.05–5.66; $p = 0.038$), pathologic Gleason 8–10 disease (HR 3.9, 95% CI 1.45–10.8; $p = 0.007$), and PSA persistence (HR 4.5, 95% CI 1.9–10.6; $p < 0.001$) were significantly associated with the risk of metastasis (Table 4). The estimated 3-, 5-, and 10-yr MFS rates were 80.2%, 74.1%, and 70.5%, respectively (Fig. 1B). No factors in the multivariable analysis were associated with PSAFS or MFS (Tables 3 and 4). Seventeen patients (22%) died, six (8%) from metastatic PC. The estimated OS rates at 3, 5, and 10 yr were 97.4%, 94.5%, and 83.3%, respectively (Fig. 1C).

A total of 35 men (45%) provided complete SSQ-8 responses following sRARP (Table 5). Of note, 80% (28/35)

Table 1 – Preoperative clinicopathologic characteristics of the 78 patients

Parameter	Result
Median age, yr (IQR)	67.0 (63.0–71.0)
Median follow-up, yr (IQR)	10.1 (5.8–12.4)
Race, No. (%)	
White	65 (83)
Black or African American	8 (10)
Asian	3 (4)
Other	2 (3)
Median body mass index, kg/m^2 (IQR)	29.0 (26.4–33.0)
Preoperative disease risk group, *n* (%)[a]	
Low risk	24 (31)
Intermediate risk	30 (38)
High risk	24 (31)
Median age-adjusted Charlson comorbidity index score (IQR)	5.0 (4.0–5.0)
Primary nonsurgical treatment, *n* (%)	
Brachytherapy	31 (40)
EBRT	30 (38)
Proton beam therapy	8 (10)
Cryoablation	5 (6)
Brachytherapy + EBRT	3 (4)
High-intensity focused ultrasound	1 (1)
Prior history of androgen deprivation therapy, *n* (%)[b]	19 (24)
Postoperative androgen deprivation therapy, *n* (%)[c]	17 (22)
Median time from primary treatment to sRARP, mo (IQR)	67.6 (46.3–96.3)
Median preoperative PSA, ng/ml (IQR)	3.7 (2.4–5.8)
Preoperative PSA quartile, *n* (%)	
0–2 ng/ml	13 (17)
>2–4 ng/ml	29 (37)
>4–6 ng/ml	17 (22)
>6 ng/ml	19 (24)
Preoperative PSA velocity, *n* (%)	
Insufficient PSA data	4 (5)
PSA <2 ng/ml/yr	53 (68)
PSA ≥2 ng/ml/yr	21 (27)
Preoperative continence, *n* (%)	
Continent	62 (79)
Incontinent	16 (21)
Preoperative potency, *n* (%)	
Potent	16 (21)
Not potent	62 (79)

IQR = interquartile range; sRARP = salvage robot-assisted radical prostatectomy; EBRT = external beam radiation therapy; PSA = prostate-specific antigen.

[a] American Urological Association risk stratification scheme for prostate cancer based on histopathologic diagnosis of localized recurrence.

[b] Androgen deprivation therapy was given to 16 patients who had received primary radiation therapy and three patients who had received primary cryotherapy.

[c] Palliative androgen deprivation therapy was given to 17 men after sRARP.

Table 2 – Summary of Clavien-Dindo minor and major complications following salvage robotic-assisted radical prostatectomy

Category	Adverse event	Minor (grade I–II)	Major (grade III–IV)	Proportion of total complications (%)
Procedural	Anastomotic leak	18	0	33.3
	Hematuria	1	1	3.7
	Urinary retention	1	1	3.7
	Bladder neck contracture	0	17	31.5
	Incisional hernia	0	1	1.9
	Meatal stricture	0	1	1.9
	Rectourethral fistula	0	1	1.9
	Repair of small bowel enterotomy	0	1	1.9
	Staple removal	0	1	1.9
	Ureteral injury	0	1	1.9
Cardiovascular	Anemia	1	0	1.9
	Atrial fibrillation	1	0	1.9
	Deep vein thrombosis or pulmonary embolism	1	2	5.6
Infectious	Urinary tract infection	2	1	5.6
	Urosepsis	0	2	3.7
Gastrointestinal	Ileus	1	1	3.7

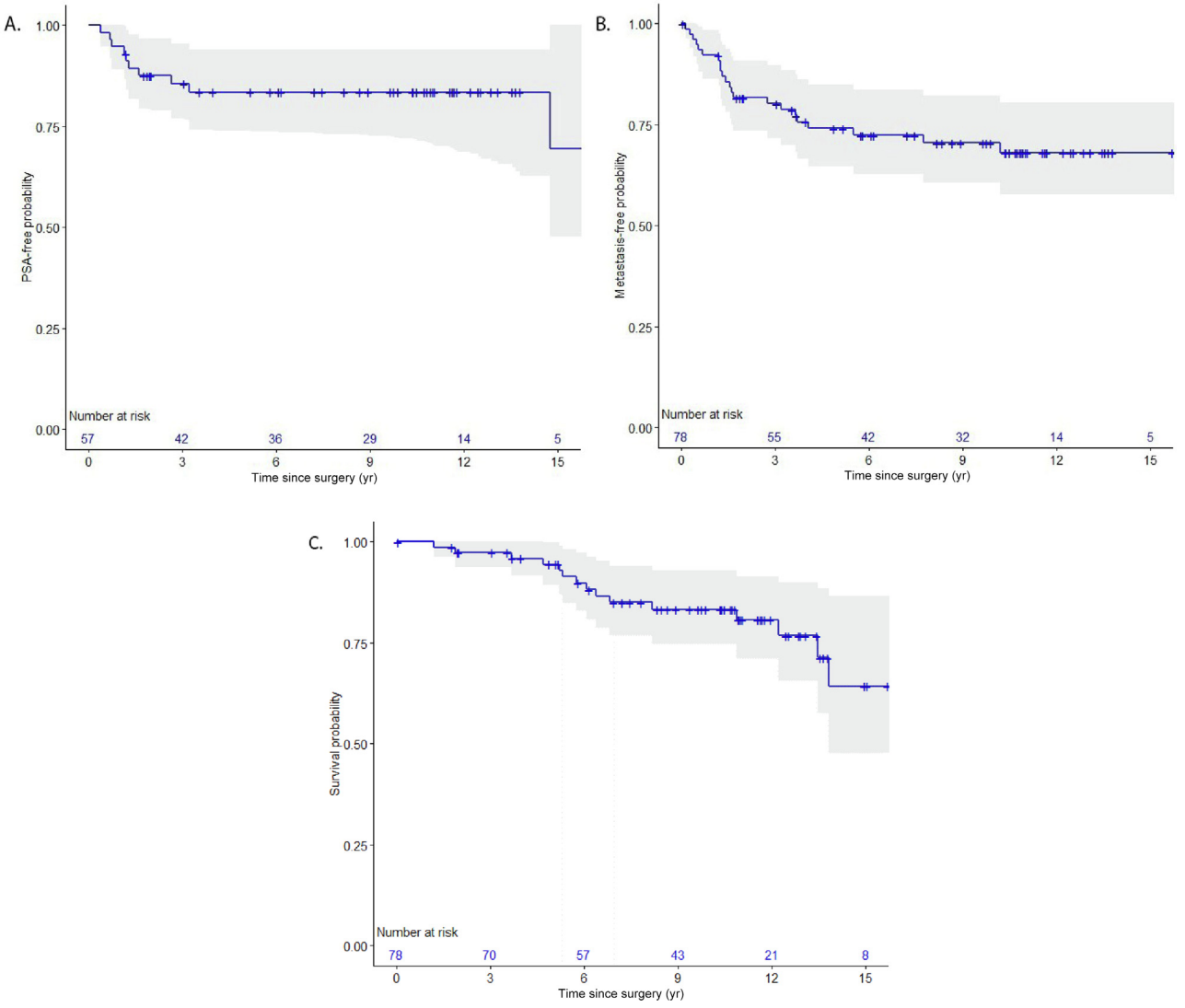

Fig. 1 – Kaplan-Meier survival analyses. (A) Prostate-specific antigen (PSA)-free survival, with estimated 1-, 3-, and 5-yr probabilities of 85.6%, 83.5%, and 83.5%, respectively. (B) Metastasis-free survival, with estimated 1-, 3-, and 5-yr probabilities of 80.2%, 74.1%, and 70.5%, respectively. (C) Overall survival, with estimated 1-, 3-, and 5-yr probabilities of 97.4%, 94.5%, and 83.3%, respectively.

of the patients were continent and 74% (26/35) were not potent preoperatively. Of these patients, three (8.5%) had disease recurrence and five (14%) underwent adjuvant therapy. There was no difference in median satisfaction score between those who experienced loss of continence and those who did not (5 vs 4; $p = 0.6$).

Table 3 – Univariable and multivariable models of PSA-free survival (*n* = 57)

	Univariable results		Multivariable results	
	HR (95% CI)	*p* value	HR (95% CI)	*p* value
Age at surgery in years	1.03 (0.94–1.14)	0.50		
Body mass index in kg/m^2	0.98 (0.87–1.10)	0.69		
Preoperative PSA level (vs 0–2 ng/ml)				
>2–4 ng/ml	0.74 (0.13–4.27)	0.73		
>4–6 ng/ml	0.53 (0.04–6.19)	0.61		
>6 ng/ml	2.19 (0.36–13.1)	0.39		
Clinical stage T2	1.66 (0.48–5.68)	0.42		
Preoperative Gleason 8–10 disease[a]	5.90 (1.72–20.3)	**0.005**	4.09 (0.72–23.3)	0.11
Extracapsular extension	3.43 (0.92–12.8)	0.067		
Seminal vesicle involvement	2.45 (0.73–8.25)	0.15		
Pathological Gleason 8–10[b]	11.4 (2.21–59.1)	**0.004**	3.20 (0.39–26.6)	0.28
Positive surgical margins	5.30 (1.32–21.2)	**0.019**	3.02 (0.59–15.6)	0.19

HR = hazard ratio; CI = confidence interval; PSA = prostate-specific antigen.
[a] Gleason score for the confirmatory prostate biopsy following biochemical recurrence.
[b] Gleason score assigned following salvage robot-assisted radical prostatectomy.

Table 4 – Univariable and multivariable models of metastasis-free survival (*n* = 78)

	Univariable results		Multivariable results	
	HR (95% CI)	*p* value	HR (95% CI)	*p* value
Age at surgery in years	0.99 (0.93–1.06)	0.80		
Body mass index in kg/m^2	0.98 (0.91–1.06)	0.60		
Preoperative PSA (vs 0–2 ng/ml)				
>2–4 ng/ml	1.09 (0.33–3.53)	0.89		
>4–6 ng/ml	0.52 (0.12–2.32)	0.39		
>6 ng/ml	1.23 (0.35–4.38)	0.75		
Clinical stage T2	0.85 (0.32–2.30)	0.75		
Preoperative Gleason score 8–10	2.40 (0.97–5.91)	0.058		
Extracapsular extension	2.44 (1.05–5.66)	**0.038**	1.62 (0.51–5.12)	0.41
Seminal vesicle involvement	1.12 (0.46–2.75)	0.80		
Pathological Gleason score 8–10	3.95 (1.45–10.8)	**0.007**	2.30 (0.70–7.51)	0.17
Positive surgical margins	1.55 (0.65–3.72)	0.32		
PSA persistence	4.54 (1.95–10.6)	**<0.001**	2.14 (0.68–6.71)	0.19

HR = hazard ratio; CI = confidence interval; PSA = prostate-specific antigen.

4. Discussion

We present a single tertiary center experience of sRARP for men whose primary PC treatment did not achieve cure. The data presented include more than a decade of follow-up and represent the longest comprehensive analysis of sRARP. Considering the rate at which sRARP is performed, the technical challenge for surgeons, and the undertaking by patients, we sought patient feedback to substantiate the oncologic and functional outcomes.

Table 5 – Patient feedback from 35 respondents for three questions (Likert-type score 1–5) from the Surgical Satisfaction Questionnaire-8

Question	Score	
	Median (IQR)	Range
How satisfied are you with the results of your surgery?	4 (4–5)	1–5
Looking back, if you "had to do it all over again," would you have the surgery again?	5 (3.5–5)	1–5
Would you recommend the surgery to someone else?	5 (3.5–5)	1–5

IQR = interquartile range.

The need for sRP may grow in the future. Estimates of primary radiotherapy and the incidence of BCR indicate that approximately 9–24% of men newly diagnosed with PC will require discussion of salvage therapy [2–4]. Furthermore, comprehensive screening, genomic risk stratification, and imaging guidance for prostate biopsy may shift the timeline for PC diagnosis. While targeting discrete lesions with focal therapy may mitigate the morbidity of whole-gland treatment, the need for long-term outcomes and accurate identification of BCR [15] will challenge patients and physicians alike in making decisions on which salvage therapy to pursue. The endorsement of PSMA/PET over conventional imaging in the most recent American Urological Association guidelines will further identify patients with localized recurrence who are eligible for salvage whole-gland therapy [5]. Therefore, it is imperative that patient selection for sRARP be optimized now and in the future so that the demand is met by an appropriate supply.

Our univariable analyses indicated that men with Gleason 8–10 PC, pT3 disease, or positive surgical margins are more likely to experience rising PSA or metastases. It has been shown that Gleason score and PSA are significant prognostic factors associated with MFS, progression-free survival, or cancer-specific survival following sRP [16–18].

A systematic review by Chade et al. [6] suggested that preoperative PSA is one of the strongest predictors of recurrence for these men. Considering that PSA and high-risk PC are themselves risk factors for adverse pathology, metastasis, or death [19–21], it is possible that patients with high-grade recurrence ultimately have an unfavorable risk/benefit ratio for sRARP.

Our PSAFS analysis indicates that PSA recurrence (≥0.2 ng/ml) occurs within the first 3 yr after sRARP and remains stable from 3 to 10 yr. Our PSAFS event rate was low (14%) as we excluded patients with PSA persistence to avoid confounding post-sRARP PSA progression and to distinguish men who achieved a cure. PSA persistence increased the risk of metastasis and therefore may be a relevant prognostic factor. A recent preliminary multi-institutional report for 242 men following sRP found that PSA persistence (≥0.1 ng/ml) was significantly associated with BCR (HR 5.6) and death (HR 3.0). Moreover, higher preoperative PSA and Gleason 8–10 recurrence were independent predictors of PSA persistence [22].

The threshold definition for PSA failure after sRP varies in the literature [8]. PSA ≥0.2 ng/ml is most often used as the point at which to initiate discussion of secondary therapy after sRP [23,24]. Thirty-one men in our cohort met the criterion for discussion of secondary therapies and 45% were managed with observation. The consideration that sRARP can achieve cure with further avoidance of ADT in close to half of patients diversifies the meaning of clinical success. Historically, as few as 5% of men elect to undergo salvage therapy with curative intent and as many as 90% pursue noncurative ADT [25]. ADT is associated with significant side effects, including hot flashes, insulin resistance, cardiovascular morbidity, and sexual dysfunction, among others [26]. A recent meta-analysis of 150 studies of both surgical and nonsurgical local salvage treatment reveal pooled 5-yr recurrence-free survival (a composite of disease- or BCR-free survival) rates of 50–53% for cryotherapy or high-intensity focused ultrasound, 56–60% for brachytherapy, and 60% for stereotactic body radiation [27]. Thus, the opportunity to avoid the lifetime costs and toxicities of palliative ADT in this patient population cannot be understated.

Our data confirm that sRARP has a higher rate of complications. Rates for total and major complications were high relative to single-center (8–38%) [23,24] and multicenter (18–33%) [6,7] sRP series. However, nearly two-thirds of the complications were the most common observed after sRP, namely anastomotic leak (33%) and bladder neck contracture (32%), and there was a comparably low rate of rectal injury (∼2%), perhaps a testament to the robotic approach. In addition, we extended capture of these complications beyond 90 days to report long-term consequences that can occur outside the perioperative period. Moreover, failed focal therapy may be associated with lower morbidity after sRP in comparison to whole-gland primary treatments evaluated in the current study [28]. In addition, the complication rate may be higher for patients pretreated with ADT [9]. In our cohort, >90% of men were treated with radiation and 24% received ADT.

We found that ∼50% of men remained continent and ∼6% remained potent after sRARP. Prior sRP studies including meta-analyses have reported variable pad-free continence rates (39–79%), and significant loss of potency (<20%) [6–7,23–25]. Importantly, continence preservation after sRP may depend on the type of primary treatment [28] and has improved with robotic assistance [9] or a Retzius-sparing approach [29]. Therefore, to determine the impact of changes in genitourinary function we solicited feedback from nearly half of the patient cohort following sRARP.

After failed primary treatment, oncologic control may be the foremost goal and maintenance of genitourinary and sexual function may be secondary. Sanderson et al. [30] reported on health-related quality of life for 62% of patients at a median of 7.5 years after open sRP, of whom 33–45% had undergone secondary procedures to treat incontinence and erectile dysfunction. The authors found no difference in subjective urinary function scores despite an ancillary procedure, >70% of respondents had minimal urinary bother, and there was no correlation between postoperative erectile function and sexual bother scores. Similarly, our respondents indicated agreement with prioritizing cancer control and risking the morbidity of sRARP. These results further support the complex discussion that should be had before proceeding with sRARP.

The limitations of the present study include the lack of an alternative salvage treatment group for comparison. Our cohort was small, albeit in the setting of an uncommon procedure, but we included a median of 10 years of follow-up to report long-term outcomes for these patients. In addition, none of the variables tested was significant in both univariable and multivariable analyses, which may limit their clinical significance. The low event rate for PSAFS (n = 11) was because of the exclusion of patients with PSA persistence as a confounder for the definition of cure. Lastly, we reported a moderate SSQ-8 response rate, with variable timing as to when patients were queried. The timing for obtaining patient feedback and the response rate impact interpretation of the responses, and the lack thereof may imply bias.

5. Conclusions

sRARP offers curative treatment and avoids the toxicities of ADT for men with organ-confined BCR following nonsurgical primary treatment for PC. PSA kinetics and the Gleason pattern of recurrence may be valuable indices for patient selection. Despite the high rates of postoperative complications, erectile dysfunction, and incontinence, patients did not voice regret regarding their decision to pursue sRARP.

Author contributions: Daniel J. Lama had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Yuh, Lama, Okunowo, Lau.
Acquisition of data: Thomas, Lama, Okunowo.
Analysis and interpretation of data: Yuh, Lama, Okunowo.
Drafting of the manuscript: Thomas, Ferenczi, Lama.

Critical revision of the manuscript for important intellectual content: Yuh, Lau, Lama, Ferenczi.
Statistical analysis: Okunowo.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: Yuh, Lau.
Other: None.

Financial disclosures: Daniel J. Lama certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

Funding/Support and role of the sponsor: None.

Data sharing statement: Data are available for bona fide researchers who request it from the authors.

Acknowledgments: The authors would like to thank Kelly Ellis and Airybelle Uchida for assistance with data acquisition.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2023.11.011.

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