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Should experienced open prostatic surgeons convert to robotic surgery? The real learning curve for one surgeon over 3 years

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OBJECTIVE

To critically analyse the learning curve for one experienced open surgeon converting to robotic surgery for radical prostatectomy (RP).

PATIENTS AND METHODS

From February 2006 to December 2008, 502 patients had retropubic RP (RRP) while concurrently 212 had robot-assisted laparoscopic RP (RALP) by one urologist. We prospectively compared the baseline patient and tumour characteristics, variables during and after RP, histopathological features and early urinary functional outcomes in the two groups.

RESULTS

The patients in both groups were similar in age, preoperative prostate-specific antigen level, and prostatic volume. However, there were more high-stage (T2b and T3, $P = 0.02$) and -grade (Gleason 9, $P = 0.01$) tumours in the RRP group. The mean (range) operative duration was 147 (75–330) min for RRP and 192 (119–525) min for RALP ($P < 0.001$); 110 cases were required to achieve '3-h proficiency'. Major complication rates were 1.8% and 0.8% for RALP and RRP, respectively. The overall positive surgical margin (PSM) rate was 21.2% in the RALP and 16.7% in the RRP group ($P = 0.18$). PSM rates for pT2 were comparable (11.6% vs 10.1%, $P = 0.74$). pT3 PSM rates were higher for RALP than RRP (40.5% vs 28.8%, $P = 0.004$). The learning curve started to plateau in the overall PSM rate after 150 cases. For the pT2 and pT3 PSM rates, the learning curve tended to flatten after 140 and 170 cases, respectively. The early continence rates were comparable ($P = 0.07$) but showed a statistically significant improvement after 200 cases.

CONCLUSIONS

Our analysis of the learning curve has shown that certain components of the curve for an experienced open surgeon transferring skills to the robotic platform take different times. We suggest that patient selection is guided by these milestones, to maximize oncological outcomes.

KEYWORDS

laparoscopy, learning curve, prostate cancer, prostatectomy, retropubic, robot-assisted

INTRODUCTION

At present patients with prostate cancer and eligible for surgery must choose between open and minimally invasive radical prostatectomy (RP) [1,2] with limited data showing differences in outcomes [3,4]. Furthermore, there is a wide variation in outcomes, and between experienced and inexperienced surgeons [5–7]. However, there is increasing evidence that robot-assisted surgery has some benefits over open RP; first, by decreasing the length of stay; second, by decreasing the time to return to normal activities; and finally by possibly improving positive surgical margin (PSM) rates and functional outcomes [8–10]. Even within individual institutions, mixed results have been reported [11–17]. Experienced open surgeons face the dilemma of whether to convert to robot-assisted surgery in view of these perceived benefits and patient demand [18].

In the present study we compared the clinical, pathological and functional outcomes of 714 consecutive retropubic RP (RRP) and robot-assisted laparoscopic RP (RALP) performed by one experienced surgeon in a tertiary referral institution. Before commencing the robotic surgery programme in February 2006, the surgeon had performed >2000 RRP cases. The learning curve was based on the number of cases needed to achieve competency in each of the following areas: console time, pathological outcome (overall, pT2 and pT3 PSM rates) and early continence (6 weeks), all prospectively documented.

PATIENTS AND METHODS

This was a prospective cohort study involving 714 patients treated concurrently by surgery

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for clinically localized prostate cancer; 212 and 502 undergoing RALP and RRP, respectively, by one surgeon (P.S.) between February 2006 and December 2008, were compared. Patients were selected to undergo RALP or RRP based on surgeon's preference taking into account the patient and tumour characteristics. In the first 50 cases of RALP, patients with factors considered to increase surgical difficulty, e.g. morbid obesity, prostate size >100 mL, large middle lobe, previous TURP, a history of laparoscopic hernia mesh repair, multiple abdominal operations and high volume tumours (D'Amico high risk group) were excluded. These characteristics were gradually introduced in a controlled manner in the subsequent cases as the surgeon became progressively more experienced.

Open RRP was performed in a standardized fashion via an infra-umbilical midline incision [19]; RALP was performed in the manner described by Patel *et al.* [10,20] by the same surgeon. All the cases were operated using the transperitoneal, six-port technique. An anterior approach was used by first isolating and ligating the dorsal venous complex with a monofilament polyglytone suture, followed by bladder neck dissection and mobilization of the seminal vesicles before ligating the prostatic pedicles. Where nerve sparing was indicated, this was done athermally by early retrograde release of the neurovascular bundles from apex to base via an intrafascial approach or by an antegrade technique in an incremental fashion. A two-layer Rocco stitch [21] was used. A continuous running suture is created using two 20-cm 3–0 poliglecaprone 25 sutures of different colour tied together. An anterior reconstruction of the bladder was also performed when required.

After RP, all patients followed a standard clinical pathway, with planned removal of the indwelling catheter at 6 and 7 days for RALP and RRP, respectively. A cystogram was always taken before the catheter was removed. All major complications and variance from the pathway were prospectively recorded and analysed.

On removal of the specimen, the prostate was fixed intact in formalin for 18–24 h. The prostate was then weighed and measured (in three dimensions), including seminal vesicles. The resection margins were then marked by painting the surface of the prostate with ink, blue anteriorly and black posteriorly. The seminal vesicles were removed and sections taken proximally and distally from each. The remaining specimen was then sectioned by removing disks of tissue representing the apex and base. These were sliced sagittally and all embedded. The remainder of the prostate was then sliced coronally into 6–10 slices. Each slice was divided into quadrants and all embedded. The prostate was therefore fully embedded. A PSM was defined as the presence of cancer cells at the inked margin.

With institutional ethics approval (n°H00/088), data were collected prospectively. Clinicopathological data included preoperative PSA level, clinical stage (TNM 2002), Gleason score, pathological stage, surgical margin status, operative time (console time for RALP), blood loss, length of hospital stay and duration of catheterization. The major complications were reviewed and graded according to the classification system described by Dindo *et al.* [22]. Early urinary continence was assessed using the Expanded Prostate Cancer Composite (EPIC) questionnaire at 6 weeks [23]. A patient was considered continent if he used no pads or just one safety pad for protection against the occasional leak of a few drops of urine.

Surgeon experience was coded as the number of RALP cases done by the surgeon before the index patient's procedure. To produce a learning curve we analysed the PSM rates and the EPIC score (%) at 6 weeks after RP, respectively, against surgeon experience as a continuous variable. The margin status of each RP specimen was recorded and a positive event was coded when the tumour extended to the inked margin. The PSM rate was calculated for each RALP case by dividing the number of positive events by the number of preceding cases. To calculate the positive margin rates for pT2 and pT3, only cases in the respective groups were included.

To estimate the number of cases (with 95% CI) after which the learning curve becomes flat (the change of marginal rate is not significantly different from zero), a joinpoint regression method was used (http://srab.cancer.gov/joinpoint). In this method several different regression lines are connected together at 'joinpoints'. The logarithm of marginal rates was fitted against the number of cases from which the rates were calculated. As the rates at the earlier stages were very unstable due to the few cases the regression was weighted by the inverse of the standard error of the rates. The minimum (0) and maximum (4, the maximum limit of the computer program) number of joinpoints were supplied that could be fitted with the data. The Monte Carlo permutation method was used after fitting each joinpoint to test whether more joinpoints were statistically significant and must have been added to the model (up to that maximum number) [24]. After each of the joinpoints, the slope of each of the regression lines was reported. To determine whether the percentage change of the rate in each regression line was significantly different from zero an 'average annual percentage change' statistic was calculated. This statistic reported the percentage of the rate changes for each additional case. The linear fit of the predicted values from the regression model, along with the scatter plot of the observed values, is presented in the joinpoint regression curves. For this analysis we used the Joinpoint Regression Program version 3.3.1 (National Cancer Institute, 2008). To estimate from what number of cases the marginal rate of the RALP group was not significantly different from the rate from the RRP group, we used a one-sample test for a binomial proportion [25]. For this test we assumed that the marginal rate in the RRP group was constant. A two-tailed P value of the binomial test was obtained for the difference between the constant marginal rate of the RRP group and the rates from the RALP group for each consecutive case. However, in the continence data the comparison factor was the average EPIC score at 6 weeks after RP to compare the two groups. An average EPIC score was calculated for each consecutive patient who completed the questionnaire. To do the same analysis, a one-sample t-test for a mean was used [25]. In this case we also assumed that the average score for the RRP group was constant. The reminder of the statistical analysis comprised comparisons of nominal variables by the Pearson chi-square test with Yate's continuity correction, while continuous variable were compared using ANOVA. All statistical tests were two sided, with $P < 0.05$ considered indicate statistical significance.

RESULTS

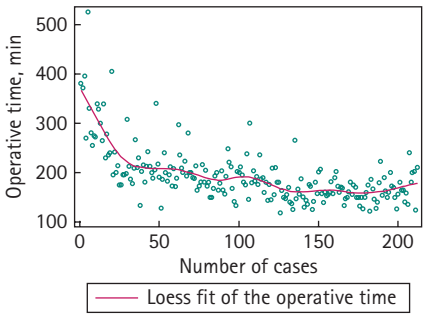
The study comprised 212 and 502 concurrent patients undergoing RALP and RRP, respectively; both groups were similar in age, preoperative PSA level and prostatic volume, but there were more high-stage (T2b and T3,

TABLE 1 The clinical and pathological variables before during and after RP, and complication rates

Mean (range) or *n* (%) variable	RALP	RRP	*P*
No. of patients	212	502	
Age, years	61.3 (41–76)	60.1 (40–78)	ns
PSA level, ng/mL	7.1 (0.7–41)	8.3 (0.9–64)	ns
Prostate volume, mL	50 (16–140)	53.2 (20–145)	ns
Clinical stage			
T1a	4 (2)	5 (1)	0.54
T1b	2 (1)	5 (1)	0.94
T1c	99 (47)	201 (40)	0.11
T2a	59 (28)	111 (22)	0.12
T2b	16 (7)	70 (14)	0.02
T2c	32 (15)	95 (19)	0.26
T3	0	15 (3)	0.02
Gleason score			
6	73 (34)	126 (25)	0.01
7	128 (61)	321 (64)	0.41
8	9 (3.5)	25 (5)	0.81
9	3 (1.5)	30 (6)	0.01
Intra- and postoperative			
Op duration, min	192 (119–525)	148 (75–330)	<0.001
Patients with a mean estimated blood loss, mL, of:			
<499	208 (98.4)	349 (69.7)	<0.001
500–999	4 (1.6)	147 (29.1)	<0.001
>1000	0	6 (1.2)	0.25
Blood transfusion	2 (0.9)	10 (2)	0.49
Other complications	0	0	
Catheter time, days	6.3 (6–21)	7.9 (6–20)	<0.001
Hospital stay, days	2.8 (2–7)	5.5 (3–10)	<0.001
Follow-up, months (SD)	11.2 (9.4)	17.2 (9.7)	0.36
Major complications (Dindo *et al.* classification [23]*)			
Grade IIIa	0	0	
Grade IIIb	4 (1.8)	1 (0.2)	0.04
Grade IV	0	2 (0.6)	0.88
Grade V	0	1 (0.2)	0.51
Total	4 (1.8)	4 (0.8)	0.38
Pathological features			
Pathological stage			
pT2a	18 (8.5)	37 (7.4)	0.71
pT2b	12 (2.4)	20 (4)	0.42
pT2c	116 (54.7)	268 (53.4)	0.37
pT3a	55 (25.9)	129 (25.7)	0.70
pT3b	11 (5.2)	48 (9.5)	0.07
Node status			
No LND†	158 (74.5)	239 (47.6)	<0.001
Negative	54 (100)	247 (94)	0.14
1 positive	0	11 (4)	0.06
>1 positive	0	5 (2)	0.33
Gleason score			
6	45 (21.2)	76 (15.2)	0.03
7	149 (70.3)	357 (71)	0.89
8	11 (5.2)	20 (4)	0.6
9	7 (3.3)	48 (9.7)	0.006
10	0	1 (0.1)	
Tumour volume, mL (SD)	1.48 (1.2)	2.07 (2.1)	<0.001
PSMs by stage			
pT2	17 (11.6)	33 (10.1)	0.74
pT3	28 (40.5)	51 (28.8)	0.004
Overall PSMs	45 (21.2)	84 (16.7)	0.18

*LND, lymph node dissection. ns, not significant. *Grade IIIa, surgical complication requiring intervention with no general anaesthesia; Grade IIIb, surgical complication requiring intervention with general anaesthesia; Grade IV, life-threatening complication or intensive-care unit management; Grade V, death.*

FIG. 1. The learning curve for the operative duration (Loess fit curve).



P = 0.02) and -grade (Gleason 9, *P* = 0.01) tumours in the RRP group (Table 1). The intraoperative data are also shown in Table 1. In the RALP group 98.4% of patients had blood loss of <500 mL, vs 69.7% in the RPP group (*P* < 0.001). A blood loss of 500–999 mL was less common in the RALP than in the RRP group (1.6% vs 29.1%, *P* < 0.001). The blood transfusion rate was higher in the RRP group (2% vs 0.9%, *P* = 0.49). There were no conversions to open surgery in the RALP group. The mean (range) operative duration was significantly different between the groups, at 192 (119–525) min for RALP and 147 (75–330) min for RRP (*P* < 0.001). As expected, the operative time for RALP decreased with experience and continued to decrease over the study period (Fig. 1); about 110 cases were needed for the operative duration to be <3 h.

The postoperative data are also presented in Table 1; the mean hospital stay was longer for RRP than RALP, at 5.5 vs 2.8 days (*P* < 0.001). Indwelling catheters were removed as per protocol at 6 and 7 days after RALP and RRP, respectively. Variance from the pathway due to anastomotic leaks, confirmed by cystogram, leading to prolonged catheterization occurred in 4% of RALPs vs 12% of RRPs. The major complications, as defined by the Dindo *et al.* classification [22] (grade III to V) are reported for up to 6 weeks after RP. One patient died (grade V) due to a cerebral vascular accident in the RRP group. Another patient in the RRP group also had a cerebral vascular accident (grade IV) but only suffered minor sensory deficits. Both patients had a history of recurrent transient ischaemic attack and were appropriately investigated before RP. One patient in the RRP group developed pulmonary embolism (grade IV), confirmed on imaging and treated with low

FIG. 2. The learning curve for overall PSM rates after RALP.

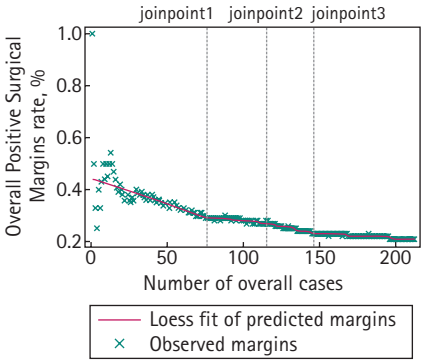


FIG. 3. The learning curve for pT2 PSM rates after RALP.

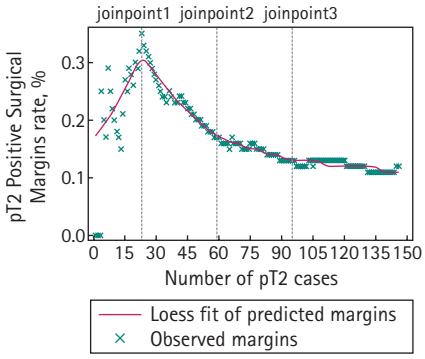
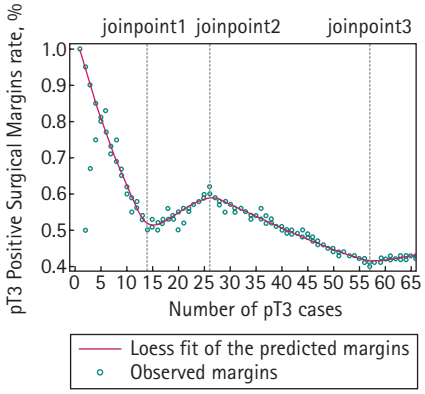


FIG. 4. The learning curve for pT3 PSM rates after RALP.



molecular weight heparin. In the RRP group, one patient returned to theatre for evacuation of a pelvic haematoma (grade IIIb) after unsuccessful attempts with percutaneous drainage under radiological guidance. In the RALP group, four patients required a return to theatre, including two with bleeding. The first patient was bleeding from the neurovascular bundle, which required oversewing. The second patient developed haematuria and clot retention. He was found to have a small pelvic haematoma but no active bleeding at the time of re-operation. One patient developed severe pain at the umbilical port site, which was explored under general anaesthesia but subsequently was diagnosed with local cellulitis. The last patient had a small bowel injury which required a repeat laparoscopic repair. This was recognized at the original operation during extensive adhesiolysis performed by an experienced laparoscopic general surgeon who made the initial repair. None of the four RALP patients required a laparotomy for access. Overall, major complication rates were 1.8% and 0.8% in RALP and RRP groups, respectively.

All 714 RP specimens were reviewed by one genitourinary pathologist (W.D.). The pathological data are also listed in Table 1. The overall PSM rates for RALP and RRP were 21.2% and 16.7%, respectively, and their difference was not statistically significant (P = 0.18). Within the pT2 group, the PSM rate was no different (11.6% vs 10.1%, P = 0.74). In pT3 group, PSM rate for RALP was higher than that for RRP (40.5% vs 28.8%, P = 0.004). For the purpose of this report, the PSM and the early continence outcomes were analysed using the learning curve.

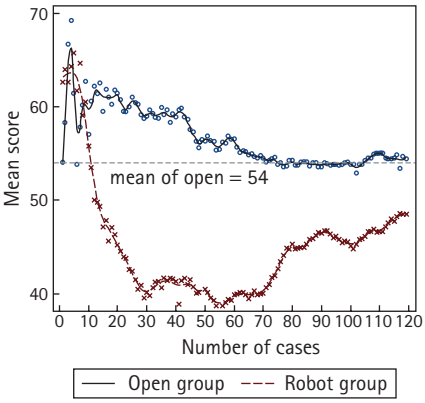
Figure 2 shows that the overall PSM rate for RALP declined as surgeon experience increased with the number of cases. Using the joinpoint regression analysis, the learning curve for overall PSM rate started to plateau (gradient not significantly different to zero) at ≈150 cases (146, 95% CI 134–159).

The learning curve for RALP and pT2 PSM tended to reach a plateau after 95 (95% CI 60–104) pT2 cases (Fig. 3). This threshold corresponded to 140 accumulated cases. However, the RALP pT2 PSM rates were statistically comparable to the RRP group after 120 cases (85 pT2 cases).

The RALP learning curve for pT3 PSM (Fig. 4) was longer than pT2 and did not reach a plateau until after 60 pT3 cases (57, 95% CI 51–62) which corresponded to 170 accumulated RALP cases. Even though the learning curve appeared to have plateaued, the pT3 PSM rate remained significantly different from the open group (40.5% vs 28.8%, P = 0.004) by the end of the series. This might be a result of the relatively few pT3 cases available for analysis, or that the surgeon was still on the learning curve. Another possible explanation might be related to the surgical technique resulting in a higher pT3 PSM rate than in the RRP group, although similar trends would also be expected for the pT2 PSM rates.

We report the early continence data on 274 patients who completed the EPIC questionnaire at 6 weeks; 56% (119) in the RALP group completed the questionnaire and were available for analysis. In the RALP group (Fig. 5) the mean EPIC scores were inferior initially then gradually improved after the

FIG. 5. he learning curve for early continence (EPIC score at 6 weeks) after RALP.



70th patient, corresponding to 130 accumulated cases. However, the curve has an upward trend and continues to approach that of the mean EPIC score for the RRP group. Interestingly, after 200 cases, the early continence rates were comparable to that of the RRP technique (P = 0.07). Caution is needed in interpreting these results due to a change in surgical technique during this period. Since November 2009, we incorporated a two-layer anterior bladder repair stitch in all RALP. It is unclear whether the improved early continence is an effect of the learning curve or modification of technique.

DISCUSSION

It was previously shown that the robotic interface helps the surgeon to master laparoscopic RP for a laparoscopically naïve but well-trained open surgeon [26]. Ahlering *et al.* [27] showed that only 10–20 cases were

TABLE 2 Comparative studies between RALP and RRP

Ref/year	No. of patients	Operating time, min	Transfusion rate, %	Length of stay, days	PSM rate, %	
					pT2	Overall
Present/2009	502 RRP	147	2	5.5	10.1	16.7
	212 RALP	192	0.9	2.8	11.6	21.2
[8]/2009	105 RRP	135	14	–	12.2	–
	103 RALP	185	1.9	–	11.7	–
[14]/2009	588 RRP	204	13.1	–	17	–
	294 RALP	236	5.1	–	15.6	–
[13]/2008	26 RRP	127	34	8	18	23
	35 RALP	195	17	5	17	28
[16]/2007	374 RRP	–	–	1.23	–	–
	629 RALP	–		1.17		
[12]/2006	103 RRP	–	2.9	–	–	–
	176 RALP	–	0.5	–	–	–
[11]/2004	60 RRP	214	2	9	9	20
	60 RALP	231	0	7	4.5	16.7
[17]/2003	100 RRP	163	67	15.8	–	23
	200 RALP	160	0	7	–	6
[15]/2002	30 RRP	138	17	2.3	–	29
	30 RALP	288	7	1.5	–	26

required to achieve '4-h proficiency'. However, the learning curve has many facets and not only includes safety and console time, but also the time to achieve satisfactory pT2 and pT3 PSM rates, and the time to achieve early and late urinary control and early and late sexual performance. Currently, men opting for surgery must choose between open and minimally invasive RP with only limited data showing different outcomes. Among the 12 published studies comparing RRP with RALP, eight were prospective and not randomized [8,11–17] (Table 2), three were retrospective comparing contemporary series of patients [14,18,28], and one retrospective study used historical series as controls [27]. There appears to be no obvious advantage of one study over the other for oncological or functional outcomes, although there is a trend towards a benefit to robotic surgery for length of stay, return to normal activities and blood loss [3]. However, none of the studies mention the endpoint of the learning curve on which the surgeon was. The length of this learning curve might depend on the volume of cases previously done, annual volume of cases, level of mentorship, individual skill of the surgeon, and the previous standard of the unit or surgeon with regard to the 'trifecta' rate [29].

In the present series we assessed an experienced, high-volume, open surgeon considering conversion to robot-assisted surgery. The learning curve to achieve '3-h proficiency' was 110 cases, ≈120 were needed to achieve an equal pT2 PSM rate, 170 to plateau for the pT3 PSM rate and 200 to achieve equivalent early continence rates to RRP. However, as this is based on one surgeon's experience, it is unclear whether these thresholds can be applied to others who might be considering converting to RALP. Furthermore, it is unclear whether the surgeon's previous experience with RRP had an effect on the learning curve. Due to 'selection bias' in the RALP group, based on preoperative oncological and patient characteristics, the actual learning curve might be longer in an unselected group of patients.

One of the limitations of this study is the short follow-up of 11.2 and 17.2 months for RALP and RRP, respectively. As a result we have not reported any long-term continence outcomes or erectile function in the present study.

When assessing the gradual introduction of a new technology, e.g. introducing robot-assisted surgery to an experienced open surgeon, it is important to recognize the effects of 'adopter bias'. In the first 50 cases we excluded patients who were morbidly obese or had a prostate of >100 mL, a large middle lobe, and those with a history of TURP, laparoscopic mesh hernia repair or extensive abdominal adhesions. Furthermore, even within the first 100 cases, patients with several difficulties, incorporating these more difficult patient characteristics, were excluded. Patients with more extensive cancer tended to have RRP in our series; this can be seen by the trend towards larger tumours (53.2 vs 50 mL) and a higher PSA level (8.3 vs 7.1 ng/mL) in the RRP series. This places a bias in favour of the RALP series and might be part of the reason for achieving a low complication rate in a relatively short learning curve.

A limitation of the current study is that it was not randomized and, as yet, we have insufficient follow-up to give meaningful data for sexual outcomes. Furthermore, we had no long-term functional or oncological data, due to the relatively short follow-up. However, a strength of the study is that the series was based on one surgeon, with consecutive patients, over a 3-year period of both RRP and RALP.

We believe that the learning curve for a high-volume, experienced open surgeon to achieve full proficiency in robotic surgery, both in terms of PSM rates and functional outcome, varies between 110 and 200 cases. We were able to achieve a low complication rate, and a relatively short learning curve, for both pT2 and pT3 tumours, by a selective policy of gradual introduction of more difficult patient and tumour variables. We suggest that it might be necessary to avoid high-volume tumours which are more likely to be pT3, particularly in the first 100 cases. Patient characteristics that should also be considered, particularly in the first 50 cases, include previous TURP, laparoscopic hernia mesh repair, morbid obesity, prostate >100 mL, a large middle lobe, extensive abdominal adhesions and priority of potency. To minimize patient regret, shorten the learning curve, minimize complication rate and appropriately counsel patients, we believe these variables should be introduced selectively, at different stages of the learning curve.

We assessed the learning curve of an experienced, high-volume, open surgeon, but for inexperienced surgeons, a fellowship training based on a modular curriculum could possibly shorten the learning curve without compromising patient outcomes, even while

the supervising surgeon is also on the learning curve [30]. It is quite likely that the RALP learning curve is shorter than those for both RRP and laparoscopic RP [26,27,31]. The method of acquiring proficiency in robot-assisted surgery should be individualized to the surgeon and their personal circumstances.

In conclusion, we showed that certain components of the learning curve for an experienced open surgeon in transferring skills to the robotic platform take different times, with 110 cases to achieve 3-h proficiency, 140 to reach a plateau for PSM rates in pT2, 170 for pT3, and 200 cases for equal results in early continence (6 weeks). Based on our experience, we suggest that patients with high-volume tumours should be avoided in the early part of the learning curve, to maximize the oncological outcomes.

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CONFLICT OF INTEREST

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Abbreviations: **RP**, radical prostatectomy; **RALP**, robot-assisted laparoscopic RP; **RRP**, retropubic RP; **EPIC**, Expanded Prostate Cancer Composite; **PSM**, positive surgical margin.