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AFRICAN UROLOGY

ISSN 2710-2750 EISSN 2710-2750 © 2021 The Author(s)

ORIGINAL RESEARCH

Analysis of the learning curve in robotic-assisted laparoscopic radical prostatectomy in a South African setting

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Background: Robotic-assisted laparoscopic radical prostatectomy (RALP) represents a modern minimally invasive technique for treating men with localised prostate cancer. The aim of the study is to demonstrate a progression in the learning curve of two South African-based urologists as both embark on their first-ever series of RALP cases.

Method: We performed a retrospective audit of patients who had a RALP with two South African urologists between the dates of September 2014 to May 2019. All RALP cases were included unless critical data could not be collected. We analysed several perioperative parameters as surrogates to demonstrate the trend in learning curve. These parameters included: D'Amico risk group classification; console time (CT); estimated blood loss (EBL), length of stay (LOS); and pathological outcomes: T-staging and positive surgical margin (PSM) rates.

Results: Our study of 600 RALP cases demonstrates that for the parameters of median CT, EBL, LOS and PSM rates, there were notable improvements between the first and last groups of both surgeons' series.

Conclusion: This study demonstrates that, similar to internationally published data, notable improvements in perioperative outcomes can be observed as each of our two surgeons gain experience in RALP. When analysing our outcomes of CT, EBL, PSM rate and LOS, we see that our results compare favourably to other internationally published data.

Keywords: robotic-assisted laparoscopic radical prostatectomy, analysis, learning curve

Introduction

Prostate cancer (PCa) is the second most common cancer in men, and the sixth leading cause of cancer death among men worldwide.¹ Radical prostatectomy (RP) is widely considered the gold standard treatment for clinically significant localised PCa in men considered eligible for radical treatment. RP can be offered as an open, laparoscopic or robot-assisted procedure depending on surgeon experience and institutional availability of equipment.

Modern urological practice has seen the rise of robotic-assisted surgeries, robotic-assisted laparoscopic radical prostatectomy (RALP) being at the forefront. There has been a rapid increase in the number of American and European centres performing RALP over the last decade.² The use of robotics in surgery in South Africa is in its relative infancy, with only six robot systems operating in the entire country at the time of writing this article.

The benefits of having available to the surgeon a comfortable seated position, magnified binocular 3D visualisation, and several ergonomic, highly articulated and non-fatigable robotic arms within the tight confines of the boney pelvis seem obvious. Although this new approach appears to offer many benefits to patients, surgeons and institutions alike, some remain hesitant to adopt it as the introduction of any innovative technology or surgical procedure is associated with an initial learning curve and with the potential of eliciting new risks and surgical complications. There has been a growing interest in recent years in analysing and understanding the learning process surrounding RALP.²

The general definition of a learning curve is the period during which a surgeon finds the procedure more technically challenging, takes longer to perform, a higher rate of complications is observed, and there is overall lower efficacy of movement because of inexperience. With repetition, one typically sees an improvement in these areas with obvious benefit to patients, surgeons, institutions and funders alike.

The aim of the study is to demonstrate a progression in the learning curve of two South African-based urologists as both embark on their first-ever series of RALP cases. Given that there exists no widely accepted definition nor measure of a learning curve, as a surrogate, we seek to assess for improvements in key parameters as each surgeon gains experience with the procedure. The chosen parameters have been selected to be in line with those defined in already published international literature, allowing for better comparisons to be made.^{2,3} An audit of these key parameters for both surgeons' first uninterrupted series of RALPs has been undertaken. We also compare our results to international publications with a similar study design to assess if local South African learning curves are similar to these.

Although available literature reports on similar outcomes in international series, to our knowledge, there have been no published analyses of South African data. We postulate that in a South African setting, we would see similar improvements in key parameters and outcomes when compared to international cohorts.

Methods

Selection and description of participants

After receiving clearance from the University of Cape Town ethics committee (HREC Ref 218/2019) we performed a retrospective folder review of patients who had a RALP with two urologists at private hospitals. The two urologists, designated Surgeon-X and Surgeon-Y, as well as any identifying patient details, have been kept anonymous for the purpose of this study. Surgeon-X recorded his very first patient on 29/9/2014, while Surgeon-Y recorded his on 06/10/2015. All patients who underwent RALP with the two surgeons were included, and only excluded if critical data regarding perioperative outcomes could not be collected. A total of two patients were excluded from the study for incomplete or missing data.

Data analysis

A retrospective folder review of all patients that met the inclusion criteria during the specified time period of September 2014 to July 2019 was undertaken. Relevant data was extracted from the clinical folders and relevant laboratory records. Pre- and postoperative data was collected.

Preoperative data collected included parameters for risk stratification of patients according to the D'Amico risk group classification. The preoperative data collected included:

- [A] mean age at time of surgery
- [B] prostate-specific antigen (PSA) value at diagnosis
- [C] clinical digital rectal findings (T-stage)
- [D] biopsy Gleason score (ISUP grading)

Postoperative data included the following:

- [1] operating/console time, excluding setup/docking time (min)
- [2] estimated blood loss (ml)
- [3] need for intraoperative blood transfusion (yes/no)
- [4] conversion to open surgery (yes/no)
- [5] length of postoperative hospital stay (days)
- [6] number of patients with positive surgical margins (positive/ negative)

[7] histology (i.e. Gleason score or International Society of Urological Pathology [ISUP] grading)

[8] pathology (i.e. T-staging, not N or M staging) data

We would have liked to include an analysis of functional outcomes with regards to postoperative continence and potency, but unfortunately, data was found to be largely incomplete and thus could not form a meaningful part of this study.

The total number of patients for both surgeons has been divided into a series of consecutive groups. The first 100 for each surgeon have been divided into groups of 25, and the subsequent patients into groups of 50. These groups have been designated A through to H, with Groups A–D representing a combined 50 cases each (i.e. 25+25), while Groups E–H represent a combined 100 cases each (i.e. 50+50).

Results

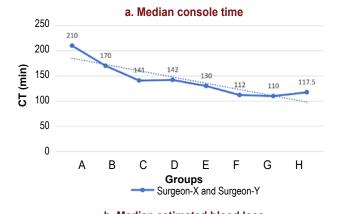
A total of 600 patients met our inclusion criteria, 300 patients in Surgeon-X's cohort, and 300 patients in Surgeon-Y's cohort. All patients had biopsy-confirmed adenocarcinoma of the prostate. The preoperative clinical characteristics of the patients for both surgeons are summarised in Table I.

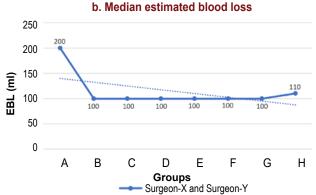
Table I: Patient preoperative characteristics for Surgeon-X and Surgeon-Y

Preop patient charateristics	Surgeon-X & Surgeon-Y				
Number of patients	600				
Median age, years (range)	64 (41–81)				
Median PSA level, ng/ml (range)	5.82 (0.3–164)				
Preop ISUP score n/%					
1	290/41.4%				
2	176/25.1%				
3	114/16.3%				
4	60/8.6%				
5	60/8.6%				
D'Amico risk group n/%					
Low	164/23.4%				
Intermediate	264/37.7%				
High	272/38.9%				

Table II: Patient intra- and postoperative data for Surgeon-X and Surgeon-Y by subgroups

Surgeon-X & Surgeon-Y	Overall	A [1–50]	B [51–100]	C [101–150]	D [151–200]	E [201–300]	F [301–400]	G [401–500]	H [501–600]	
Median CT, min (range)	129 (63–296)	210 (136–296)	170 (100–270)	141 (92–239)	142 (105–230)	130 (5–1 200)	112 (74–218)	110 (63–258)	117.5 (65–190)	
Median EBL, ml (range)	100 (0–1 200)	200 (0-700)	100 (50–700)	100 (35–500)	100 (20–500)	100 (10–700)	100 (10–700)	100 (20–1 100)	110 (20–900)	
Mean LOS, days (range)	1.5 (0–10)	2.0 (1–5)	1.8 (1–4)	1.5 (1–3)	1.9 (1–9)	1.5 (1–4)	1.3 (0-4)	1.3 (0–6)	1.5 (1–10)	
D/C day 1 (%)	59.5	30	38	56	46	60	71	71	70	
PSM rate amoung group, % (calc)										
Overall	15 (90/600)	20 (10/50)	20 (10/50)	12 (6/50)	24 (12/50)	13 (13/100)	15 (15/100)	11 (11/100)	13 (13/100)	
D'Amico low risk	3.9 (6/155)	7.7 (1/13)	16.6 (3/18)	10 (1/10)	-	-	-	3.6 (1/28)	-	
D'Amico intermediate risk	15.6 (36/231)	14.3 (3/21)	15 (3/20)	11.1 (1/28)	38.9 (7/18)	18.4 (7/38)	19 (8/42)	10.3 (4/39)	5.7 (2/35)	
D'Amico high risk	22.4 (48/214)	37.5 (6/16)	33.3 (3/12)	13.6 (3/22)	23.8 (5/21)	20 (6/30)	18.9 (7/37)	18.2 (6/33)	25.6 (11/43)	
pT2 disease	7.9 (28/354)	7.5 (3/40)	18.8 (6/32)	5.9 (2/34)	28 (7/25)	4 (2/50)	5.7 (3/53)	3.1 (2/65)	5.5 (3/55)	
pT3 disease	25.5 (61/239)	70 (7/10)	25 (4/16)	26.7 (4/15)	20 (5/25)	22.9 (11/48)	23.9 (11/46)	26.5 (9/34)	22.2 (10/45)	





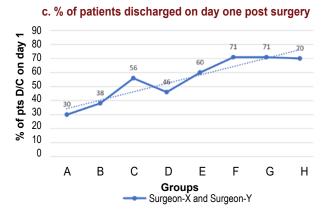


Figure 1: Surgeon-X and Surgeon-Y median console time (CT), median estimated blood loss (EBL), and % discharge on day one, by subgroups

Analysis of console times and conversion to open surgery

Neither of our two surgeons reported any of their patients requiring conversion to open surgery. Median console times (CT) in minutes was calculated for both surgeons (Table II and Figure 1a). The CT refers to the length of time that the surgeon was operating the robot from the console and did not include anaesthetic nor robot setup/ docking times.

The overall median CT for Surgeon-X and Surgeon-Y (n=600) was 129 min (range 63–296 min). For both, there were 254 patients (42.3%) that had CT less than or equal to 120 min, the vast majority of these from Group E onwards (i.e. > 100 patients for each surgeon), with only one of these coming from Group B (26–50 cases for each surgeon); 13 from Group C (51–75 cases for each surgeon); and 10 from Group D (76–100 cases for each surgeon). For both, there were 49 patients (8.1%) that had CT of less than or equal to 90 min, these occurred exclusively from Group E onwards (i.e. > 100 cases for each surgeon).

Analysis of estimated blood loss and length of postoperative hospital stay

Median estimated blood loss (EBL) in ml was calculated for both surgeons (Table II and Figure 1b). Of note, Surgeon-X did not report a requirement for intraoperative blood transfusion, while Surgeon-Y reported only two cases in his entire series.

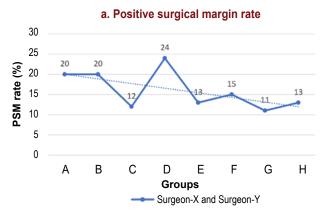
Mean length of hospital stay (LOS) for both surgeons was calculated (Table II). We also calculated the percentage of patients discharged on day one after surgery for both surgeons (Figure 1c).

Analysis of positive surgical margins

Oncological outcome is the most significant endpoint for patients with PCa receiving RP. The percentage of patients in each group with pathological positive surgical margins (PSM) was calculated for both surgeons (Table II and Figure 2a). A PSM was defined as the presence of cancer cells at the inked margin.

Whenever discussing PSM with regard to PCa, we already know that there is an association between the pathological stage of the tumour (pT) and the risk of obtaining a PSM.² In our entire series

b. Positive surgical margin rate for pathological T3 disease



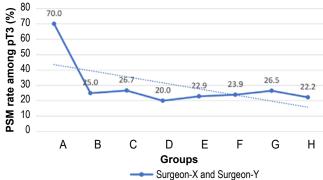


Figure 2: Surgeon-X and Surgeon-Y positive surgical margin rates by subgroups

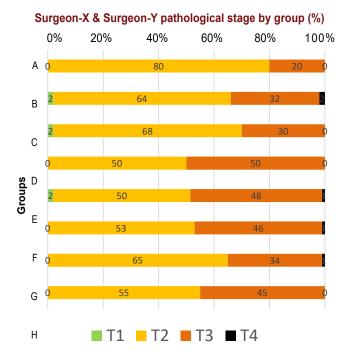


Figure 3: Surgeon-X and Surgeon-Y pathological staging based on final histology report by subgroup

of 600 cases, the number of patients in each pathological staging group was as follows: 0.5% (3/600) were pT1 disease; while 59% (354/600) were pT2; 39.8% (239/600) were pT3; and 0.7% (4/600) were pT4. When assessing the learning curve for PSM in each successive subgroup, it becomes important to know the staging of each subgroup (Figure 3).

The PSM rate for Surgeon-X and Surgeon-Y for their entire series of 600 patients is 15% (90/600), with 31.1% of PSMs (28/90) being pT2 disease while 67.8% (61/90) were pT3 disease on final histology (Table II and Figure 3). For Surgeon-X and Surgeon-Y, the PSM rate was 7.9% (28/354) and 25.5% (61/239) for pT2 and pT3 disease, respectively. The PSM rate for pT3 disease for both surgeons from Groups A to H is illustrated in Figure 2b.

Discussion

Summary of findings

To our knowledge, there are currently no large-scale studies of RALP outcomes that have been reported in South Africa. Our study of 600 patients who underwent RALP demonstrates that in a South African setting, for the parameters of median CT, EBL, LOS, and PSM, there were notable improvements between the first and last groups of the surgeon's series. Although each parameter tends to fluctuate around a median value, there is a general trend towards improved outcomes. These can be seen depicted in the slope of each parameter's trendline (Figures 1 and 2).

When comparing the first (Group A) and last groups (Group H) of both surgeons, there was a significant reduction in the median CT (p < 0.001; 210 min vs 117.5 min), median EBL (p < 0.001; 200 ml vs 110 ml), and mean LOS (p = 0.007; 1.96 days vs 1.47 days). However, there was no significant change in PSM rates between the first and last groups (p = 0.262; 20% [10/50] vs 13% [13/100]).

Furthermore, PSM rates among pT2 disease did not differ between the first and last groups (p = 0.460; 7.5% [3/40] vs 5.5% [3/55]). However, a higher proportion of patients with pT3 disease had a PSM in the first compared to the last group (p = 0.014; 70% [7/10] vs 22.2% [10/45]).

Several initial reports on RALP having a favourable learning curve exist,⁴⁻⁶ with the eminent robotic surgeon Dr VP Patel reporting that as few as 20–25 cases are required in order to complete the learning curve of RALP. These reports make the use of RALP rather appealing considering that other studies report a learning curve for laparoscopic radical prostatectomy (LRP) being approximately 250 cases.⁷⁻⁹ In some studies, the learning curve parameters for LRP did not start reaching a plateau even after 750 cases.¹⁰

These early series, however, were unlikely to have sufficient numbers to identify the plateau of the learning curve (the number of cases required to no longer demonstrate notable improvements in outcomes). In fact, every procedure and surgeon is likely to have their own distinct learning curve, with the number of cases required to become adept varying widely. Add to this that in our study, as in most studies examining a learning curve for a surgical procedure, there are differing numbers of cases required to become proficient depending on which parameter is being assessed. In other words, there are different learning curves within the overall learning curve for RALP.

This can be demonstrated in a study by Eden et al.9 reported that the learning curve for both OT and EBL plateaued within the first 100-150 cases, while that for both complications and continence rates took longer at 150-200 cases to reach a plateau. The parameter that took the longest to plateau was potency, at 700 cases. Thompson et al.11 reported that odds of a pT2 PSM in their series of RALPs only started to become lower after 108 cases and reduced by 55% (OR 0.45; 95% CI 0.22-0.92) by the 866th RALP. In the same study, the odds of a pT3/4 PSM started to plateau only around 200-300 RARPs with an OR of 1.15 (0.68-1.95) at the 866th RALP. This study also reported potency only reaching a plateau in learning curve around 600-700 cases. Sooriakumaran et al. 12 in a multi-institutional review of 3 794 patients, showed a learning curve of more than 1 000 RALP cases before the pT3 PSM rate plateaued. The same study suggests that proficiency in RALP involves a much longer learning curve than previously recognised. Mean operating time plateaued only after 750 cases, while 1 600 cases would be required to get an overall PSM rate of < 10%. All these studies seem to support the notion of RALP being centralised in a small number of high-volume centres where the relevant surgeons may attain the case experience required to offer their patients outcomes of the highest calibre.7,17

In our series, we saw that when assessing CT, Group C was faster than Groups A and B, but only seems to plateau by Group F. When assessing EBL, we saw that Group A seems to have a high blood loss compared to other subsequent groups and plateaus after that. LOS declined from the first group to the last group; however, there was an increase at Group D and thereafter, a plateau is

Table III: Comparison of reported outcomes in published contemporary series

								PSM rate (%)			
Reference	Year	No pts	No surgeons	OT (min)	EBL (ml)	LOS (days)	D/C day 1 (%)	Overall	pT2	pT3	pT4
Patel et al.4	2005	200	1	141	75.1	1.1	95	10.5	5.7	26.2	33
Patel et al. ²⁰	2007	500	1	130	50	-	97	9.4	2.5	(a) 23/(b) 46	53
Patel et al. ²¹	2008	1 500	1	105	111	-	97	9.3	4	33	40
Coelho et al.22	2010	2 500	1	90	100	1	95	10.6	5	27.5	-
Patel et al. ²	2011	4 000	1	75	100	1	-	10.8	5.8	26.1	-
Carlucci et al.13	2009	700	1	124	69.3	-	-	11.9	10	(a) 40/(b) 57	-
Zorn et al.14	2009	700	2	234	222	1.2	-	18.8	12.9	44.8	-
Sharma et al.15	2011	500	2	170	200	-	-	24	16.1	(a) 30.4/(b) 55	100
Patel et al.2*	2011	> 11 500	Multiple	174	185.8	1.58	-	14.8	8.92	33	-
Ou et al. ¹⁶	2014	500	1	134	137	-	-	34.2	15.6	41	96
Vasdev et al.17	2014	300	3	224	248	2.3	-	26.7	-	-	-
Good et al.18	2015	531	2	124	272	1	-	14	6	31	-
Tobias-Machado et al.19	2016	60	1	236	245	1.6	-	21.6	12.5	50	-
De Jager et al.	2020	700	2	129	100	1.5	59.5	15	7.9	25.5	-

Year – year of publication, OT – operating time, EBL – estimated blood loss, LOS – length of hospital stay, D/C day 1 – rate of discharge day one after surgery

demonstrated. No plateau for the variable of PSM rates could be conclusively demonstrated.

When comparing our series of 600 patients to that of other contemporary international series (Table III), we can see that the parameters of operating time (OT), EBL, LOS and PSM rate appear to be as favourable in our setting as in those reported overseas. If we use Patel et al.'s "critical review of pentafecta outcomes"2 as a direct comparison, we can see that our CT is better (129 min vs 174 min); our EBL is better (100 ml vs 185.8 ml); and our LOS is the same (1.5 days vs 1.58 days). This comparison is especially true for the important parameters of PSM rates where we see that our overall PSM rate is similar (15.0% vs 14.8%); our pT2 PSM rate is slightly better (7.9% vs 8.92%); and our pT3 PSM rate is also better (25.5% vs 33%). As this study depicts the weighted mean values of 17-19 different international studies, with a total patient cohort of more than 11 500 cases, we feel this is probably the one study that likely represents a fair overall impression of how our results compare to international series.

Of particular interest is the progression in parameters in the four consecutive 200, 500, 1 500, 2 500 and 4 000 patient series of Patel et al.^{2,4,20-22} that fail to show dramatic improvements in most of the recorded parameters, excepting CT, at even very high single surgeon case experience.

Conclusion

This study demonstrates that, like other internationally published data, notable improvements in perioperative outcomes can be observed as both surgeons gain experience in this relatively new operative approach to managing men with localised PCa in South Africa. The overall picture is one of improved outcomes with each consecutive group analysed and, when individually assessed, these outcomes display differing rates of improvement depending on

which is being assessed. When looking at our outcomes of CT, EBL, PSM rate and LOS, we see that our results compare favourably to other internationally published data. For all intents and purposes, our learning curve and perioperative results are on par with our overseas counterparts.

Our study also confirms that RALP can feasibly, safely and effectively be introduced in a South Africa setting without oncological outcomes being compromised. Within a structured training and mentorship programme, evidence suggests that satisfactory outcomes can be achieved along the demonstrated learning curves for those novice surgeons willing to dedicate themselves to this surgical approach. We would agree with the concept of RALP being taught to surgeons and offered to patients in a smaller number of high-volume centres that will more likely attain the high case experience required to reach their optimal learning curve and thus improve outcomes for their patients.

Conflict of interest

The authors declare no conflict of interest.

Funding source

Funding from the UCT Department of Urology for payment of a statistician only.

Ethical approval

Ethics approval was obtained from University of Cape Town ethics committee (HREC Ref 218/2019).

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The first five studies (darkened) represent successive publications of a single surgeon's (Dr VP Patel) experience in RALP

^{*}This study (highlighted in green) takes the weighted means of 17–19 studies combined and these are the values depicted Additional referees: 13–19

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