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ORIGINAL ARTICLE

Robot-assisted laparoscopic prostatectomy: analysis of an experienced open surgeon's learning curve after 300 procedures

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Abstract To critically analyse the learning curve for a single experienced open surgeon converting to robotic surgery. From February 2006 to July 2009, 300 patients underwent a robot-assisted laparoscopic prostatectomy (RALP) by a single urologist. This study is a prospective analysis of the baseline patient and tumour characteristics, intraoperative and postoperative data, and histopathologic features. To analyse the RALP learning curve, the joinpoint regression method was used. Mean age of the patient was 61.3 years (range 46–76). Mean pre-operative PSA level was 7 ng/ml (range 0.7–41), and follow-up was 14 months (0.7–41). The mean operating time was 185 min (range 119–525). One hundred and ten cases were required to achieve 3-h proficiency. There were no conversions. The mean hospital stay was 2.8 days (range 2–7). Major complications rate was 1.3%. The blood transfusion rate was 0.6%. The overall positive surgical margin (PSM) rate was 21.3%. pT2 and pT3 PSM rate was 10 and 44%, respectively. The joinpoint regression method showed that the learning curve started to plateau for the overall PSM rate after 205 cases (95% CI 200–249). For pT2 and pT3, PSM rate, the learning curve tended to flatten after 130 and 170 cases, respectively. The analysis of an experienced open surgeon learning curve in transferring his skills to the robotic platform has shown that 3-h proficiency requires 110 cases. The overall, pT2, and pT3 PSM rate take approximately 200, 130, and 170 cases, respectively, to flatten.

Keywords Laparoscopy · Learning curve · Prostate cancer · Radical prostatectomy · Robot-assisted laparoscopic prostatectomy

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Introduction

For many years, radical prostatectomy has represented a surgical challenge which led to significant morbidity. The organ, placed deep within the male pelvis with a robust vascular supply, challenged even the most experienced surgeons. These technical challenges led to significant surgical morbidity that was potentially life-threatening for the patient. Over subsequent decades the procedure has been refined largely into one that is less harmful to the patient and provides improved quality of life, especially since introduction of the anatomical concept of nerve-sparing radical prostatectomy by Walsh and Donker in 1982 [1]. RRP has been shown to improve survival in patients with prostate cancer [2]. Although there has been significant improvement in the technique and quality of outcomes, it is still associated with a high perioperative morbidity which has led to the search for less invasive options. Although there has been noticeable improvement in the technique and quality of outcomes, it is still associated with a high perioperative morbidity which has led to the search for less invasive options. Moreover, many patients intuitively perceive minimally invasive approaches to reduce complications compared to conventional open operations and prefer them because of smaller incisions requiring less analgesics and shorter hospital stays, even at greater costs [3].

Robot-assisted laparoscopic prostatectomy (RALP) has been slowly incorporated into the mainstream of urologic practice. Nowadays the use of the da Vinci® robot (Intuitive Surgical, Sunnyvale, CA, USA) is growing in an increasing number of institutions in Australia. The shift from open to laparoscopic surgery represented a completely new experience for surgeons. The robotic systems are supposed to reduce the difficulty involved in laparoscopic radical prostatectomy (LRP), not only in the ability to improve functional results without impairment of oncological outcomes but also in terms of shorter learning curves. Factors at risk during this learning curve include safety (complication rate and blood loss), functional outcomes (continence and erectile function), and oncological outcomes (positive surgical margins).

The purpose of this study was to analyse the oncological outcomes during the learning curve for a high-volume open surgeon making transition to RALP.

Patients and methods

Among 693 RALP performed in our institution between February 2006 and July 2009, 300 were performed by a single surgeon (PS). In the first 50 cases of RALP, patients with factors considered to increase surgical difficulty such as morbid obesity, prostate size >100 cc, large middle lobe, prior transurethral resection of prostate (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 subsequent cases as the surgeon became progressively more experienced. All patients followed a standard clinical pathway postoperatively with planned removal of the indwelling catheter on day 6. A cystogram was always performed before the catheter was removed. All major complications and variance from the pathway were prospectively recorded. RALP was performed in the manner described by Patel and co-workers [4] by the same surgeon. All the cases were carried out using the transperitoneal, six-port technique. An anterior approach was taken to the procedure by first isolating and ligating the dorsal venous complex with a 12-in monofilament polyglytone suture on a CT-1 needle, followed by placement of a puboperiurethral retropubic stitch (12-in monofilament polyglytone suture), bladder neck dissection, and mobilization of the seminal vesicles prior to ligation of the prostatic pedicles. When nerve-sparing was indicated, this was performed athermally by early retrograde release of the neurovascular bundles from apex to base via an intra-fascial approach or by an antegrade technique in an incremental fashion. A two-layer Rocco stitch [5] was performed. 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. The specimens were reviewed by a single pathologist in accordance with standard guidelines. Data were collected prospectively with institutional ethics approval (no. H00/088). Clinico-pathological data included preoperative PSA, clinical stage (TNM 2002), Gleason score, pathological stage, surgical margins status, operative time (console time), blood loss, length of hospital stay, and duration of catheterisation. The major complications were reviewed and graded according to the classification system described by Dindo et al. [6].

Statistical analysis

To estimate the number of cases (with 95% confidence interval) 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. Because the rates at the earlier stages were very unstable, because of the small number of cases, the regression was weighted by the inverse of the standard error of the rates. The Monte Carlo permutation method was carried out after fitting each joinpoint to test whether more joinpoints were statistically significant and had to be been added to the model [7]. After each of the joinpoints, the slope of each of the regression line 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 (AAPC) statistic was calculated. This statistic reported the percentage of the rate changes for each additional case performed. Linear fit of the predicted values from the regression model along with the scatter plot of the observed values were presented in the joinpoint regression curves. We undertook the analysis by using the Joinpoint Regression Program version 3.4.0 (Statistical Research and Application Branch, National Cancer Institute, 2009).

Results

The study cohort consisted of 300 RALP. Preoperative, intraoperative, and postoperative data are presented in Table 1. The mean operative time was 185 min (range 119–525). As expected, the operative time decreased with experience (Fig. 1). The learning curve to achieve 3-h proficiency was 110 cases. Indwelling catheter was removed as per protocol on day 6 postoperatively. Variance from the pathway due to anastomotic leaks confirmed by cystogram leading to prolonged catheterization occurred in 4%. Overall major complications rate, as defined by the classification system of Dindo et al. [6] (grades III–V), up to 6 weeks postoperatively, was 1.3% in total and comprised four patients requiring return to theatre, including two patients with bleeding. The first patient was bleeding from a 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 diagnosed as local cellulitis. The last patient had a bowel injury which required repeat laparoscopic repair. None of the four RALP patients required a laparotomy for access. All 300 prostatectomy specimens were reviewed by a single genitourinary pathologist. Pathological data are listed in Table 2. The overall positive surgical margin (PSM) rate for RALP was 21.3%. PSM rates in patients with pT2 and pT3 tumours were 10% (20/200) and 44% (44/100), respectively.

For the purpose of this study, the PSM rates were analysed using the learning curve. In Fig. 2a, the overall PSM rate declined as surgeon experience increased. Using the joinpoint regression analysis, the learning curve for overall PSM started to plateau (gradient not significantly different from 0) around 205 cases (95% CI 200–249). The learning curve for pT2 PSM tended to flatten after 85 (95% CI 58–93) (Fig. 2b). This threshold corresponded to 130 accumulated cases. The learning curve for pT3 PSM tended to flatten after 59 (95% CI 56–61) (Fig. 2c) which corresponded to 170 accumulated RALP cases. The learning curve for pT2 showed a slightly downward trend after 165

Table 1 Preoperative, intraoperative, and postoperative data

No. of patients	300
Age (years)	61.3 (46–76)
PSA (ng/ml)	7 (0.7–41)
Prostate volume (cc)	50.3 (16–140)
Mean operative time (min)	185 (119–525)
Blood transfusion (%)	2 (0.6)
Mean catheter time (days)	6
Mean hospital stay (days)	2.8 (2–7)
Major complications (Dindo et al. classification [6])	
Grade IIIa (%)	0 (0)
Grade IIIb (%)	4 (1.3)
Grade IV (%)	0 (0)
Grade V (%)	0 (0)

Grade IIIa, surgical complication required intervention without general anaesthesia; Grade IIIb, surgical complication required intervention with general anaesthesia; Grade IV, life-threatening complication or intensive care unit management; Grade V, death

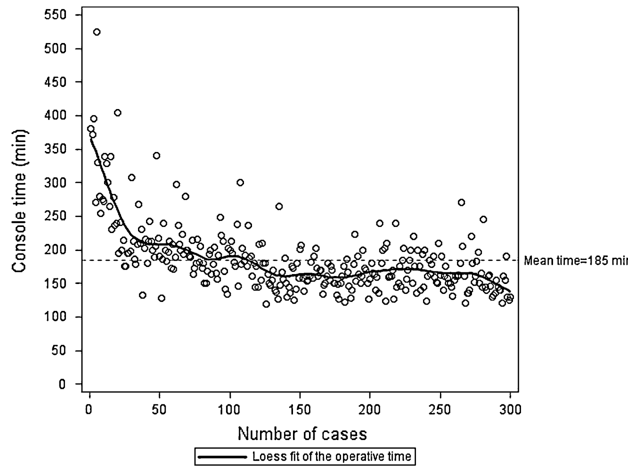

Fig. 1 Operative time during the learning curve (LOESS fit curve)

Table 2 Clinical stages and pathological features

Clinical stage (%)	
T1a	4 (1.3)
T1b	2 (0.6)
T1c	147 (49)
T2a	79 (26.4)
T2b	22 (7.4)
T2c	45 (15)
T3	1 (0.3)
Pathological stage (%)	
p T2	200 (66.6)
p T3	100 (33.3)
Postoperative Gleason scores (%)	
6	62 (20.7)
7	209 (69.7)
8	15 (5)
9	14 (4.6)
10	0 (0)
Mean tumour volume (cc)	1.51 (0.05–6.1)
Positive surgical margins (%)	
p T2	20/200 (10)
p T3	44/100 (44)
Overall	64/300 (21.3)

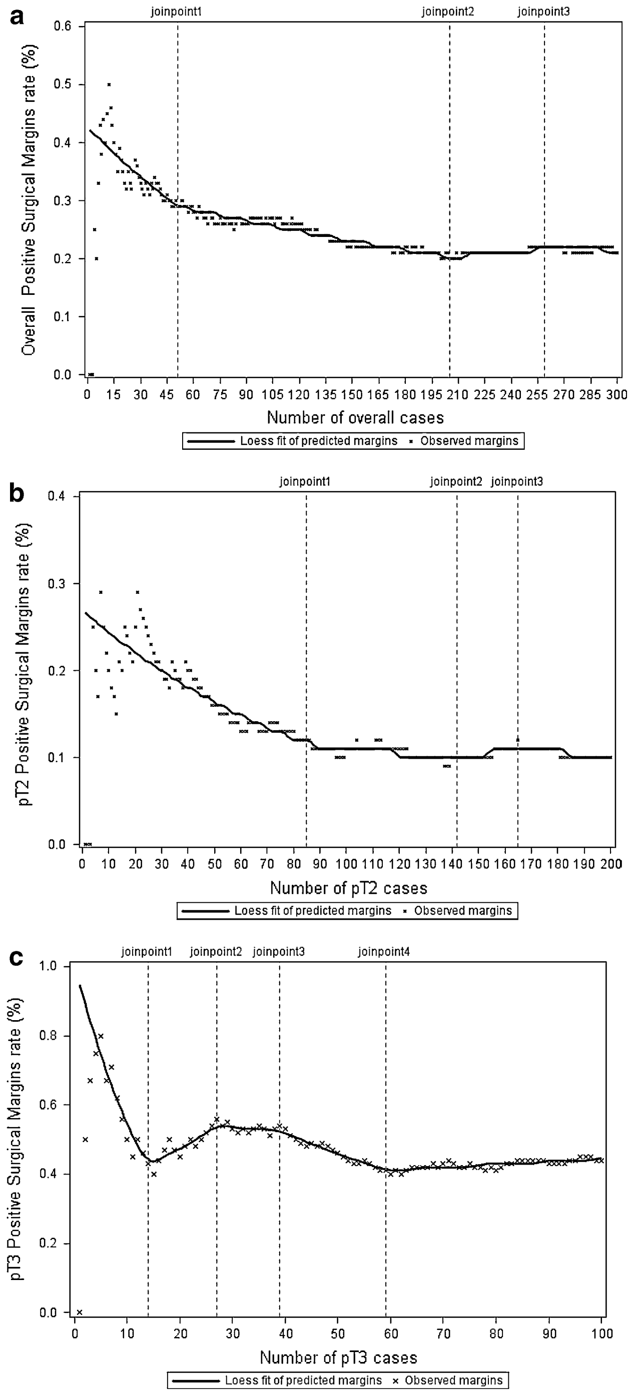

Fig. 2 **a** Overall positive surgical margin rates during the learning curve (joinpoint regression analysis). **b** pT2 Positive surgical margin rates during the learning curve (joinpoint regression analysis). **c** pT3 Positive surgical margin rates during the learning curve (joinpoint regression analysis)

cases (245 accumulated cases) whereas the curve for pT3 had a slightly increasing trend after 60 cases (175 accumulated cases). Because none of pT2 and pT3 curves reached plateau we did not have a sufficient number of cases to determine the number of cases after which the surgeon's efficiency becomes statistically stable.

Discussion

For an experienced open surgeon with a high trifecta rate, the learning curve to acquire proficiency in RALP may be quite prolonged compared with a less expert open surgeon. Despite all the advantages of digitally enhanced laparoscopic images, for example features like magnification and illumination, conventional laparoscopic surgery requires acquisition of new anatomical perspectives, hand-to-eye coordination lacking usual tactile feedback, and three-dimensional vision. All these restrictions contribute to the long learning curve of laparoscopy. The shift from open to laparoscopy surgery represented a completely new experience for surgeons. The robotic system (da Vinci robot, Intuitive Surgical, Sunnyvale, CA, USA) is supposed to reduce the difficulty involved in LRP by improving the precision and accuracy of anatomical dissection with 3D vision, wristed instrumentation with seven degrees of freedom of motion, lack of tremor, and comfortable seated position making it ideal for a technically challenging reconstructive procedure.

Currently, men opting for surgery must choose between open and minimally invasive radical prostatectomy with only limited data demonstrating different outcomes. Among the 12 published studies comparing RRP with RALP, eight were prospective non-randomised studies [8–12] three retrospective studies comparing contemporary series of patients [13–15], and one a retrospective study using historical series as controls [16]. There seems to be no obvious advantage of one study over the other with regard to oncological or functional outcomes, although there is a trend towards a benefit of robotic surgery with regard to length of stay, return to normal activities, and blood loss [17]. None of the studies, however, mentions what end point of the learning curve the surgeon was on.

When looking at the gradual introduction of a new technology, e.g. introducing robot-assisted surgery to an experienced open surgeon, it is important to recognise the effects of adopter bias. In our first 50 cases, we excluded patients who were morbidly obese or had a prostate size >100 cc, 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 multiple difficulties, incorporating these more difficult patient characteristics, were excluded. Tsao et al. reported their experience with a particular focus on patient safety and outcomes. They showed that RALP perioperative data improved throughout the first 100 cases and postoperative outcomes remained "acceptable" [18].

However, the weakness of the study was, first, a small number of patient to assess the real learning curve and, second, the arbitrary cut-points used by the authors (four groups of 25 patients).

In our series, we looked at an experienced, high-volume, open surgeon considering conversion to robot-assisted surgery. We found that for the learning curve to achieve 3-h proficiency 110 cases were needed, approximately 130 cases to plateau for pT2 positive margin status, and 170 cases to plateau for pT3 positive margin rates. If we focus on the oncological outcomes, we intuitively know that the positive margins rate is related to experience [19]. The largest RALP experience to date, consisting of 2,652 patients, was reported by Menon et al. [20]. In their series the median operative time was 148 min, the overall PSM rate was 13%. Patel et al. [4] published a large series of 1,500 cases with an overall positive margin rate of 9.3%.

Vickers et al. looked at the learning curve for RRP and laparoscopic radical prostatectomy (LRP). They first demonstrated that the probability of recurrence after RRP initially dropped steeply then reached a plateau once a surgeon had performed about 250–350 procedures [21]. They then analysed data from 4,702 patients treated laparoscopically. They showed statistically that the probability of recurrence decreased as the experience of the operating surgeon increased. Outcomes seemed to improve more slowly for LRP and surgeons with previous experience of RRP had poorer laparoscopic results [22]. Large series have been developed with emphasis on the learning curve for RALP. Menon et al. [23] initially showed that as surgeons complete the learning curve, operative times decreased substantially, as demonstrated in the community setting [24]. Jaffe et al. evaluated outcomes on a 293 RALP series to define the RALP learning curve. They found there was no gradual decrease in operative times, but some abrupt breakpoints (12 and 189 patients) [25]. These breakpoints divided the series into three groups and PSM were compared in these three groups of patients. However, conclusions about the learning curve were driven by arbitrary cut-points and not by the shape of the learning curve.

Surgeons frequently make statements about the time point at which they were "over he learning curve". This is a self-declared perception of expertise that depends not only on self-perception, but also on the definition of expertise. Highly experienced open surgeons may place a greater demand on themselves before declaring expertise. This can result in artificial prolongation of the learning curve. The strength of our study is the use of a statistical method to analyse this learning curve. To estimate the number of cases after which the change of marginal rate was not significantly different from zero (the learning curve becomes flat), we used the "joinpoint regression method" (http://srab.cancer.gov/joinpoint). This method is capable of detecting break-points in a curve with statistical significance. Thus, we statistically found that the learning curve to achieve 3-h proficiency was 110 cases, 130 cases to flatten for pT2 PSM rate, and 170 cases to flatten for pT3 PSM rate. However, pT2 PSM and pT3 PSM rates did not reach a statistical plateau meaning that the surgeon is still on his learning curve after 300 procedures. Indeed, the trend to propose RALP for higher-volume tumours when the surgeon becomes more and more comfortable during his learning could be an explanation of the slightly upward trend in pT3 PSM rate after 170 procedures. The main limitation of our study is a short follow-up to give meaningful data with regard to biochemical failure rates and functional outcomes.

Conclusion

This statistical analysis of the learning curve of an experienced open surgeon considering conversion to robot-assisted laparoscopic prostatectomy has shown that overall, pT2, and pT3 PSM rate take 205, 130, and 170 cases, respectively, to flatten. However, the length of the learning curve may be dependant upon annual volume of cases, level of mentorship, and individual skill of the surgeon.

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