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TOPIC PAPER

Salvage robotic-assisted radical prostatectomy: oncologic and functional outcomes from two high-volume institutions

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Abstract

Introduction While no consensus on the optimal salvage treatment exists, only 3% of these patients will get salvage radical prostatectomies due to the assumed technical challenges of this procedure.

Objectives Our goal is to analyze the perioperative, oncologic and functional outcomes of patients undergoing salvage robotic-assisted radical prostatectomy (sRARP) after primary treatment failure.

Materials and methods Data were prospectively collected and retrospectively reviewed from a combined database of more than 14,800 patients who had undergone RARP. We identified 96 patients who underwent sRARP after RT or ablative techniques. Primary cancer characteristics, surgical data, pathology results, perioperative complications, oncologic and functional outcomes were analyzed.

Results Sixty-eight patients (70.8%) received some source of RT as a primary treatment. The remaining 28 patients: 18 (18.75%) received cryotherapy, seven (7.92%) HIFU, one electroporation, one microwave and one Tookad. complication was seen in 25 (26%) patients (21 minor and 4 major complications). Anastomotic leak was the most common complication, found in 14 (14.6%) of the cases. No rectal injuries occurred. Fourteen (15%) patients had a biochemical failure after a median follow-up of 14 (IQR 5–24) months. Fifty-five (57.3%) of them self-reported to be pad-free at 12 months. Seventeen (55%) of 31 pre-operative potent patients (SHIM score > 21), were potent with or without the use of PDE5i at 12 months.

Conclusions sRARP is a feasible alternative for PCa recurrence. Technically the procedure is challenging and should be performed by experienced PCa surgeons. Major complications are uncommon. Continence and potency recovery is possible, but at lower rates than for non-salvage patients.

Keywords Salvage robotic-assisted radical prostatectomy (sRARP) · Prostate cancer recurrence · Radiotherapy · Cryotherapy · High-intesity focused ultrasound (HIFU) · Brachyterapy · Complications

Introduction

Prostate cancer represents the most commonly diagnosed non-cutaneous cancer in men and is the second leading cause of cancer-related death in the United States [1]. Primary treatment for prostate cancer is varied, in addition to surgery, which includes minimally invasive or ablative procedures such as radiotherapy, cryotherapy, and high-intensity focused ultrasound (HIFU). Unfortunately, a large proportion of these patients, especially with high-risk features, receiving these forms of therapy may experience disease recurrence within 10 years [2, 3]. Of patients who experience biochemical relapse, up to 70% will have a local failure within the prostatic gland [4]. While no consensus on the optimal salvage treatment exists, only 3% of

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these patients will get salvage radical prostatectomies due to the assumed technical challenges of this procedure. In these cases, treatment options include: observation, androgen deprivation therapy (ADT), brachytherapy, cryoablation, HIFU and salvage radical prostatectomy (sRP). These modalities have had varying degrees of success; however, there is no consensus on the optimal salvage treatment [5].

Minimally invasive techniques have become increasingly employed to mitigate the complications associated with an open-sRP approach [6]. On the other hand, salvage robot-assisted radical prostatectomy (sRARP) has shown to provide a durable cure for recurrent localized disease without increasing rates of complications in a number of case series. This fact is most likely due to the advantages provided by robotic instrumentation that has improved operator dexterity, allowing precision dissection and tissue manipulation [7–11]. In the present study, to the best of our knowledge, we report the largest series of sRARP published in the literature from two high-volume institutions. We aimed to evaluate the feasibility, safety, and efficacy of sRARP on the incidence of perioperative complications, oncological and functional outcomes.

Methods

Study population

From January 2001 to April 2016, a total of 96 patients who underwent sRARP, after failure of the primary treatment, performed in both institutions (GRI and Montsouris) were included. Only four (4.16%) patients were lost in follow-up, but included in the analysis. PCa recurrence was biopsy-proven in all cases. A total of 68 patients (70.8%) received radiation as a primary treatment: 37 (38.54%) EBRT, 14 (14.58%) brachytherapy, 13 (13.54%) EBRT + brachytherapy combined three (3.13%) cyberknife and one (1.04%) proton beam. Of the remaining 28 patients: 18 (18.75%) received cryotherapy, seven (7.92%) HIFU, one (1.04%) electroporation, one (1.04%) microwave and one (1.04%) Tookad (Table 1).

Inclusion and exclusion criteria

We included all patients with a localized, biopsy-proven PCa recurrence after radiotherapy or any ablative technique, with a life expectancy of > 10 years who after been counseled and consented underwent sRARP at the mentioned institutions. Patients with salvage surgery other than robotic approach were excluded from the present analysis.

Table 1 Primary treatment

Initial treatment	Number of patients (%)
External radiotherapy	37 (38.54%)
Brachytherapy	14 (14.58%)
EBRT + brachy	13 (13.54%)
Cyberknife	3 (3.13%)
Proton beam	1 (1.04%)
Cryotherapy	18 (18.75%)
HIFU	7 (7.92%)
Tookad	1 (1.04%)
Electroporation	1 (1.04%)
Microwave	1 (1.04%)
Total patients	96 (100%)

Surgical technique

At Global Robotics Institute, all sRARP were performed using the transperitoneal six-port technique with the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA). Our technique for retrograde NS and the use of the "landmark" artery for locating the NVB has been previously published [12]. Bilateral, retrograde, athermal nerve sparing (NS) RARP was performed when oncologically and technically feasible and the patient had some degree of functionality preserved (pre-op SHIM score ranging 12–25). A bladder neck reconstruction, an anterior suspension stitch, and posterior reconstruction [13–15] were performed in all cases. Finally, a modified Van Velthoven technique using a running double-needle suture for the vesico-urethral anastomosis (VUA) was performed. Additionally, and only for the last 16 patients of this group, a scaffold of porcine urinary bladder extracellular matrix (UB-ECM) was incorporated into the base of the VUA and bladder neck [16]. An 18-Fr Foley catheter was inserted. The specimen was then removed through the primary trocar incision, and a 19 Fr Jackson–Pratt drain was positioned in the pelvic gutter.

Montsouris port placement did not differ from their primary RARP. An extraperitoneal approach was performed with balloon dissection as previously described [9, 17]. Endopelvic fascia was preserved and the bladder neck was dissected as usual, with no difficulties encountered. Seminal vesicles and posterior planes have dense fibrosis, making this step of the procedure technically demanding. The routine approach was not modified. In patients with primary focal treatment, we tackled the untreated side first, as a reference to search for anatomic planes, especially in the apical dissection.

The extension of the lymphadenectomy has varied over the 15 years of patient inclusion for this analysis. The overall tendency over these years has been to perform a more

extended lymph node dissection; however, is difficult to establish exactly how many patient of this series received a standard or an extended lymphadenectomy. In the recent years, the individual risk of identifying positive lymph nodes was assessed using pre-operative nomograms. When the risk for nodes metastasis was over 5%, an extended pelvic lymph node dissection was performed.

Follow-up and assessment

Retrograde and voiding cystograms were performed in all the patients at day 10. If no contrast extravasation was observed, the catheter was removed the same day, otherwise the catheter remains and a second cystogram will be scheduled a week later.

The patient's PSA was routinely followed-up at 6 weeks, then at 3, 6, 9, 12, 18 and 24 months after surgery. Erectile function and continence were also assessed at each of these time points through direct questions and validated questionnaires, such as the Sexual Health Inventory for Men (SHIM) and the American Urological Association Symptom Score (AUASS).

Definitions

Biochemical Recurrence (BCR) was defined as PSA $\geq$ 0.2 ng/mL after sRARP, followed by a subsequent confirmatory PSA value $\geq$ 0.2 ng/mL [18].

The definition of continence was based on the response to the item selected to reflect the range of incontinence severity: "How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks?" Continence was defined as the use of no pads (score: 0).

Potency was defined as the ability to achieve and maintain satisfactory erections firm enough for sexual intercourse, with or without the use of PDE-5 inhibitors [19].

Data source and management

Following institutional board review (IBR) approval, the perioperative data collected prospectively were retrospectively analyzed from a combined database of more than 14,800 robotic prostatectomies. Pathologic analysis were performed and confirmed at each institution and specimens were processed according to the recommendations of the American Society of Clinical Pathologists [20] or the pathology committee of the European Randomised Study of Screening for Prostate Cancer (ERSPC). Pathologic staging was performed according to the 2002 TNM system [21]. A positive surgical margin was defined as the extension of the tumor to the inked surface of the specimen. NS was subjectively evaluated by the surgeons [22]. Post-operative complications were classified using the Clavien–Dindo criteria.

Statistical analysis

Clinical data are presented as absolute numbers and simple percentages. Continuous variables were reported as the median values and interquartile range (IQR). All statistical analyses were performed using IBM SPSS v.21.0 for Mac (SPSS Inc., Chicago, IL, USA).

Results

Demographics

Median age of the patients was 65.75 years old (IQR: 61.29–71.10), the median body mass index (BMI) was 28.32 (IQR: 25.54–30.88) and the median Charlson's score 2 (IQR: 2–3). Median time from primary treatment to BCR was 81.50 months (IQR: 18.25–335.5), with a median pre-operative PSA of 4.0 ng/mL (IQR: 2.61–6.30) (Table 2).

The primary treatment has been previously described (see "Study Population" section Table 1). Of the 31 patients that received an ablative treatment as primary treatment, 14 (45.2%) were on focal treatment. The median follow-up time of the patients was 14 (IQR: 5–24) months.

Perioperative and pathological features

The median operative time was 125 min (IQR 119–138). The median estimated blood loss (EBL) was 100 mL (IQR: 100–200). Lymphadenectomy was performed in 85 patients (88.54%). The median hospital stay was 1 day (IQR: 1–2), while the median indwelling bladder catheter time was 12 days (IQR: 10–28) (Table 3).

Sixteen (16.7%) patients presented positive surgical margins (PSM) in the surgical specimen after sRARP; ten of them (10.4%) presented the PSM at the apex or near the apex. Ten of these patients had a locally advance disease (pT3) while the other six cases were patients with a confined disease to the prostate (pT2). The rest of the pathological findings can be found in Table 4.

Table 2 Baseline characteristics of the cohort

N = 96	Median (IQR)
Age (years)	65.75 (61.29–71.10)
BMI	28.32 (25.54–30.88)
Charlson's Comorbidity Index	2.0 (2.0–3.0)
Initial PSA (ng/mL)	5.89 (4.23–8.60)
PSA before RARP (ng/mL)	4.0 (2.61–6.30)
Time to BCR (months)	81.50 (18.25–335.5)

Table 3 Perioperative outcomes

Operative time (median) (IQR)	125 min (119–138)
Estimated blood loss (median) (IQR)	100 mL (100–200)
Lymphadenectomy (number) (%)	
Yes	85 (88.6%)
No	11 (11.4%)
Nerve sparing (number) (%)	
Partial	71 (74%)
Full	14 (14.6%)
None	11 (11.4%)
Length of hospital stay (median) (IQR)	1 day (1–2)
Indwelling Foley catheter (median) (IQR)	12 days (10–28)

Table 4 Pathological outcomes

Positive surgical margins	16 (16.7%)
Tumor stage	
pT2a and b	16 (16.6%)
pT2c	32 (33.3%)
pT3a	24 (25%)
pT3b	22 (22.9%)
Unknown	2 (2%)
Final Gleason Score	
≤ 6	4 (4.2%)
7	53 (55.3%)
≥ 8	29 (30.2%)
Deferred	10 (10.3%)
Lymph nodes	
pN0	77 (80.2%)
pN1	8 (8.3%)
pNx	11 (11.5%)

Complications

Post-operative complications were rigorously recorded by both institutions following Clavien–Dindo criteria [23]. Twenty-two minor complications were reported in this series. Of the 21 minor complications, 12 were asymptomatic urinary leaks observed on the cystogram on day 10 after the sRARP, and in all cases, solved with longer catheterization time. The rest of the low-grade complications were: four urinary tract infections (UTI) treated with antibiotics, two acute urinary retention (AUR) after catheter removal, two post-operative bleeding with one of them requiring a blood transfusion and one epididymitis.

Only four major complications were reported. Again the most common were two urinary leaks that needed a Foley catheter reinsertion to resolve them, one myocardial infarction (MI) during the first 30 days after the surgery and one symptomatic lymphocele that needed to be drained percutaneously. Complications are summarized in Table 5.

Functional and oncological outcomes

All the patients were continent before the sRARP. At 12 months, 55 (57.3%) patients were pad-free, while another 25 (26%) patients were using 1–2 pads/day. Sixteen (16.7%) patients presented a more severe degree of incontinence requiring ≥ 3 pads/day. Regarding potency, only 31 (32.3%) presented a SHIM score ≥ 21 pre-operatively, another 34 patients (35.4%) a SHIM between 10–20, and 31 (32.3%) a severe erectile dysfunction with a SHIM < 10. In 85 of the cases (88.54%) some degree of nerve sparing (NS) was performed (see Table 3). At 12 months after surgery, 17 patients (17.7%), were potent with or without the use of PDE5i (Table 6).

Ninety-one patients (95%) achieved undetectable PSA after the surgery. With a limited follow-up of 14 moths, 81 patients (84.38%) remain free of BCR after 12 months from surgery (Table 6). At the end of the follow-up there were no reported deaths. Seventy (72.9%) patients were not taking or receiving any additional treatment, and 26 (27.1%) were on anti-androgen deprivation therapy (ADT).

Table 5 Medical and surgical 30-day complications by organ system using the Clavien–Dindo classification

Systems	Complications	I	II	IIIa	IIIb	IV	V	Total
Medical								
Infectious	Urinary tract infection	4	–	–	–	–	–	4
	Epididymitis	1	–	–	–	–	–	1
Cardiac	Myocardial infarction	–	–	–	–	1	–	1
Surgical								
Lympho-vascular	Lymphocele	–	–	1	–	–	–	1
	Post-op bleeding	1	1	–	–	–	–	2
Urologic	Acute urinary retention	2	–	–	–	–	–	2
	Urinary leak	12	–	–	2	–	–	14

Table 6 Functional and oncological outcomes

Continence at 12 months (pads/days)	
No	55 (57.3%)
1–2	25 (26%)
> 3	16 (16.7%)
Potency at 12 months	
Yes (with or w/o PDE5i)	17 (17.7%)
No	79 (82.2%)
Biochemical recurrence (BCR) at 12 months	15 (15.6%)

Discussion

Within the last three decades, there has been a great deal of development in prostate cancer treatment. Although local therapy is curative for many patients, the rate of relapse is still high, with some estimates being over 60% especially in intermediate and high-risk cohort [2, 3]. According to the literature, if salvage therapy was withheld, up to two-thirds of patients developed bone metastases within 10 years [24]. This leaves patients in the position of having to choose from a vast array of therapeutic options.

Due to the difficulty and complications associated with salvage radical prostatectomy, including the risk of incontinence, impotence, and rectal injury, SRP is commonly avoided. Because of this, most clinical centers prefer ablative techniques [9] or non-invasive treatment, such as ADT. Of men with radio-recurrent disease from the CapSURE database, more than 68% of those who underwent treatment received ADT. ADT avoids the demanding challenges of surgery; however, it is not with curative intent [25, 26].

There are several studies that have shown the efficacy and safety of sRARP [7–12]. However, to our knowledge, this series represents the largest series published and the only one with results from more than one institution. Our series not only shows more evidence to support the feasibility of this technique, but also shows that a NS technique can be attempted if it is oncologically appropriate to obtain better functional outcomes without compromising surgical margins Table 7. In terms of BCR-free rate, contemporary studies have reported ranges of 43–82%. Our overall BCR-free survival rate was 84.6%, after a median follow-up of 14 months, which may represent a short follow-up time, but comparable to most of the sRARP contemporary series [7, 8, 10, 11]. In terms of the functional outcomes, 57.3% of the patients were continent at 12 months of follow-up. This is also a comparable rate to the other published series of sRARP, which ranged from 33 to 54% [7, 8, 10, 11], when the same criteria of "0 pads/day" was used to defined continence, but still far way from the continence rates from contemporary series of RARP in naive treatment patient (84–96%) [27, 28], which leads us to conclude that even in the hands of master surgeons, the incontinence is clearly higher than in the non-salvage patients. The same conclusion can be applied to the potency rate; however, one of the most striking findings was that 17 patients regained potency after this procedure, representing 17.7% of the total patients in the series, but is 55% of the patients with a pre-operative SHIM score of > 20. This is the highest rate amongst all published series. Our results in functional outcomes are in large part due to meticulous, complete nerve sparing or near complete nerve sparing (> 75%) of the neurovascular bundle performed, using all advantages that the robotic technique provides.

In our series, no rectal injuries were reported, which seems to be in agreement with other contemporary sRARP series with reported rates of rectal injuries between 0–3% [7, 8, 10–12]. Kenney et al. [7] compared their sRARP with their open salvage prostatectomy series, among the differences found, in the 20 patients who underwent sRARP no rectal injuries were reported (0%) while in the open salvage prostatectomy group, two rectal injuries in eight patients were reported (25%). The explanation for this difference may be that in open surgery this dissection of the plane is performed almost blindly, but with the robotic approach, excellent visualization of this plane, allows the prostate to be dissected off the rectum without causing any damage.

The retrospective nature of the study may affect the number of complications and eventually lead to an underestimation of these; this is why we believe this is the main limitation of this analysis. Some other potential criticisms of this study are: the lack of a control group, the short follow-up (14 months), and the relatively short size of the cohort. We must also add to the limitations the limited data about the primary treatment received by these patients; this is due to the fact that the majority of these patients were referrals from outside institutions.

Conclusion

sRARP is a feasible alternative for PCa recurrence after ablative or radiation therapies. Technically the procedure is challenging and should be performed by experienced robotic surgeons. The proportion of major complications is acceptable and rectal injuries seem to be uncommon with the use of robotics. Continence and potency recovery is possible, but at lower rates than for non-salvage patients, thus providing reason why these patients need to be counseled regarding the risks and benefits of this procedure.

Table 7 Comparison between contemporary series of sRARP

Author	*N*	Year	Initial treatment	Complications (Clavien–Dindo)	Follow-up (months)	Potency definition	Potency rate	Continence definition	Continence rate (%)	BCR definition	BCR-free survival rate (%)
Eandi et al. [10]	18	2010	8 Brachy 8 EBRT 2 PBT	Grade I–II: 6 Grade III–IV: 1 Total: 7 (39%)	18	ESI	0/8 (0%)[a]	0–1 pad/day	33	PSA > 0.2	67
Kaffenberger et al. [8]	34	2013	13 Brachy 11 EBRT 6 Brachy + EBRT 4 HIFU	Grade I–II: 12 Grade III–IV: 1 Total: 13(38.2%)	16	ESI	5/17 (29%)[a]	0–1 pad/day	39	PSA > 0.2	82
Yuh et al. [7]	51	2013	22 Brachy 18 EBRT 1 Brachy + EBRT 6 PBT 1 HIFU 3 Cryo	Grade I–II: 13 Grade III–IV: 22 Total: 35(68.6%)	36	ESI	3/13 (23.1%)[a]	0–1 pad/day	45	PSA > 0.2	57[b]
Zugor et al. [11]	13	2014	6 Brachy 7 EBRT	Grade I–II: 4 Grade III–IV:	12	–	3/13 (23.1%)[a]	–	53.8	PSA > 0.2	53.8
Kenny et al. [7][c]	20	2016	7 Brachy or Brachy + EBRT 13 EBRT or PBT	Grade I–II: 15 Grade III–IV: 7 Total: 22 (%)	17	NA	NA	No pads	5	NA	78[d]
Ou et al. [12]	14	2017	11 EBRT 2 HIFU 1 Cyberknife	Total: 4 (28.6%) Clavien–Dindo classification was not used	32.4	Subjectively estimated	2/3 (66.7%)[a]	Subjectively estimated	71.4	PSA > 0.2	78.5
GRI and IMM	96	2017	37 EBRT 14 Brachy 13Brachy + EBRT 3 Cyberknife 1 Proton Beam 18 Cryo 7 HIFU 1 Tookad 2 Electropo 1 Microwave	Grade I–II: 21 Grade III–IV: 4 Total: 25 (26%)	14	ESI	17/31 (54.8%)[a]	No pads	57.3	PSA > 0.2	84.6

Brachy brachytherapy, *EBRT* external beam radiotherapy, *PBT* proton beam radiotherapy, *HIFU* high-intensity focused ultrasound, *Cryo* cryotherapy, *Electropo* electroporation, *ESI* erection sufficient for intercourse

[a]Pre-op potent patients

[b]This series has the longest follow-up with 36 months

[c]Only sRARPs were included

[d]78% of the patients presented undetectable PSA after sRARP

Author contributions GOP project development, data analysis, manuscript writing. ELE data collection, data analysis, manuscript editing. EC data collection, manuscript writing. CJ manuscript writing and editing. XC project development, manuscript editing. RSS project development, data analysis, manuscript editing. VP project development, data analysis, manuscript editing.

Compliance with ethical standards

Conflict of interest All authors have no conflict of interest to declare. This project includes human participants, but all procedures performed are within the regular clinical practice, no experimental procedures were performed and all the patients signed an informed consent before the treatment.

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