African Journal of Urology

ORIGINAL RESEARCH

Open Access

Pentafecta outcomes of robotic laparoscopically assisted radical prostatectomy during the initial experience in a university hospital

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Abstract

Background Robotic laparoscopically assisted radical prostatectomy (RARP) is an option for the treatment of localized prostate cancer. The objective of the present study was to evaluate the pentafecta outcomes (biochemical recurrence, continence, potency, surgical complications and surgical margins) in patients undergoing RARP during the initial experience in a university hospital.

Methods This is a retrospective study of patients who had RARP for localized prostate adenocarcinoma at a university hospital from August 2013 to October 2019 to evaluate pentafecta outcomes (biochemical recurrence, continence, potency, surgical complications and surgical margins). Data were collected and stored via Microsoft Office Excel program and analyzed using SPSS Software, version 20.0.

Results One hundred and sixty-three RARP were performed, the mean age is 64.16 ± 6.54 years, PSA 6.20 (IQR = 4.91–8.95) ng/dl, BMI 27.14 (IQR = 24.22–29.26) kg/m^2, D'Amico risk classification was 35 (22.3%) low risk, 81 (51.6%) intermediate risk and 41 (26.1%) high risk. One hundred and fifty-four patients entered the analysis of pentafecta with a rate of 38.3% reaching this outcome. Complications: Twenty-three (14.1%) patients had minor complications (Clavien I and II) and eight patients had major complications (Clavien IIIa, IIIb and IVa). Surgical margins were negative in 69.9% of patients. The biochemical recurrence-free rate was 89.5%. The overall continence rate was 93.5%, and the potency rate was 63.5%. Multivariate analysis showed that T2 patients are 2.7 times more likely to achieve pentafecta outcome than patients ≥ T3 ($p < 0.05$), while younger age and lower BMI data were found as a protective factor with RR of 0.95 and 0.94, respectively.

Conclusions Preliminary pentafecta outcome of RARP in this university hospital is promising.

Keywords Pentafecta, Prostatectomy, Robotic, Continence, Initial experience

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1 Background

In Brazil, prostate cancer (PCa) is the second most common cancer among men, determining 14,484 deaths in the year 2015 and estimates are 68,220 new cases in 2018 [1].

Radical prostatectomy is one of the treatment options and can be chosen according to some diagnostic criteria such as PSA, clinical staging, baseline urinary function, comorbidities and patient age [2].

The primary objective of the surgical treatment of localized and locally advanced PCa is oncological control with curative intent, maintaining continence and sexual potency. These main outcomes were classically reported as Trifecta, which indicate the achievement of urinary continence and sexual potency, in addition to the absence of biochemical recurrence [3, 4]. In 2011, a new concept called pentafecta was proposed. In the pentafecta outcome, negative surgical margins and absence of surgical complications were included, besides the Trifecta outcomes [5, 6].

Among surgical techniques, robot-assisted radical prostatectomy (RARP), introduced in the year 2000, has already surpassed the number of open radical prostatectomies performed in the USA and Europe [7]. In Brazil, first reports were from the year 2008 and since then the number of robotic platforms has been increasing in the country [8].

As a consequence of the increase in the number of robotic surgeries in Brazil, there is also a need for publications that depict the initial RARP outcomes in the Brazilian population.

Therefore, the objective of this study was to evaluate the pentafecta outcomes in patients submitted to RARP during the initial experience in a university hospital.

2 Methods

This is a retrospective study of patients who had RARP for localized prostate adenocarcinoma at a university hospital from August 2013 to October 2019. Institutional Review Board (IRB) Approval Under Number: 092097/2016. Informed consent was obtained from all individual participants included in the study.

RARP was offered as a primary form of treatment for patients diagnosed with clinically localized PCa. The convenience sample consisted of 163 patients ($n = 163$) submitted to this treatment in this period. Surgeries were performed on the Intuitive Surgical (Sunnyvale, CA, USA) da Vinci SI com robotic system with two consoles and the first 24 cases were guided by an experienced robotic surgeon.

2.1 Surgical technique

RARP was performed through standard transperitoneal approach with antegrade nerve bundle dissection. We use a four-arm robotic approach for port placement, with the third robotic arm positioned on the right and one assistant port on the left flank, as described by Chopra et al. [9]. After completion of RARP and PLND prostatectomy, posterior reconstruction with a modified Rocco stitch and vesicourethral anastomosis were performed according to Van Velthoven's technique [10, 11]. A 18F Foley catheter was left usually for 7 days. At the end of the surgery, a 15F Blake drain was placed in the pelvis through the right robotic trocar.

2.2 Variables

The data were collected using a standardized protocol that included age, BMI, previous surgeries, prostate size assessed by transrectal echography at the time of biopsy, Gleason score, PSA, clinical staging by the American Joint Committee on Cancer TNM system (2010), intraoperative bleeding, surgical time and data related to the anatomopathological study of the surgical specimen and lymph nodes, when resected.

The variables related to trifecta (erection, urinary continence and biochemical recurrence) and pentafecta (trifecta, postoperative complications and surgical margins) were evaluated as follows:

1. Patients were asked in the postoperative period if they had erections that were firm enough for sexual intercourse using or not phosphodiesterase-5 inhibitors (iPDE5). This variable was evaluated in outpatient consultations at 6 weeks, 3, 6 and 12 months after treatment.
2. Urinary continence was defined as the use of no pads or the use of one safety pad per day. This variable was evaluated at outpatient clinics at 6 weeks, 3, 6 and 12 months after surgery.
3. Biochemical recurrence was assessed by PSA dosing at outpatient clinics at 6 weeks, 3, 6 and 12 months. The absence of biochemical recurrence was considered as PSA < 0.2 ng/dl
4. Postoperative complications were defined as complications related to the procedure in the first 30 days and graded according to the Clavien-Dindo Surgical Complications Scale [12].
5. The evaluation of the surgical margins was made through an anatomopathological study of the surgical specimen.

2.3 Statistical analysis and ethical aspects

Data were stored in a database in the Microsoft Office Excel program with researchers' exclusive access. Initial characteristics of all patients were presented as median (interquartile range) or mean (standard deviation) for continuous variables and frequencies and percentage for categorical variables. To evaluate the normality the Kolmogorov–Smirnov test was performed. Student's *T* test and ANOVA (continuous variables) and Chi-square (categorical variables). Logistic regression was used for univariate analysis to compare the group that reached and did not reach pentafecta. Statistical analysis was performed in SPSS Software, version 20.0.

The study was approved by the Local and National Ethics and Research Committee. The patients submitted to the study signed a Free and Informed Consent Term previously the evaluation of the data.

3 Results

During the study period, 163 patients underwent RARP for clinically localized prostate adenocarcinoma. All patients were included in the evaluation of the demographic profile of the study population.

The mean age is 64.16 ± 6.54 years. The median prostate weight was 35.6 (IQR = 27.0–45.8) grams. Preoperative PSA presented a median of 6.20 (IQR = 4.91–8.95) ng/dl. For the tumor clinical staging analysis, 157 patients were included. Six patients were excluded due to lack of data in the medical records. According to the D'Amico risk classification, 35 (22.3%) patients were classified as low risk, 81 (51.6%) intermediate risk and 41 (26.1%) high risk [13]. These and additional data are summarized in Table 1.

The median bleeding was 50 (IQR = 0–150) ml, and the mean surgical time was 286.14 ± 78.81 min. The median length of hospital stay was 3 (IQR = 2–4) days, and the patients stayed with Foley catheter for a median period of 7 (IQR = 7–10) days.

Table 1 Patients' demographics

Age (years), mean ± SD (*n* = 163)	64.16 ± 6.54
BMI (kg/m^2), median (IQR) (*n* = 153)	27.14 (24.22–29.26)
Prostate size (g), median (IQR) (*n* = 155)	35.6 (27.00–45.80)
PSA (ng/dl), median (IQR) (*n* = 158)	6.20 (4.91–8.95)
	***N* (%)**
Clinical T Stage (n = 157)	
cT1a	01 (0.6)
cT1c	65 (41.4)
cT2a	38 (24.2)
cT2b	20 (12.7)
cT2c	30 (19.1)
cT3	03 (1.9)
Gleason score biopsy (n = 159)	
≤6	49 (30.8)
7	90 (56.6)
≥8	20 (12.6)
D'Amico risk stratification (n = 157)	
Low risk	35 (22.3)
Intermediate risk	81 (51.6)
High risk	41 (26.1)
Pathologic stage (n = 163)	
pT2	118 (72.3)
≥ pT3	45 (27.7)
Specimen Gleason Score (n = 163)	
≤6	46 (28.2)
7	99 (60.7)
≥8	18 (11.0)

SD standard deviation, *BMI* body mass index, *IQR* interquartile range, *PSA* prostate specific antigen

Table 2 Variable comprising the pentafecta

Variable	Proportion of patients	%
NSM	114/163	69.9
BCR-free rate	137/153	89.5
Potency	94/148	63.5
Continence	145/155	93.5
No complication	132/163	81.0
Pentafecta rate	59/154	38.3
Trifecta rate	82/147	55.8

NSM negative surgical margin, *BCR* biochemical recurrence

Of the 163 patients submitted to surgery, 111 (68.1%) underwent lymphadenectomy with a median of resected lymph nodes of 8 (IQR = 5–13).

The Trifecta and Pentafecta outcomes are summarized in Table 2.

3.1 Oncologic outcomes: surgical margins and biochemical recurrence

Surgical margins were negative in 69.9% of the patients. Regarding pathological staging, the surgical margin was positive in 18.6% of the pT2, 60.0% of the ≥ pT3 ($p < 0.05$). The biochemical recurrence free rate was 89.5% among 153 patients evaluated. Related to pathological staging, biochemical recurrence occurred in 5.3% of pT2 and 25.6% of ≥ pT3, $p < 0.001$.

3.2 Functional outcomes: urinary continence and potency

The overall rate of continence was 93.5% of 155 patients evaluated. Among patients who achieved total continence, the median time to achieve total continence was 30 (10–60) days. Potency was assessed in 148 patients and reached a rate of 63.5%. Regarding pathological staging, satisfactory erection occurred in 68.8% of pT2 and 48.7% of ≥ pT3 ($p < 0.05$).

3.3 Perioperative outcomes

According to the classification of surgical complications of Clavien-Dindo, 81% of the patients did not present any alteration of the normal course of the postoperative recovery. Fifteen patients (9.2%) were classified as Clavien-Dindo 1 and 8 patients (4.9%) as Clavien-Dindo 2. One patient (0.6%) was classified as Clavien-Dindo 3a due to an infected lymphocele. Six (3.7%) patients were classified as Clavien-Dindo 3b, that is, they required intervention under general anesthesia. The reasons for the intervention were compartment syndrome requiring fasciotomy in the leg, hypovolemic shock in the postoperative period requiring exploratory laparotomy, and four patients had evisceration in the portal requiring suture of the abdominal wall. One patient (0.6%) was classified as Clavien-Dindo 4a for needing hemodialysis after rhabdomyolysis (Table 3).

3.4 Pentafecta and trifecta

The overall rate of pentafecta was 38.3% among the 154 patients included in this analysis. Postoperative erectile dysfunction was the most common cause for not achieving pentafecta (56.8%) followed by positive surgical margins (50.5%).

Table 4 shows the comparison between patients who achieved pentafecta with patients who did not achieve this outcome. There was a statistically significant difference in the variables age, BMI and pathological staging.

Univariate logistic regression is summarized in Table 5. There was statistical significance for the following variables: age, BMI and pathological staging.

Multivariate analysis of the three factors that showed statistical significance in the univariate analysis (age, BMI and pathological stage) demonstrated that T2 patients had a 2.68 times greater chance of reaching Pentafecta than patients ≥ T3 ($p < 0.05$). Age was a protective factor to reach pentafecta, each year the patient had a 4.6% higher risk of reaching pentafecta ($p < 0.05$). BMI also presented as a protective factor to reach pentafecta, presenting an RR of 0.942 (CI 0.887–1.00) and $p = 0.049$.

The overall rate of patients who achieved trifecta was 55.8%, 82 of the 147 patients evaluated. Of the 65 patients who did not reach trifecta, erectile dysfunction was present in 54 (83.0%), urinary incontinence in 11 (16.9%) and biochemical recurrence in 14 (21.5%). Fifty-two patients did not reach trifecta by a single criterion.

We divided the patients between the first and last quarters to assess the pentafecta rate at the beginning of the learning curve and at the end. Fifteen of the first 40 (37.5%) and 19 of the last 40 (47.5%) achieved pentafecta ($p = 0.567$).

4 Discussion

RARP is a surgical technique for the treatment of prostate cancer that is well-established in several centers of reference. Because it is an innovative procedure, RARP generates a high expectation in patients regarding their

Table 3 Clavien-Dindo classification

	N (%)
No complications	132 (81.0)
Clavien-Dindo 1	15 (9.2)
Clavien-Dindo 2	8 (4.9)
Clavien-Dindo 3a	1 (0.6)
Clavien-Dindo 3b	6 (3.7)
Clavien-Dindo 4a	1 (0.6)

Table 4 Analysis of factors related to pentafecta

Variable	Outcomes		*p* value
	Pentafecta achieved	Pentafecta not achieved	
Age ± SD	62.32 ± 6.79	65.26 ± 6.35	0.007
BMI (IQR)	25.8 (23.5–27.8)	27.4 (24.7–29.8)	0.010
PSA (IQR)	5.85 (5.00–7.97)	6.53 (4.74–9.87)	0.150
	***N* (%)**	***N* (%)**	
D'Amico risk stratification			
Low risk	15 (25.9)	19 (20.7)	0.116
Intermediate risk	33 (56.9)	43 (46.7)	
High risk	10 (17.2)	30 (32.6)	
Pathologic stage			
T2	52 (88.1)	59 (62.1)	0.001
≥T3	7 (11.9)	36 (37.9)	

Table 5 Univariable analysis: independent predictors of the pentafecta

	p value	Relative risk	CI (95%)
Age	0.004	0.961	0.934–0.988
Body mass index (BMI)	0.038	0.931	0.869–0.996
D'Amico risk stratification			
Low risk × High risk	0.090	1.765	0.915–3.403
High risk × Intermediate risk	0.069	1.737	0.958–3.149
Pathologic stage (T2 × ≥T3)	0.003	2.878	1.420–5.831

outcomes and, therefore, urologists should be careful when reporting the risks and benefits of the procedure in the preoperative period to avoid frustration [14].

RARP presents a lower learning curve when compared to laparoscopic prostatectomy and may present satisfactory outcomes even in hospitals that are initiating the robotic surgery program [15, 16].

The trifecta rate was one of the ways to evaluate the oncological and functional outcomes of radical prostatectomies [4]. The present study presented a trifecta rate of 55.8%. In the literature, this rate varies between 38 and 86% [4, 17, 18]. Another more comprehensive way of reporting the surgical outcomes of radical prostatectomy is pentafecta. In this study, the pentafecta rate was 38.3%. In 2011, Patel et al. published the evaluation of the outcomes of a series of 1111 patients undergoing RARP, and the pentafecta rate was 70.8% [5]. However, this high rate was the result of a single surgeon with more than 4000 RARP and all patients analyzed had a preoperative SHIM ≥ 21. Other studies describe lower rates of pentafecta ranging from 45.6 to 60.4% [6, 19, 20]. The multivariate analysis showed that patients with T2 pathological staging were more likely to reach pentafecta (RR: 2.68) than patients ≥ T3. In the same analysis, the age and BMI data were presented as a protective factor with RR of 0.95 and 0.94, respectively.

Of the 163 patients evaluated for the surgical margin, their involvement occurred in 30.1% of the cases. A multi-institutional study compared the rate of surgical margins involved in 22,393 open, robotic and laparoscopic radical prostatectomies. Minimally invasive techniques demonstrated a lower rate of involvement of surgical margins, 13.8% in RARP, 16.3% in laparoscopic radical prostatectomies and 22.8% in open radical prostatectomies. Same study demonstrated that this rate is influenced by the number of robotic and laparoscopic surgeries performed [21]. Other studies that evaluated the surgical margins reported rates varying between 17.2 and 26.8%, and the studies that describe initial experiences in robotic surgery described higher rates of positive surgical margins [6, 20, 22, 23].

Postoperative oncological follow-up is done by PSA dosing and biochemical recurrence determines, in most cases, the implementation of additional treatments. A study that evaluated the 5-year biochemical recurrence of 289 patients reported a global biochemical recurrence-free rate of 84.9%, and pT2 patients achieved 94.4% biochemical recurrence free rate and pT3 patients reached 47.1% [24]. The present study showed a biochemical recurrence-free rate of 89.5% at a mean follow-up time of 43.9 months. Analyzing groups by pathological staging, biochemical recurrence-free rate was 94.7% for pT2 and 74.4% for ≥ pT3, $p < 0.001$. Other studies found a similar biochemical recurrence-free rate ranging from 84 to 92.4% at 3-year follow-up [25–28].

At 5-year follow-up, biochemical recurrence occurs in approximately 42–64% of the patients with PSM [29]. According to the study by Evren, et al. the compromise,

the location of the compromised margin and the Gleason detected at the margin site were not able to predict biochemical recurrence. However, the high preoperative PSA value proved to be an independent prognostic factor for biochemical recurrence [30]. The study by Alkhateeb, et al. demonstrated that the compromised surgical margin is an independent predictor of biochemical progression in a patient with intermediate and high-risk prostate cancer. Patients with low-risk disease, on the other hand, had a favorable long-term outcome regardless of the status of the margin [31]. In the present study, although the compromise of the surgical margins was slightly above that reported in the literature, this fact was not reflected in the oncological result, the rate of biochemical recurrence being similar to that found in the literature in the pT2 group and the ≥ pT3 group.

Complications related to the surgical procedure occurred in 19% of the patients. Of the 31 patients who presented complications, 23 presented minor complications (Clavien I and II) and eight patients had major complications (Clavien IIIa, IIIb, IV). The complication rates related to RARP vary in the literature between 6.6 and 16.6% (5, 6, 20, 32) and appear to be influenced by the number of cases operated, stabilizing the number of major complications after 100 cases [32]. In addition to the experience of the surgeon, meticulous preoperative evaluation, surgical planning with magnetic resonance imaging and the execution of the procedure by a trained and dedicated team for robotic procedures are also key points for the prevention of complications [33].

In this study, postoperative potency rate was 63.5% in 12 months and was the factor that most influenced the pentafecta rate, being present in 56.8% of patients who did not reach pentafecta. In the literature, the preservation of potency varies greatly among studies presenting rates between 39.1% and 90% in 12 months [5, 34]. The recovery of potency in the postoperative period is influenced by several factors including preserving neurovascular bundles, surgical technique and the quality of the erection before the procedure, so it is important the preoperative evaluation of the erection to perform the appropriate counseling to the patient [35, 36]. The present study included in the analysis all patients undergoing the procedure in order to have a greater representativeness of the population and consequently a more reliable rate of pentafecta. If only patients with preoperative SHIM ≥ 21 entered the analysis, the rate of sexual potency would be 73.46% in 49 patients analyzed, and the rate of pentafecta would be 42.8% in this restricted group of patients.

The continence rate of the study in 12 months was 93.5%, which is compatible with data found in the literature ranging from 69 to 96% [5, 37]. The factors of age, BMI, lower urinary tract symptoms and prostate volume were the most relevant preoperative predictors for postoperative urinary incontinence [38]. The surgical technique used for vesicourethral anastomosis seems to also influence urinary continence. Techniques with complex reconstructions of anterior and posterior structures seem to influence the rate of early continence [39, 40].

When we performed a sub-analysis to evaluate the learning curve, we observed an increase in 10% of patients who reached pentafecta comparing the last 40 cases to the first 40. This shows a tendency to improve the results at the end of the series, although without statistical significance.

The fact that a validated questionnaire was not used for the evaluation of erection and urinary continence can be considered a limitation of this study. Despite this, the evaluation of the number of pads and the question to the patient if they have erections firm enough to perform sexual activity are widely used methods, and it is possible to have a real representativeness of the functional outcomes. In addition, the inclusion of patients submitted to RARP with partial preservation or without preservation of the neurovascular bundles may have influenced the pentafecta rate.

5 Conclusions

It is possible to achieve good overall results using pentafecta as the ideal RARP outcome during the learning curve. This study presented similar pentafecta rates to the literature. Acquiring experience with a greater number of cases is necessary to improve results and make them compatible with centers with large volume of procedures.

Abbreviations

PCa	Prostate cancer
PSA	Prostate specific antigen
RARP	Robotic laparoscopically assisted radical prostatectomy
PLND	Pelvic lymph node dissection
BMI	Body mass index

Acknowledgements

Not applicable.

Author contributions

Each author made substantial contributions to this paper. Study concept and design are done by E.C., M.B. and B.N. Acquisition of data was done by E.C., A.P., P.K., P.B. and L.B. Analysis and interpretation of data were done by E.C., A.P., L.B., M.B. and B.N. Drafting of the manuscript was done by E.C. and A.P. Critical revision of the manuscript for important intellectual content was done by E.C., A.P., L.B., M.B. and B.N. Statistical analysis was done by E.C. None of them involved in administrative, technical or material support. Supervision was done by BN. Other: None.

Funding

Not applicable.

Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional and/or National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. HCPA Institutional Review Board (IRB) approval under number: 092097/2016 in May 2016. Written informed consent was obtained from all individual participants included in the study.

Consent for publication

Each author have approved the submitted version (and any substantially modified version that involves the author's contribution to the study) and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved and the resolution documented in the literature.

Competing interests

The authors declare that they have no competing interests.

Received: 20 June 2022 Accepted: 13 January 2023
Published online: 04 February 2023

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