Safety and Efficacy of Robot-assisted Radical Prostatectomy in a Low-volume Center: A 6-year Single-surgeon Experience

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Abstract. *Aim: To analyze safety and efficacy of robot-assisted radical prostatectomy (RARP) in a low-volume centre. Patients and Methods: From 2008 to 2015, 400 consecutive patients undergoing RARP were prospectively enrolled. Complications were classified according to the Modified Clavien System. Biochemical recurrence (BCR) was defined as two consecutive prostate-specific antigen (PSA) values ≥0.2 ng/ml. Functional outcomess were assessed using validated, self-administered questionnaires. Results: Median patient age was 64.5 years. Mean standard deviation (SD) preoperative PSA level was 11.3 (11.7) ng/ml. Median interquartile range (IQR) follow-up was 36 (12-48) months. Overall complication rate was 27.7% (minor complications rate 16.2%). Overall 1-, 3- and 6-year BCR-free survival rates were 85.7%, 77.5% and 53.9%, respectively; these rates were 94.1%, 86.2% and 70.1% in pT2 diseases. At follow-up, 98.4% of patients were fully continent (median (IQR) time to continence was 2 (1-3) months) and 68.2% were potent (median (IQR) time to potency of 3 (3-4) months). Conclusion: RARP appears to be a valuable option for treating clinically localised prostate cancer also in a low-volume institution.*

Radical prostatectomy is an established therapeutic option for clinically localized prostate cancer (1). Since its introduction, minimally invasive robot-assisted radical prostatectomy (RARP) has gained increasing popularity worldwide. Currently, several reports on RARP outcomes from high-volume referral Centres demonstrate that RARP provides excellent results in terms of oncological and functional outcomes with a favourable safety profile (2-6).

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However, surgical volume might affect RARP outcomes, leading to a discrepancy between high- and low-volume centres regarding postoperative results. More importantly, results from high-volume referral institutions cannot be generalized to community settings, where most procedures are performed and the majority of surgeons are employed (7–9). Hence, it remains unclear whether RARP is able to offer the same excellent outcomes in low-volume centres as in referral institutions with high surgical caseload.

In fact, whereas results of large RARP series are available (2-6), to date, data on the safety and efficacy of RARP in centres with limited caseload are lacking. To the best of our knowledge, no study has provided a comprehensive evaluation of outcomes for RARP in a low-volume institution so far. Notably, available publications on small case series consist of initial RARP experiences or subgroup analyses from high-volume institutions.

The aim of the present study was to systematically evaluate perioperative, oncological and functional outcomes, as well as complications of RARP over a 6-year experience at our low-volume institution.

Materials and Methods

Study cohort. We analysed prospectively collected clinical, surgical and pathological data of 400 consecutive patients undergoing RARP for clinically localised prostate cancer at our low-volume centre (approximately 60 RARPs per year; Luzerner Kantonsspital, Lucerne, Switzerland) from November 2008 to April 2015 by a single experienced open and laparoscopic surgeon (A.M.). All patients of the learning curve were included. Preoperative urinary continence status and erectile function were assessed by the International Continence Society male short form (ICSmaleSF) and International Index of Erectile Function-5 (IIEF-5) questionnaires, respectively. All patients provided written informed consent.

Surgical procedure. RARP was performed as previously described (10, 11). Intermediate- and high-risk disease patients underwent an extended pelvic lymph node dissection.

Intraoperative and postoperative measurements. Pathological examination was performed using a standardised technique (11).

Transurethral catheter was removed on the 5th postoperative day after a pressure-controlled cystogram. Complications were classified according to the Modified Clavien System (12) and assessed not only during the intra- and early postoperative phase but also within the entire duration of follow-up. Biochemical recurrence (BCR) was defined as two consecutive prostate-specific antigen (PSA) values ≥0.2 ng/ml. Urinary continence status was investigated using the ICSmaleSF questionnaire and defined as no leakage at all.

Only patients with no or mild erectile dysfunction (baseline IIEF-5 score >21) who did undergo nerve-sparing RARP were evaluated concerning potency recovery. Men were excluded if they were not interested in erections, used phosphodiesterase-5 inhibitors (PDE5-Is) preoperatively or did require any adjuvant therapy (radiation, orchiectomy and androgen-deprivation therapy). After surgery, men were considered potent based on an IIEF-5 score >17 with or without PDE5-Is.

Patients were scheduled to be followed at 3, 12 months and yearly thereafter.

Statistical analysis. Categorical variables are reported as frequency and percentage; continuous variables as median and interquartile range (IQR) or mean and standard deviation. Time from surgery to BCR, as well as continence and potency recovery was assessed using the Kaplan-Meier method. Patients were censored at the time of BCR or at last follow-up if they were BCR-free and if they died of causes other than prostate cancer. The log-rank test was used to compare the BCR curves. Statistical analysis was performed using SPSS v.20.0 (IBM Corp., Armonk, NY, USA). All reported *p*-values are two-sided and statistical significance was set at $p<0.05$.

Results

Demographic characteristics are listed in Table I. D'Amico risk group was intermediate or high in 75.6% of patients. Positive surgical margins (PSMs) were found in 53 (13.2%) patients; among those, rates were 3.1%, 10.2% and 29.0% in patients with pathological Gleason score 6 or lower, 7 and 8-10, respectively.

The median (IQR) duration of follow-up was 36 (12-48) months. A total of 125 complications were reported in 111 (27.7%) patients. The incidence and description of complications are shown in Table II. Minor complications represented the most frequent events (72/125; 60.2%) and observed in 65 (16.2%) patients. Lymphoceles represented the most prevalent complications (38/125; 30.4%). However, only 11 (3.6%) patients required drainage of symptomatic lymphoceles.

There were 77 (21.0%) cases with BCRs; 7 (1.7%) patients developed metastases but no patient died of prostate cancer. Median (IQR) time to BCR was 12 (3-18) months; 88.2% of BCRs occurred within 2 years and 97.1% within 4 years. The 1-, 3- and 6-year BCR-free survival (BCR-FS) rates were 85.7%, 77.5% and 53.9%, respectively. Specifically, these rates were 94.1%, 86.2% and 70.1% in pT2 diseases.

Figure 1 illustrates the BCR-FS stratified by disease severity subgroups. Kaplan-Meier plots and log-rank statistics showed significant differences in BCR-FS outcome by preoperative PSA, clinical risk group, pathological stage, pathological Gleason score, pathological nodal status and surgical margin status (Figure 1A-F).

Concerning urinary continence, 364 (98.4%) patients were fully continent postoperatively. Median (IQR) time to continence was 2 (1-3) months. Specifically, 88 (23%) patients were continent immediately after catheter removal. The 1-, 3- and 6-year continence rates were 98.4%, 98.5% and 100%, respectively (Figure 2A).

Regarding sexual function, 179 patients met inclusion criteria and considered in our analysis. Overall potency rate was 68.2%, with a median (IQR) time to potency of 3 (3-4) months (Figure 2B).

Discussion

Currently, several large series (2-7, 13-30) confirm that RARP is an effective treatment for clinically localised prostate cancer, if performed in high-volume referral institutions.

However, these results may not be applicable to patients treated at low-volume centres. Based on these considerations, we sought to evaluate the safety and efficacy of RARP in our low-volume institution.

The primary goal of RARP is the complete removal of tumour. In this regard, PSM status is considered as a predictor of cancer control. In a recent review on RARP outcomes from high-volume centres, Patel *et al*. (6) reported an overall PSM rate of 15.7%. In our experience, overall PSM rate was 13.2%, particularly 9.8% in pT2 and 25.6% in pT3 cases. Accordingly, our local cancer control rate is in line with those from referral institutions (4-6, 13-19). In fact, they are consistent with those from large RARP series, such as from Badani *et al*. (13) showing an overall PSM rate of 13% in 2,766 RARP patients, with 13% for pT2 and 35% for pT3 disease. Recently, in 184 patients, Suardi *et al*. (15) reported a 15.7% PSM rate, with 2.5% for pT2, 34% pT3a and 50% for pT3b patients, respectively. Higher PSM rates (for all pT, pT2 and pT3 cases) were observed in other high-volume reports by Ficarra *et al*. (16) (29.5%, 10.6% and 59%, respectively), Galfano *et al*. (17) (26.0%, 15.0% and 45.0%, respectively) and Sooriakumaran *et al*. (18) (21.6%, 16.0% and 59.1%, respectively), whereas excellent results were shown by Coelho *et al*. (19) (10.6%, 5% and 27.5%, respectively). Although PSM occurrence is highly variable (6.5% to 32%) after RARP (4), these findings suggest that RARP offers good results regarding PSM status both in low- and high-volume centres.

Overall, RARP has shown to provide effective BCR-FS rates also at a long-term follow-up (13-15, 18, 20, 21). In one of the largest RARP series published in the literature on 2,766 patients, Badani *et al*. (13) noticed 95 (7.3%) cases with BCR and a 5-year BCR-FS rate of 84%. In another

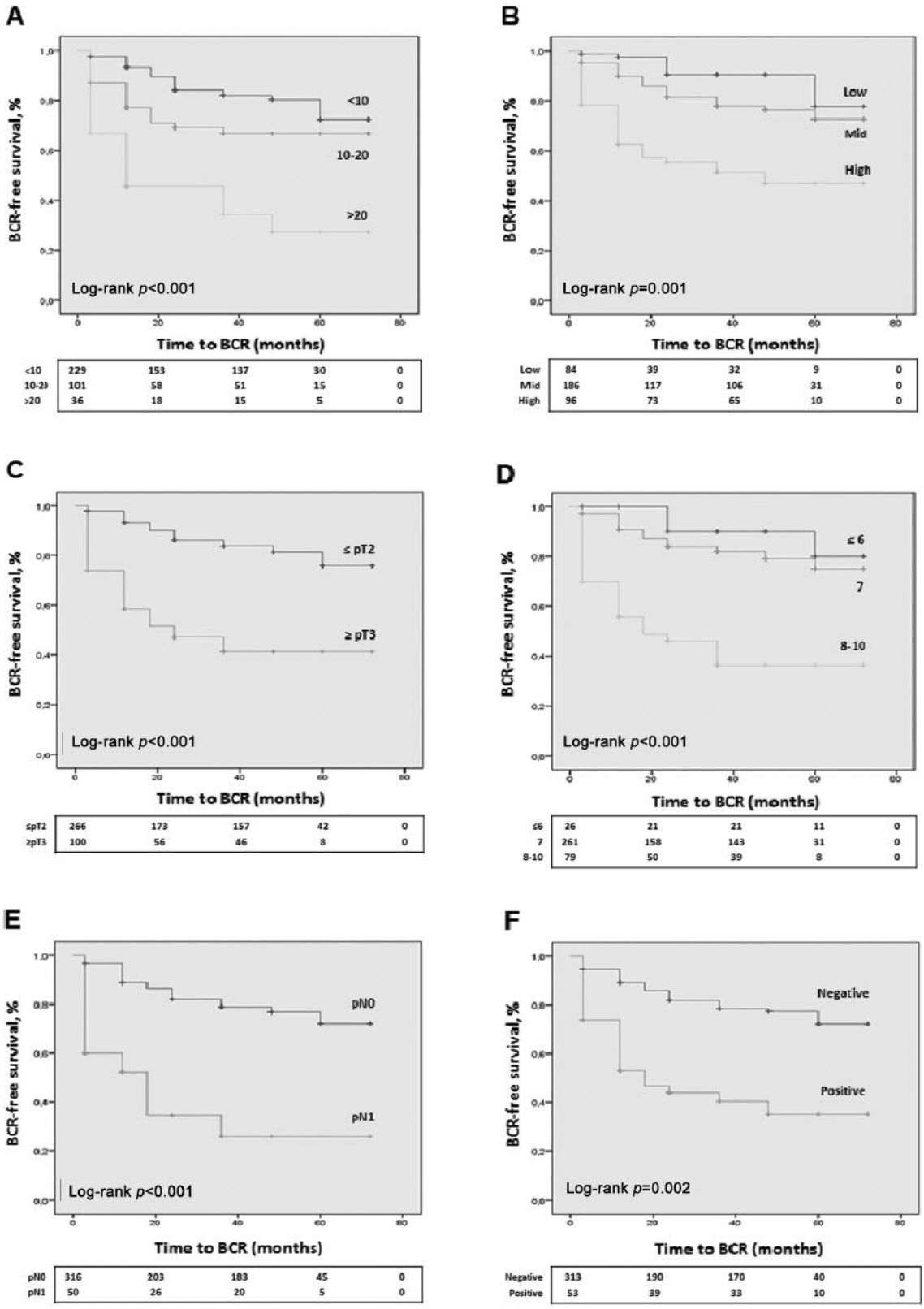

Figure 1. *Biochemical recurrence (BCR)-free survival curves for (A) preoperativePSA level, (B) D'Amico risk, (C) pathologic stage, (D) pathologic Gleason score, (E) pathologic nodal status and (F) surgical margin status.*

Table I. *Demographic characteristics*.

Variable	Value
Age, years,	
mean (SD)	63.8 (5.6)
median (IQR)	64.5 (60.0-68.0)
PSA, ng/ml	
mean (SD)	11.3 (11.7)
median (IQR)	8.1 (5.8-12.9)
BMI (kg/m^2), mean (SD)	26.9 (3.7)
CCI[2] score, n. (%)	
≤1	137 (34.3)
2	149 (37.3)
3	81 (20.3)
≥4	33 (8.1)
D'Amico risk group, n (%)	
Low	98 (24.4)
Intermediate	201 (50.3)
High	101 (25.3)
Prostate volume, g, mean (SD)	44.4 (18.9)
Attempted nerve sparing, n. (%)	
None	122 (30.5)
Monolateral	161 (40.2)
Bilateral	117 (29.3)
Operative time, min, median (IQR)	245 (219-289)
Pathological stadium, n (%)	
pT2	290 (72.5)
pT3	108 (27.0)
pT4	2 (0.5)
Pathological Gleason Score, n (%)	
≤6	27 (6.8)
7	287 (71.7)
8-10	86 (21.5)
N. of dissected lymph nodes, median (IQR)	17 (13-22)
Positive lymph nodes, n (%)	56 (14)
Positive surgical margins, n (%)	
Overall	53 (13.2)
pT2	26 (9.8)
≥pT3	27 (24.8)
Length of stay, days mean (SD)	7 (2)
Catheter-free patients on POD 5, n (%)	368 (92.5)

BMI, Body-mass-index; POD, postoperative day; CCI, Charlson comorbidity index; SD, standard deviaion; IQR, inter-quartile range.

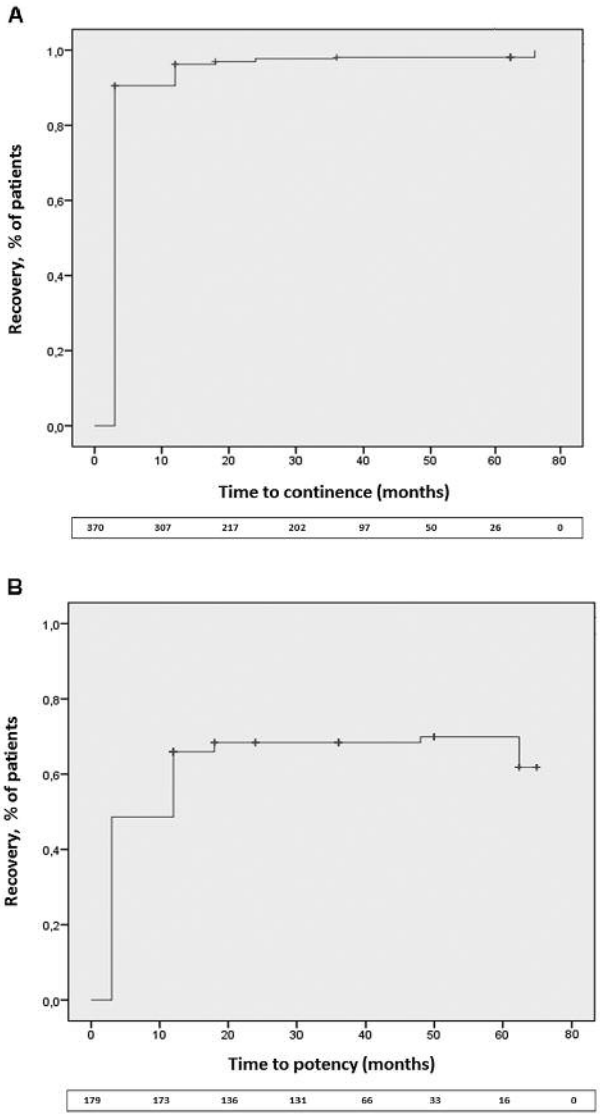

Figure 2. *Kaplan-Meier plot depicting continence (A) and potency (B) recovery after robot-assisted radical prostatectomy (RARP).*

large cohort of 944 patients, Sooriakumaran *et al*. (18) reported a BCR-FS rate of 84.8%: the 5-, 7- and 9-year BCR-FS rates were 87.1%, 84.5% and 82.6%, respectively. Recently, Diaz *et al*. (21) followed 483 men after RARP at a high-volume tertiary centre, showing a 10-year BCR-FS rate of 73.1%.

When analyzing BCR in our cohort, cumulative BCR-FS rate was 79.0%, with1-, 3- and 6-year BCR-FS rates being 85.7%, 77.5% and 53.9%, respectively. Overall, our BCR rates appear to be higher than those from high-volume centres (13-15, 18, 21). However, since BCR is strongly predicted by factors, such as D'Amico risk groups, as well as pathological Gleason score, stage and margin status (18, 20, 21), accurate comparison among series must take these predictors into account. Indeed, compared to reports from referral institutions, our cohort shows higher baseline PSA levels and includes higher rates of intermediate- and high-risk cancers (75.6%). Furthermore, the proportions of cases with pathological Gleason score 7-10 (93.2%), as well as positive nodes (14%), appear to be higher in our cohort. In sum, these selection biases have to be considered. In addition, our BCR-FS rates have to be interpreted with caution considering the high number of patients lost at 4- and 6-year follow-up. This might be attributed to the Swiss

Table II. *Intra- and postoperative complications**.

Grade	Details
All	125 in 111 patients (pts) (27.7%)
Minor	72 in 65 pts (16.2%)
I	29 in 29 pts (7.2%)
	Lymphocele (27), sciatic nerve deficit (1), constipation (1)
II	43 in 38 pts (9.5%)
	Obturator nerve deficit (5), transfusion (9), wound infection (1), Addison crisis (1), malignant hyperthermia (1), pressure skin ulcer (7), paralytic ileus (1), pulmonary embolism (1), vein thrombosis (3), urinary tract infection (13), femoral nerve deficit (1)
Major	53 in 51 pts (12.7%)
IIIa	34 in 34 pts (8.5%)
	Pelvic hematoma (1), ascites (1), rectovesical fistula (1), myocardial infarction (1), pressure skin ulcer (1), ureteral injury (2), lymphocele (9), urinary retention (9), clot retention (4), anastomosis stricture (4), urethral stricture (1)
IIIb	11 in 11 pts (2.7%)
	Postoperative bleeding (4), rectovesical fistula (1), incisional hernia (1), port hernia (1), ureteral injury (1), ureteral stricture (1), urethral stricture (1), pelvic abscess (1)
IV	4 in 4 pts (1.0%)
	Pulmonary embolism (1), urinary sepsis (1), infected lymphocele (1), colon injury (1)
V	4 in 4 pts (1.0%)
	Urinary sepsis (2), infected lymphocele (1), colon injury (1)

*Assessed intra- and postoperatively during the entire follow-up period according to the Modified Clavien classification of surgical complications.

Grade	Definition
I	Any deviation from the normal postoperative course without the need for pharmacologic/surgical/radiological intervention.
II	Complication requiring pharmacologic treatment.
III	Requiring surgical/endoscopic/radiological intervention.
IIIA	Intervention without general anesthesia.
IIIB	Intervention under general anesthesia.
IV	Life-threatening complication requiring intensive care unit (ICU) management.
IVA	Single organ dysfunction.
IVB	Multiorgan dysfunction.
V	Patient mortality.

health care system where most patients receive late follow-up with local urologists or general practitioners. This, again, can lead to case selection over time. On the whole, the abovementioned factors might have adversely affected BCR-FS in our cohort.

Preservation of functional outcomes is fundamental after RARP due to great impact on patient satisfaction and quality of life. In the literature, few studies report on the long-term functional outcomes after RARP (6, 17, 20, 22). In our cohort, 98.4% of patients were fully continent after surgery, with the 1-, 3- and 6-year continence rates being 98.4%, 98.5% and 100%, respectively. Overall, our results are equivalent to those from high-volume centres, showing mean (range) for continence rate of 91.8% (70-97%) at 12 months (6, 17, 20, 22). Thus, our data are consistent with results from large series, such as Menon *et al*.'s (22) showing a continence rate of 95.2% at 1-year follow-up. In another paper by Ficarra *et al*. (20) on 183 patients, 146 (79.8%) were fully continent at follow-up with rates of 73% at 3 months, 87% at 6 months and 91% at 1 year, respectively. Encouraging outcomes were also reported by Galfano *et al*. (17) with no patient using safety liners at 1 year after RARP.

Potency recovery after radical prostatectomy is influenced by numerous factors, including baseline patient characteristics, nerve-sparing techniques, definition of potency and methods used to collect data (3). In our cohort, overall potency rate was 68.2% with a median (IQR) time to potency of 3 (3-4) months. In the literature, RARP series from referral centres show mean (range) values for potency rates of 70% (54-90%) and 79% (63-94%) at 1- and 2-year follow-up, respectively (3). Notably, excellent results were reported by Menon *et al*. (23) with a potency rate of 94% at 18 months. Similar rates were observed also by Patel *et al*. (24).

The 'best case scenario' outcomes after RARP are represented by the 'trifecta' (25), including the concurrent achievement of continence, potency and cancer control.

Trifecta results after RARP were first reported by Shikanov *et al*. (26) who showed rates of 16%, 44% and 44% at 3, 12 and 24 months, respectively. Subsequently, Novara *et al*. (27) evaluated 242 consecutive patients after RARP and a trifecta outcome was achieved by 137 (57%) patients at 12 months. Excellent results were observed by Patel *et al*. (28) with 65.3%, 86% and 91% at 3, 12 and 18 months, respectively. Particularly, the outcomes during the learning curve were not included in this study. More recently, Xylinas *et al*. (29) evaluated 500 consecutive patients and a trifecta outcome was achieved in 44% and 53% of men at 12 and 24 months, respectively. In the present series, trifecta rate approached 55% at 6 years after RARP. However, trifecta score is greatly influenced by tumour and patient characteristics, such as preoperative potency status, and surgical experience. In addition, in the present analysis, we included all cases of the surgical learning curve. The mentioned factors might have influenced trifecta outcomes in our series.

Safety profile represents a major outcome after RARP. Previous studies have shown conflicting results, with complication rates ranging from 3% to 26% (5). Indeed, in the literature, several limitations are associated to complication reporting. Specifically, lack of standardisation for defining, different methods of collection and incomplete reporting of data render this outcome a difficult one to be assessed and compared among series. Applying the Modified Clavien System (12), we identified complications in 27% of patients. Our complication rate appears to be higher than those reported by high-volume institutions (5, 19, 22, 30). However, such a difference might be partly attributed to the strict methodology of data collection in our study. As mentioned above, first, all patients of the learning curve were included. Second, we assessed complications not only during the intra-operative and early post-operative phase but also over the entire duration of follow-up. Third, any deviation from the perioperative standard was classified as a complication, including clinically insignificant events, such as asymptomatic lymphoceles requiring no treatment. Notably, those represented the most prevalent complications (27/125; 21.6%).

The present study has some limitations. Although data were collected prospectively, the analysis is retrospective and, thus, subject to the inherent limitations of retrospective analyses. Additionally, the high rate of patients with more aggressive diseases has to be taken into account when analysing oncological outcomes in our cohort. Follow-up might be impaired by selection bias, attributed to established processes within the Swiss health care system. Most importantly, all our results have to be considered from the perspective that all patients of the learning curve were included. Strengths of our study include the solid data acquisition, using validated tools to assess functional outcomes, as well as a strict reporting of complications. Moreover, all procedures were performed by a single experienced surgeon. Nevertheless, this study confirms that also centres with limited caseload can offer RARP with good oncological and functional results.

In conclusion, in our low-volume centre RARP confirmed to be a valuable option for the treatment of clinically localised prostate cancer. Although all cases of the learning curve were included and we operated mostly on intermediate- to high-risk patients, the results of the present study are consistent with those from high-volume referral centres. Therefore, RARP proved to be an excellent treatment option with favourable oncological and functional outcomes also in a low-volume institution.

Conflicts of Interest

None of the contributing Authors has any conflict of interest, including specific financial interests or relationships and affiliations relevant to the subject matter or materials discussed in the manuscript.

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