Title Page

Full title (80 characters):

The Australian Laparoscopic Radical Prostatectomy Learning Curve

Running title (40 characters):

Australian LRP learning curve

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Abstract

Introduction

International estimates of the laparoscopic radical prostatectomy (LRP) learning curve extend to as many as 1000 cases, but is unknown for Fellowship trained Australian surgeons.

Methods

Prospectively collected data from nine Australian surgeons who performed 2943 consecutive LRP cases was retrospectively reviewed. Their combined initial 100 cases (F100, n=900) were compared to their second 100 cases (S100, n=782) with two of nine surgeons completing fewer than 200 cases.

Results

The mean age (61.1 vs 61.1 years) and PSA (7.4 vs 7.8 ng/ml) were similar between F100 and S100. D'Amico's high, intermediate and low risk cases were 15%, 59% and 26% for the F100 vs 20%, 59% and 21% for the S100 respectively. Blood transfusions (2.4% vs 0.8%), mean blood loss (413mL vs 378mL), mean operating time (193min vs 163min) and length of stay (2.7days vs 2.4days) were all lower in the S100. Histopathology was organ confined (pT2) in 76% of F100 and 71% of S100. PSM rate was 18.4% in F100 vs 17.5% in the S100

(P=0.62). F100 and S100 PSM rates by pathological stage were similar with pT2 PSM 12.2% vs 9.5% (P=0.13), pT3a PSM 34.8% vs 40.5% (P=0.29) and pT3b PSM 52.9% vs 36.4% (P=0.14).

Discussion

There was no significant improvement in PSM rate between F100 and S100 cases. Perioperative outcomes were acceptable in F100 and further improved with experience in S100. Mentoring can minimise the LRP learning curve, and it remains a valid minimally invasive surgical treatment for prostate cancer in Australia even in early practice.

Introduction

The learning curve for conventional laparoscopic radical prostatectomy (LRP) is well recognised, with technical challenges relating to straight instruments and a two dimensional view, when compared with robotic-assisted laparoscopic radical prostatectomy (RALP). Multicentre analyses have reported that improvements in surgical outcomes, especially for positive surgical margin (PSM) rates, can be observed for anywhere between 200 to 1000 cases. [1-3]

However, 'second generation' surgeons who have undertaken Fellowship training in high volume LRP centres appear to have an abbreviated learning curve, with improved surgical outcomes and PSM rates after fewer cases.[1, 2, 4-6]

We sought to examine the learning curve of nine Fellowship trained Australian LRP surgeons, comparing perioperative outcomes and PSM rates of their first 100 (F100) to their second 100 (S100) cases.

Materials & Methods

The case composition, perioperative outcomes and postoperative PSM rates of Australian prostatectomy surgeons who had completed a one year or greater formal Fellowship in laparoscopic radical prostatectomy, and who had completed at least 100 consecutive laparoscopic radical prostatectomies were sought by open invitation. Results included all independent cases of each surgeon, including their initial and subsequent cases in consecutive order.

Preoperative data collected included patient demographics, preoperative prostate specific antigen (PSA), clinical stage and Gleason score. Perioperative data included mean blood loss, blood transfusion rate, mean operative time, and length of stay. Postoperative data included pathologic stage, and PSM status. Learning curve was defined as the period prior to achievement of stable perioperative and postoperative outcomes as a function of the number of LRPs completed by contributing surgeons.

Ethics approval was obtained from the Hunter New England Human Research Ethics Committee (14/07/16/5.07).

Analysis was performed using SPSS™ version 9. A Raosoft estimated minimum sample size of 377 patients was required to observe significant predictors of any learning curve at a 95% confidence level. Pearson s Ç2 was used for correlation of bivariate outcome data, with ± set at 0.05.

Results

Prospectively collected data was obtained from nine Australian surgeons who had performed 2943 consecutive LRP cases between 2003 and 2014 with a mean annual case load of 45 patients, with some surgeons active for only a portion of the study period. Their combined F100 cases each (n=900) were compared to their combined S100 cases (n=782), with two of nine surgeons having not completed a total of at least 200 cases.

The mean age and preoperative PSA was similar between the F100 and S100 (Table 1). There was a small though significant trend towards a greater proportion of D'Amico's high risk patients in the S100, and low risk patients in the F100 (Table 1).

Perioperative outcomes improved in S100 with blood transfusions, mean blood loss, mean operating time and length of stay all higher in the F100 compared with the S100 (Table 2). Length of stay was similar between F100 and S100, as was the conversion to open rate. A similar proportion of organ confined disease was present in the F100 and S100 (Table 2).

Although there was a trend towards better overall PSM and pT2 PSM rates between the F100 and S100, there was no significant difference in overall PSM, or PSM rate by pathological stage between F100 and S100 (Table 3).

There was no difference in PSM rates between the F100 and S100, including when pT2, pT3a, pT3b PSM rates were examined separately (Table 3).

When the PSM rate, stratified for pathological stage (Y axis) was charted against surgeons' previous experience with LRP, established by the number of cases they have completed (X axis), there was no trend in PSM rate (Figure 1).

Comment

The challenging learning curve for LRP is well described. [1-3, 7] Studies that compare the learning curve for LRP with that of RALP conclude that competence with RALP is achieved sooner, and that outcomes reach acceptable levels with fewer cases than with LRP [8]. Learning curve length is increasingly relevant as a trend towards active surveillance reduces training case numbers across urological practice.[9] Specific training in LRP is known to abbreviate the learning curve, and surgical simulation may play a role. [1, 4-6, 10]

Robotic-assisted laparoscopic radical prostatectomy (RALP) was first described in 2000, and experienced explosive growth in popularity, accounted for 66% of radical prostatectomies performed in the United States by 2011. [11, 12] The ongoing trend towards RALP is away from both open radical prostatectomy and LRP. [11]

We wished to describe the local learning curve in Australia for fellowship trained LRP surgeons, by examining a subset of a larger Australian laparoscopic radical prostatectomy series.[13]

The perioperative outcomes of blood loss, operative time, transfusion rate and length of stay in the F100, though comparing favourably to international series, continued to improve with experience in the S100 such that blood transfusion rates decreased below one percent, mean operating time reduced below three hours, and mean length of stay reduced below 2.5 days (Table 2). [14]

However, PSM rates were observed to plateau well within 100 cases at levels consistent with recorded benchmarks (Figure 1). [1, 4, 5, 12, 14] The early achievement of satisfactory PSM rates is in contrast with previous reports. [2, 4]

We infer that Fellowship training itself is responsible for abbreviation of the local learning curve below 100 cases, when compared with the previously reported 200 to 1000 cases required to achieve satisfactory results. [2, 5, 6, 14] The implication is that oncologic outcomes from LRP may be taught, and with Fellowship training, acceptable outcomes may be seen early in independent practice, not just after many hundreds of cases.

Because the surgeons in this study used the same techniques and similar equipment to their mentors, abbreviation of the oncologic learning curve is unlikely to be due to incremental improvements in technology or changes in operative technique. [15]

The tendency for experienced surgeons to attempt more difficult cases (Table 1) does not conceal improvements in oncologic outcomes, as subset analysis of PSM rate by pathologic grade and D'Amico risk still does not differentiate between the F100 and S100. Likewise, no individual surgeon had a significant improvement in PSM rate between their F100 and S100. Possible explanations for the non-significant trend towards a higher PSM rate for pT3 tumours in the S100 (Figure 1) include operators taking on higher volume disease, or increasing their use of nerve sparing techniques for higher risk patients.

Strengths of this study include the prospective collection of data, open invitation for contributing surgeons, and stratification by operator, patient and histopathologic factors to identify confounding or concealment of any underlying learning curve. The 1682 patients who made up the F100 and S100 well exceeded the 377 required to demonstrate a significant difference between these two groups (at ± 0.05, 95% confidence level).

The comparison of F100 to S100 was chosen as previously published LRP learning curve estimates meet or exceed 200 cases, and because the paucity of perioperative events such as transfusion and conversion in this study prohibited examination at a finer resolution.[1-3] The comparison of F100 to S100 precluded analysis beyond 200 cases, which precluded observation of further improvement with higher case numbers. Good et al. observed their PSM rate to plateau at 200 cases, at levels that were similar to those of larger series of open radical prostatectomy, LRP and robotic-assisted LRP.[4, 14] However we propose that as our oncologic outcomes were comparable to these series, and stable within 200 cases, further unrecognised improvement beyond this case number is unlikely.[14] In particular, the pT2 PSM of 12.5% in this study compares favourably with international series of 12.4% and 9.6% for LRP and robotic-assisted LRP respectively. [14]

Potency and continence rates are not addressed in this study because not all contributing surgeons had data, though limited results are reported in the descriptive publication of this series.[13]

RALP technique is widely perceived to be easier to master than LRP, with estimates of 30 cases for surgeons unfamiliar with the technique to achieve results equivalent to Fellowship trained robotic-assisted LRP surgeons. [16, 17] Prior LRP experience also assists with transition to RALP. [8, 18] A frequent patient preference for 'robot' surgery based on perception of superiority, may explain the decline in LRP in favour of RALP, especially amongst surgeons who are trained to perform LRP.

However, it is worth noting that in this Australian series, surgical outcomes of Fellowship trained LRP surgeons were comparable to those achieved in RALP series, and were achieved well within 100 cases rather than the hundreds reported previously. [1-3, 14, 17] Further, Fellowship training of LRP surgeons has been demonstrated not to adversely affect the outcomes of training cases. [6]

Despite the popularity of RALP, Australian Fellowship trained LRP surgeons achieve comparable perioperative and oncologic outcomes to their robotic-assisted peers.

Conclusions

Although the significant learning curve for LRP is reported in international literature, there was no significant difference in PSM rate for the F100 compared with the S100 cases of Fellowship trained Australian LRP surgeons.

Perioperative outcomes were acceptable in each surgeon's F100 and further improved with experience in their S100, despite a greater proportion of high D'Amico risk patients.

This suggests the learning curve for LRP can be abbreviated with formal training, that oncologic outcomes can be effectively taught, and that LRP remains a valid minimally invasive surgical treatment for prostate cancer in Australia, even in the early experience of Fellowship trained surgeons.

Compliance with Ethical Standards

Relevant ethical standards were complied with through this research. Ethics approval was granted by the Hunter New England Human Research Ethics Committee (approval 14/07/16/5.07)

Conflict of Interest

The authors declare that they have no conflict of interest.

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Table 1 Patient characteristics

		First 100 (Mean, n=900)	Second 100 (Mean, n=782)	*P*-value
Age (years)		61.1	61.1	0.91
Pre-operative PSA (ng/mL)		7.4	7.8	0.11
D'Amico Risk Classification (%)	Low	26	21	0.02*
	Intermediate	59	59	
	High	15	20	

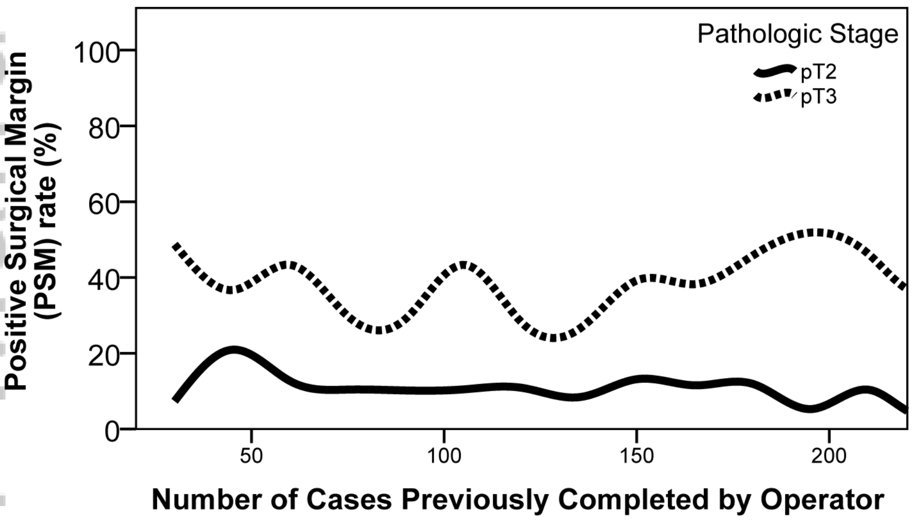
Table 2 Perioperative results

	First 100 (Mean, n=900)	Second 100 (Mean, n=782)	*P*-value
Operative time (min)	193	163	<0.01*
Blood loss (mL)	413	378	0.02*
Blood transfusion (%)	2.4	0.8	<0.01*
Open conversion (%)	0.3	0.7	0.19
Discharge day	2.7	2.4	<0.01*
Organ confined disease (pT2 %)	76	71	0.26

Table 3 Postoperative results – First 100 vs Second 100 Cases

		First 100 (Mean, n=900)	Second 100 (Mean, n=782)	*P*-value
Positive surgical margin rate (%)	All stages †	18.4	17.5	0.62
	pT2	12.2	9.5	0.13
	pT3a	34.8	40.5	0.29
	pT3b	52.9	36.4	0.15

† Excluding pT4 disease



LRP_LC_Fig1_PSM rate by grouped operator experience oncologic learning curve.tif