

# Robotic-assisted laparoscopic prostatectomy (RALP): a new way to training

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**Abstract** The implementation of RALP program is usually associated with a steep learning curve (LC). Fellows are proctored for few cases, with long operating times, inferior outcomes and an increased number of complications. We report the initial results of 100 RALP procedures performed in Rio de Janeiro, Brazil, with the implementation of a structured program. Our goal was to evaluate if our approach to training would yield a safer outcomes for patients undergoing the procedure during the LC. From October 2012 to January 2014, five surgeons began a training program in RALP. Each surgeon attended a certification course, wet lab, dry lab, didactic course and observed live cases. Each trainee performed 20 cases of RALP under supervision of an experienced preceptor. The median surgical time was 175 min [interquartile range (IQR) 141–180 min]. There were four complications Clavien II (4 %) and three Clavien IIIa (3 %), no conversions nor transfusions. The median estimated blood loss was 200 ml (IQR 150–300 ml). The median hospital stay was 2 days (IQR 1–2 days). The median catheterization time

was 7 days (IQR 6–7 days). Overall positive surgical margin rate (PM) was 19 %; stage-specific PSM rates were 12 % in pT2 and 53 % in pT3. The biochemical recurrence-free survival rate (PSA < 0.01 ng/ml) was 91 % over an average follow-up of 6 months. The continence rates were (no pad) 74 % within 3 months and 94 % within 6 months. The implementation of a training program with advanced precepting allowed us to overcome the initial LC with reasonable results and with minimal complications.

**Keywords** Robotic prostatectomy · Learning curve · Training · Safety · Education

## Introduction

RALP was first performed in 1999 by Binder [1]. Since that time, approximately 3102 *da Vinci*<sup>®</sup> Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) platforms have been implemented worldwide, including 2153 in the United

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States, 499 in Europe, and 450 in other countries. In the United States, the percentage of all radical prostatectomies that were performed by robotic surgery was 63 % in 2007, reaching 85 % in 2009 [2]. Today, approximately 93 % of medical residency programs in urology in the United States have a *da Vinci*<sup>®</sup> system.

In Brazil, there are only 13 robotic systems installed, with only one of these aimed at training (Sírío Libanês Hospital). In Rio de Janeiro, the National Cancer Institute, Samaritano Hospital, and Marcilio Dias Naval Hospital have had this technology since 2012. However, many hospitals with this technology do not offer sufficient training to surgeons or the operative team. These hospitals do not have a system to collect and analyze data, to improve the procedure, correct faults, and enhance scientific production. Surgeons are typically supervised for only a very few cases, leading to long operating times and higher levels of complications [3]. As a result, the robotic method has higher costs and may be rejected [4].

The objective of this study was to evaluate the safety, perioperative outcomes margins and early continence and the results of implementing a robotic-assisted laparoscopic prostatectomy (RALP) training program, based on the experience of Samaritano Hospital (Rio de Janeiro, Brazil).

## Materials and methods

This study was retrospective analysis of a prospective collected database of a robotic urology surgical training program at Samaritano Hospital (Rio de Janeiro, RJ, Brazil) from October 2012 to January 2014. The study was conducted in accordance with the regulations of the local ethics committee. This program involved providing training to five urological surgeons, experienced in both laparoscopic and conventional surgery.

First, this entire team spent a week in Florida Hospital (Celebration, FL, USA) for an observational program in robotic surgery. Training addressed how the robotic surgical theater functions, with a focus on live cases of RALP. Surgeons underwent 8 h of hands-on training with an animal model. The next step involved online training for the *da Vinci Si*<sup>TM</sup> System (Intuitive Surgical, Sunnyvale, CA, USA) and practical training about the operation of the system, lasting 8 h. From December 2012, all surgeons practised for 4 h each week, over 24 weeks, on a *Mimic*<sup>TM</sup> simulator (Mimic Technologies Inc., Seattle, WA, USA) [5].

After this first phase, the team began the program of surgeries performed with the help of a preceptor at Samaritano Hospital. Surgeries were performed with the direct intervention of one of four preceptors (V.P., K.P., R.C. and B.R.) at different steps, with graded approach to

the learning curve (LC). The program was structured, allowing each of the five selected surgeons had the opportunity to perform 20 RALPs with the *da Vinci Si*<sup>TM</sup> System. All the surgical steps—from the positioning of the patient to the docking, surgical technique, and postoperative care—were supervised by the preceptors and based on protocols established by our preceptors.

The inclusion criteria were: younger than 78 years; diagnosis of adenocarcinoma of the prostate; body mass index (BMI) less than 35 kg/m<sup>2</sup>; low, intermediate or high d'Amico stratification risk [6]; prostate volume less than 100 mL, as measured by abdominal ultrasonography (USGA); and no history of previous radiation or hormone therapy. The same transperitoneal, antegrade surgical technique with six portals was used in all cases, as described by Patel et al. [7].

An anterior urethral suspension stitch and posterior reconstruction was performed in all cases to improve continence as described by Patel, Coelho and Rocco [8, 9]. Anastomosis was performed with Quill VP<sup>TM</sup> 2.0 suture (Surgical Specialties Corporation, Vancouver, BC), in a continuous manner, as described by Van Velthoven [10]. Nerve preservation was performed via athermal dissection and, preferably, by retrograde means as described by Patel et al. [11, 12]. Pelvic lymphadenectomy was performed on patients with intermediate or high oncological risk, in accordance with the criteria of the Pasadena Consensus Panel [13]. The operating time was recorded from the start of the cutaneous synthesis incision, with the surgeon present throughout the surgical period.

After the surgery, patients were ambulated approximately 6 h. Patients started a liquid oral diet on the same day as the surgery. Analgesia involved the use of regular dipyrrone, without opioids. The drain was removed when the output was lower than 200 ml. All patients had an 18-Fr silicone Foley catheter.

All surgeries were recorded and reviewed by the surgeons and preceptors. The five urologists were present during all procedures and assisted in an equal number of surgeries.

Complications were defined. Perioperative blood transfusion was usually indicated for symptomatic patients and/or hemoglobin levels 7 g/l. For intermediate hemoglobin concentrations (i.e., 7–10 g/dl), blood transfusion was indicated in case of potential or actual ongoing bleeding or in the presence of risk factors for complications secondary to inadequate oxygenation (i.e., cardiac ischemic disease). Ileus was defined as postoperative nausea, vomiting, and/or abdominal distension requiring hospitalization time >2 days in the absence of mechanical bowel obstruction. Symptomatic lymphocele was defined as a pelvic fluid collection (especially along the iliac vessels) in patients who underwent pelvic lymph node dissection (PLND) and associated

with pelvic pain or pressure, unilateral leg edema and/or pain, hydronephrosis, deep vein thrombosis (DVT), or infection/sepsis.

A single nurse collected the data on surgical time and blood loss (BL). The surgeon and preceptor filled in the clinical–surgical data before and after each procedure on a form that contained preoperative information, such as age, PSA level, clinical staging through DRE, BMI, previous pathological history, comorbidities, and prostate size by USGA. A databank was built with the following additional information: the histopathological result; time of the patient’s stay in the hospital; complications, according to the Clavien system [14]; time that the drain remained; time of Foley catheter; postoperative PSA level; continence that was defined as no pads as reported by the patients during postoperative office visits; and need for adjuvant cancer treatment.

The sample was divided into five groups of 20 consecutive patients to analyze the evolution of compromised margins, operative time, and average BL. Quantitative variables were presented through measurements of their central tendency (averages and median) and measures of dispersal [standard deviation (SD) and interquartile range (IQR)]. Comparative analysis between groups was conducted by Student’s *t* test and one-way analysis of variance (ANOVA) for continuous data. Mann–Whitney and Kruskal–Wallis tests were applied for categorical data, using the standard significance value of  $p < 0.05$ . To quantify the relationship between surgical time and progression, we performed the Pearson correlation test. Statistical analyses were performed with the GraphPad Prism program, version 5 (GraphPad Software Inc., La Jolla, CA, USA).

## Results

Between October 2012 and January 2014, 100 surgeries were performed (20 surgeries per surgeon-in-training). Each surgeon-in-training performed between one and three surgeries per month. The average follow-up period was 6 months. Table 1 shows the epidemiological, operative data and preoperative histopathological Gleason, clinical stage and the histopathological findings after RALP.

Among the 100 prostates that were treated by RALP, 18 (18 %) had an enlarged median lobe. No patient needed narcotics for pain after surgery. The average hospitalization time was 24 h for 38 patients and 48 h for 62 patients. The Foley catheter was removed on the sixth day in 42 patients and seventh day in 58 patients. No patient had a drain remaining after their hospital check-out.

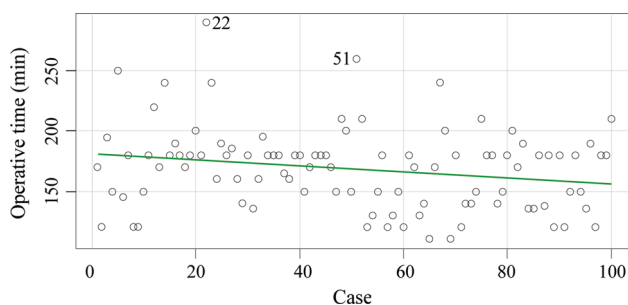
Figure 1 shows the slight tendency of the surgical time to fall over the course of the 100 surgeries, showing an inverse correlation of  $-20\%$  ( $p = 0.04$ ). Table 2 shows

**Table 1** Overall baseline patient characteristics, perioperative parameters and pathological preoperative and postoperative data for 100 patients undergoing robot-assisted radical laparoscopic prostatectomy (RALP)

Characteristic	IQR	Median	Range
Age (years)	56–69	62	45–75
PSA (ng/dl)	5.2–8.9	6.3	0.8–40
Prostate volume (ml)	20–40	35	20–127
Body mass index (kg/m <sup>2</sup> )	23–27	25	18–32
Operating time (min)	141–180	175	110–260
Blood loss (ml)	150–300	200	50–1000
Conversion rate (%)	None	None	None
Blood transfusion (ml)	None	None	None
			Number (%)
<i>Preoperative Gleason score</i>			
6 (3 + 3)			59 (59)
7 (3 + 4)			28 (28)
7 (4 + 3)			10 (10)
8 (4 + 4)			2 (2)
9 (4 + 5)			1 (1)
<i>Clinical stage</i>			
T1			59 (59)
T2			40 (40)
T3			1 (1)
T4			0
<i>Pathological Gleason score</i>			
6 (3 + 3)			21 (21)
7 (3 + 4)			51 (51)
7 (4 + 3)			22 (22)
8 (4 + 4)			6 (6)
9 (4 + 5)			2 (2)
<i>Pathological stage</i>			
T2a			6 (6)
T2b			5 (5)
T2c			73 (73)
T3			16 (16)
T4			0

the average operative time, average blood loss and positive margin (PM) rates, global and in patients with pT2 tumors by group of 20 patients undergoing RALP, in chronological order of cases. Table 3 shows the complications.

Urinary continence was defined as no pads as reported by the patients during postoperative office visits. The continence rate was 74 % within 3 months and 94 % within 6 months after RALP. The mean time to recover continence was approximately 5.5 weeks (range 0–10 weeks). Twenty-eight patients (28 %) remained totally continent from the moment the Foley catheter was removed.



**Fig. 1** Tendency of the operative time according to the number of patients operated on during the period between October 2012 and January 2014 for 100 patients undergoing robot-assisted radical laparoscopic prostatectomy (RALP)

In terms of oncological results, the overall positive margin rate was 19 %, with 12 % of pT2 tumors and 53 % of pT3 tumors having PMs. Figure 2 shows the distribution of PMs by location. During follow-up at an average of 6 months, 91 patients (91 %) were free of biochemical recurrence.

## Discussion

Nearly all related studies of initial series demonstrate some point at which the surgeon-in-training overcomes the LC. The number of surgeries needed to reach this point remains uncertain and ranges from 20 to 250 cases [15]. Studies have demonstrated the negative impact of LC on the percentage of PMs, particularly in pT2 tumors [16–18]. However, there is no consensus and no rule about how surgeons should be trained, such that they are ready to perform procedures without compromising the results and safety of patients [19]. Lavery et al. compared LC of surgeons-in-training when performing radical prostatectomy performed by laparoscopy or robotic assistance. To reach a sufficient level of proficiency to perform radical prostatectomy safely, surgeons-in-training needed to perform

60–100 laparoscopic procedures, compared to only 25–40 robotic-assisted procedures [20].

Menon et al. reported on the initial results of 50 cases of RALP. The average surgical time was 274 min and intra-operative BL was 256 ml. There were no blood transfusions, and one case of paralytic ileus was treated conservatively. The percentage of PMs was 17.5 %. After 18 cases, the average surgical time for RALP was lower than that for laparoscopic radical prostatectomy performed by an experienced surgeon who had performed more than 500 laparoscopic radical prostatectomies [21].

Surgical time is one of the most commonly used criteria to evaluate the LC. Some centers initially obtained fairly elongated times, increasing the risk to the patient. In an initial experiment, O'Malley et al. [22] reported an average time of 300 min for the first 10 cases, which reached a plateau after approximately 50 cases. For their first 50 cases, Mayer et al. [23] published results showing an average operating time of 369 min and BL of 700 ml, with 12 % of patients requiring blood transfusions.

Robotic surgery was implemented by Samaritano Hospital, intending to starting a differentiated training program that would enable the LC to be safely overcome, and also to achieving desirable functional and oncological results during the training period. We estimated that these results could be reached by each surgeon-in-training within 20 procedures when an experienced surgeon served as a preceptor. We obtained safe and satisfactory results.

In our series, we obtained more favorable figures for the operating time and BL from the beginning of the case series. As Fig. 1 shows, the points were grouped together up to the midpoint of the case series. After this period, despite a tendency to decrease, the points were more dispersed. These results may be explained by the higher level of direct participation by the preceptor in the initial cases, which conferred less variation to the surgical time at the start of the series. No transfusions were necessary in any of the high-risk or enlarged prostate (>40 mL) cases. When grouped into five groups of 20 cases each, neither the mean

**Table 2** Average operative time, average blood loss and positive margin rates, global and in patients with pT2 tumors by group of 20 patients, in chronological order of cases for 100 patients undergoing robot-assisted radical laparoscopic prostatectomy (RALP)

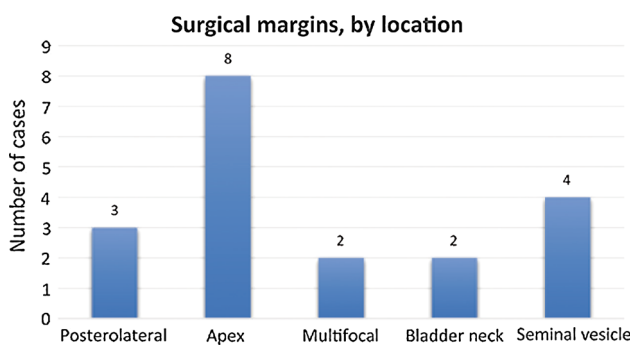
Parameter	Cases series					<i>p</i>
	0–20	21–40	41–60	61–80	81–100	
Average operative time (min)	180	180	160	160	175	0.315
IQR	(150–191)	(160–181)	(145–180)	(140–180)	(135–180)	
Average volume of blood loss (ml)	200	235	200	200	225	0.695
IQR	(150–300)	(150–250)	(150–250)	(137–300)	(150–350)	
Global PM rate (%)	20 %	25 %	15 %	25 %	10 %	0.697
PM rate in pT2 tumors (%)	13.3 %	13.3 %	10.5 %	22.2 %	5.5 %	0.671

IQR Interquartile interval, PM positive margin

**Table 3** Overall complications for 100 patients undergoing robot-assisted radical laparoscopic prostatectomy (RALP)

Clavien Grade	Complication	Number (%)
I	None	0
II	Urinary infeccion	3 (3 %)
	DVT	1 (1 %)
IIIa	Incisional Hernia	3 (3 %)
IIIb	None	0
IVa	None	0
IVb	None	0
V	None	0
Total		7 (7 %)

DVT Deep vein thrombosis



**Fig. 2** Distribution of the positive surgical margins for each location in the prostate per number of cases

surgical time nor the BL volume showed a statistically significant difference between groups ( $p = 0.31$  and  $p = 0.69$ , respectively; Table 2).

With respect to the oncological result, we encountered a global PM rate of 19 %, although 16 % of the tumors were pT3. Although there was no significant difference on PM rates among the five groups (Table 2), the two first groups had worse results for the global PM rate, probably because of the higher number of pT3 tumors in these groups (20 % pT3 tumors each in the first and second groups). Most PMs for these case histories were found at the apex (42 %). In their first 30 cases, Ou et al. reported a PM rate of 50 % (13 % in pT2 tumors and 85 % in pT3 tumors). They considered apical dissection important for reducing the margins in pT2 tumors [24]. We also considered apical dissection to be a critical moment for PMs, especially in the first 10 cases; therefore, active participation of the preceptor was greater and particularly important at this point in the surgery. After 1 day of training on the *da Vinci*<sup>®</sup> system and two prostatectomies in cadavers, Ahlering et al. [25] performed 45 cases of RALP and reported a global PM rate of 35.5 %. And Lott et al. reported 32 % of PM and 18 % of complications and an average surgical time of 271 min (140–570 min) on the

first 50 cases done in INCA (Rio de Janeiro, Brazil) [26]. These results reinforce the hypothesis that continued supervision of surgeons-in-training can reduce the risks of poor oncological outcomes during training.

We obtained a 94 % level of continence (no pad) in 6 months, and the average recovery time was 5.5 weeks. There was no difference between the groups of 20 patients in terms of the time necessary to reestablish total continence ( $p = 0.107$ ). These data are similar to those of a large-volume series as Patel et al. [27] in which 1111 patients achieved a 94 % level of continence within 6 months.

During training, the five surgeons in the present study obtained similar results to those reported in meta-analyses, comprising data from RALP centers of excellence [95 % overlapping confidence intervals (CIs)]. We obtained an average surgical time of 169 min (95 % CI 162–175 min) compared to 152 min (95 % CI 90–291 min), an average BL of 247 ml (95 % CI 213–280 ml) compared to 166 ml (95 % CI 69–534 ml), and a global PM rate of 19 % (95 % CI 11–28 %) compared to 15 % (95 % CI 6.5–35 %) in the meta-analysis [28–30]. Although this comparison involves studies with different designs, nevertheless, it may indirectly reflect the safety of our training program.

The average surgical time was controlled by the preceptors throughout the training, so that the surgeries did not surpass a time limit of 4 h. Therefore, the point at which the LC was overcome for the surgical time parameter cannot be affirmed. However, the surgeons-in-training were able to perform the procedure in less than 3 h, without the active intervention of the preceptor, in approximately 10 cases each.

We should point out some of the limitations of this study, such as the particular characteristics inherent to each surgeon’s skill. An individualized evaluation of the LC by surgeon was not the aim of this study. We did not measure the exact time or percentage of interventions by the preceptor in the surgeries on a case-by-case basis. Doing so would have given more consistency to the analysis in terms of the exact point at which the surgeons-in-training started to perform the procedure without the intervention of the preceptor. The data presented to date only cover the perioperative results, because the short follow-up period made it difficult for us to analyze the functional results consistently, especially erectile function.

We believe that the design of our hospital’s training program—with established determinations of the operative time, safety regulations, discussions of videos of the performed surgeries, and the continuous presence of an experienced preceptor throughout the procedure over a large number of cases (20 per surgeon, in this study)—was the reason why, despite the LC, the patients did not obtain results outside an acceptable range and, thus, were not

harmed. The time-course results show that the surgeons achieved acceptable results from their very first cases, a fact that was sustained up to the end of the program when the surgeons were already operating without the active interference of the preceptor.

## Conclusion

The implementation of a structured training program with advanced preceptoring allowed our program to overcome the initial LC with reasonable operating times and with minimal patient complications. We believe that this type of program maximizes the benefits to the patient and surgeon.

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## Compliance with ethical standards

**Conflict of interest** The authors Raphael Rocha, Gilberto Buogo, Maurício Rubinstein, Rodrigo Frota, Rogério Mattos, Rafael Coelho, Kenneth Palmer, and Vipul Patel declare that they have no conflict of interest.

**Ethical standards** 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.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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