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The surgical learning curve for laparoscopic compared to open radical prostatectomy: a retrospective cohort study

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Abstract

Background—We previously reported the learning curve for open radical prostatectomy, defined in terms of prostate cancer recurrence. We sought to characterize the learning curve for laparoscopic radical prostatectomy.

Methods—We conducted a retrospective cohort study of 5328 prostate cancer patients treated laparoscopically by one of 29 surgeons from 7 institutions in Europe and North America between 1998 and 2007. Multivariable models were used to evaluate the association between surgeon experience at the time of each patient's operation and prostate cancer recurrence, with adjustment for established predictors.

Findings—After adjusting for casemix, greater surgeon experience was associated with a lower risk of recurrence ($P=0.0053$). The 5-year risk of recurrence decreased from 17% to 16% to 9% for a patient treated by a surgeon with 10, 250 and 750 prior laparoscopic procedures (risk difference 8.0% 95% CI: 4.4%, 12.0%). The learning curve for laparoscopic radical prostatectomy was slower than the previously reported learning curve for open surgery ($p<0.001$). Surgeons with previous experience of open radical prostatectomy had significantly poorer results than those whose first operation was laparoscopic (risk difference 12.3%; 95% CI: 8.8%, 15.7%).

Interpretation—Increasing surgical experience is associated with substantial reductions in cancer recurrence after laparoscopic radical prostatectomy. Improvements in outcome seem to accrue more slowly in comparison with open surgery. Laparoscopic radical prostatectomy appears to involve skills that do not translate well from open experience.

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Introduction

Surgical procedures are often highly complex and it is reasonable to suppose that a surgeon must develop experience with a procedure before being able to perform it optimally. As such, the “learning curve” is a ubiquitous concept amongst surgeons. To date, however, the learning curve literature has focused on technical aspects, such as operating time(1) or blood loss(2). Such endpoints are of less interest to patients than those related to the reason for their operation, such as relief of symptoms, improvement of function, or cure of cancer.

We previously analyzed data from 7765 patients treated with open radical prostatectomy to calculate a learning curve for surgical efficacy, defined in terms of prostate cancer recurrence. The probability of recurrence initially dropped steeply then plateaued once a surgeon had conducted approximately 250 – 350 operations.(3) We subsequently reported that the learning curve for organ-confined cancer approached zero recurrences for the most experienced surgeons (1500 or more operations). This suggests that cancer recurrence in these patients is largely the result of limitations in surgical technique and that the plateau in our original report was driven by disseminated disease in locally advanced cancer.(4)

In this paper, we report the learning curve for laparoscopic radical prostatectomy. This serves as a replication study on an independent (and international) cohort. Moreover, the study allows us to make comparisons between open and laparoscopic learning curves.

Patients and Methods

Study Cohort and Data Sources

We have previously established a multicenter, international retrospective cohort of patients treated by laparoscopic radical prostatectomy, without robotic assistance.(5) Seven participating institutions (Cleveland Clinic Foundation, Institut Mutualiste Montsouris, Memorial Sloan-Kettering Cancer Center, Hospital Universitario La Paz, Klinikum Heilbronn, Lahey Clinic, and Krankenhaus der Elisabethinen) provided recurrence data, for a cohort of 5328 patients who were treated between January 26 1998 and June 13 2007. Patients who received adjuvant (n=7) or neoadjuvant therapy (n = 329), had missing data for the treating surgeon (n = 1) or for clinical covariates (PSA, Gleason grade or stage, n=78) or were not followed for biochemical recurrence (n=211) were excluded, leaving a total of 4702 patients eligible for analysis. All information was obtained with appropriate Ethical Committee or Institutional Review Board waivers, and data were de-identified prior to analysis. As this was a retrospective study of routinely collected clinical data, patient consent was not required.

Eligible patients were treated by one of 29 surgeons. Surgeons who had previously conducted radical prostatectomies, either open or laparoscopic, before their first laparoscopic procedure on the dataset were asked to provide their prior caseload. Only one surgeon reported previous laparoscopic radical prostatectomies on nonstudy patients – a previous laparoscopic experience of 285 operations - and we therefore have the entire laparoscopic experience of all but one surgeon. One notable feature of our cohort is that it includes the very first and all subsequent patients treated by the surgeon who originated the laparoscopic radical prostatectomy (BG).

Outcomes

Patient follow-up was conducted according to accepted clinical practice at each institution. Cancer recurrence was defined independently by each institution as either a rising PSA level > 0.2 ng / ml (four institutions) or > 0.1 ng/ml (three institutions). Although the definitions differed slightly between institutions, they remained constant within each institution, and thus such differences do not affect the recurrence probabilities for an individual surgeon. The definition of recurrence was kept constant for the one surgeon who switched between

institutions. Nonetheless, we planned a sensitivity analysis including only the institutions using the 0.2 ng / ml definition.

Statistical methods

All statistical tests were two sided, with $p < 0.05$ considered to be statistically significant. Surgeon experience was coded as the number of laparoscopic radical prostatectomies performed by the surgeon prior to the index patient's operation. If a surgeon conducted open radical prostatectomy prior to their first laparoscopic patient, this was recorded, but open procedures were not counted towards laparoscopic surgical experience. Associations between patient characteristics and surgeon experience were tested using linear regression (age, PSA, and year of treatment), logistic regression (stage) or ordinal logistic regression (Gleason score), clustering by surgeon. To evaluate the association between a surgeon's laparoscopic experience and recurrence after radical prostatectomy, we created a multivariable, parametric survival-time regression model using a log-logistic distribution to model hazard over time. We examined various parameterizations of the hazard function. All had approximately similar performance in terms of log likelihood that was far superior to a Cox model; we used the log-logistic for consistency with our prior paper on the open learning curve(3). Surgeon experience was entered as a continuous variable, using restricted cubic splines with knots at the tertiles to allow a non-linear relationship between experience and recurrence. We adjusted for casemix by including the following covariates in our model: preoperative PSA, pathologic stage (presence or absence of three separate variables: extracapsular extension, seminal vesicle invasion, and lymph node involvement), and pathologic Gleason grade.

Our previous analysis of the learning curve for open radical prostatectomy included year of treatment as a covariate(3). We did not include year in these analyses for two reasons. First, we did not expect and saw no evidence of stage migration in this contemporary cohort (1998 – 2007): there was no appreciable association between year and pathologic stage ($p = 0.89$); PSA decreased ($p = 0.0070$) over time, but only by a small amount (0.33 ng / ml / year) and there was a slight increase in Gleason score near the end of our series, possibly due to greater use of active surveillance for patients with low grade disease. Second, year was highly associated with both generation of surgeon (see below) and whether the surgeon had conducted previous open radical prostatectomies ($p < 0.001$ for both), and it was thought that both of these might affect the learning curve.

Within-surgeon clustering was incorporated into our analyses using a generalized estimating equations approach(6) by specifying the cluster option in Stata 10.0 (Stata Corp., College Station, TX). There was no clustering by institution as there is no plausible mechanism how institution could affect the learning curve, given that, with one exception, surgeons practiced at only a single institution. To produce a learning curve, we calculated the five-year recurrence-free probability predicted by the model for each level of surgical experience, using the mean value for covariates.

In order to compare the learning curve of laparoscopic radical prostatectomy to our previously published learning curve for open radical prostatectomy, we fit two separate multivariable models adjusting for stage, grade and PSA. In order to account for stage migration, we restricted the open cohort to patients seen after 1995, a subgroup defined in our previous papers in which we saw no association between time and tumor characteristics. To obtain a learning curve, we calculated the predicted probability of recurrence before five years for a patient with covariates at the mean of the laparoscopic cohort.

We also investigated whether results differed between the surgeons who initially developed laparoscopic radical prostatectomy (“first generation”) and those who were able to learn the technique from another surgeon (“second generation”). We defined as “first generation” those

surgeons who performed their first laparoscopic radical prostatectomies before January 2001 (three years after the procedure was first performed), had performed at least 100 procedures before the end of this study (July 2007) and were either the first or second surgeon at their institution to conduct a laparoscopic radical prostatectomy.

Role of the funding source

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Results

Patients and surgeons

The distribution of surgeons by the total number of lifetime operations is shown in Table 1. Although many of the surgeons performed fewer than 50 laparoscopic radical prostatectomies (the fewest number performed was 2), approximately half had performed more than 100 procedures, with a maximum experience of 1066 procedures. Clinical and pathologic information of patients is shown in Table 2, stratified by surgeon experience. Thirty percent of patients (1404/4702) were seen by a surgeon who had performed fewer than 100 prior procedures, while half (50%, 2352/4702) were seen by a surgeon with more than 250 prior procedures. There was no association between surgeon experience and either PSA, Gleason score, extra capsular extension, lymph node involvement or seminal vesicle invasion. There was a small but statistically significant difference in age, with more experienced surgeons seeing very slightly younger patients. The predictive accuracy of the model was fair (concordance index of 0.68), suggesting that our model provides a reasonable control for casemix, especially given the lack of any difference in tumor characteristics by surgeon experience.

There were 402 biochemical recurrences, with a five-year recurrence-free probability of 82% (95% CI: 80%–84%). Although median followup for patients without recurrence was short, 1.7 years, this is largely a function of increasing surgical volumes over time, with many operations conducted in recent years: 1183 and 470 patients were recurrence-free at follow-ups of 3 and 5 years respectively.

Association between experience and outcome

Initial descriptive analysis suggested that patients who were treated by surgeons with more experience had a lower probability of recurrence than patients who were treated by surgeons with less experience (Table 2 and Figure 1). In the model adjusted for casemix, greater surgeon experience was associated with a lower probability of recurrence ($P=0.0053$). The risk of recurrence at five years decreased from 17% (95% CI: 11%, 24%) to 16% (95% CI: 10%, 23%) to 9% (95% CI: 5%, 14%) for a patient treated by a surgeon with 10, 250 and 750 prior laparoscopic procedures, respectively (risk difference between 10 and 750 procedures of 8.0%; 95% CI: 4.4%, 12.0%).

Figure 2 shows the results of the adjusted analysis. There is a relatively smooth improvement in cancer outcome with increasing experience. In comparison, Figure 3 shows the learning curve reported previously for open radical prostatectomy: this increases rapidly and then reaches a plateau. The vertical difference between the two lines, that is, which technique leads to lower recurrence probabilities at any particular level of experience, depends on appropriate adjustment for both casemix and for the slight difference in recurrence definitions; furthermore,

the right hand tails of the learning curves are based on limited numbers of surgeons. As such, the two learning curves cannot easily be compared with respect to which leads to better results. Nonetheless, the shape of each curve remains constant irrespective of adjustment between groups. Using a permutation test (see appendix), the difference between the shape of the two learning curves was highly significant ($p < 0.001$). Accordingly, it is reasonable to conclude that laparoscopic radical prostatectomy is associated with a slower learning curve.

Modifiers of the learning curve

In a multivariable model adjusting for casemix and surgical experience, prior open experience ($p = 0.014$), but not generation ($p = 0.13$), was found to be associated with recurrence. Surgeons who conducted open radical prostatectomy before their first laparoscopic procedure had poorer outcomes: for a typical patient treated by a surgeon with 100 prior patients, the absolute risk of recurrence at five years increased from 7.8% to 20.1%, an absolute risk difference 12.3% (95% CI: 8.8%, 15.7%), if the surgeon had conducted a prior open radical prostatectomy. This effect does not appear to be a result of casemix as patients seen by surgeons with prior open experience had similar (indeed, slightly more favorable) tumor characteristics. Nor does it result from the strong overlap between generation and prior experience: results are similar if the analysis is restricted only to second generation surgeons ($p < 0.001$; risk difference for 100 prior surgeries: 13.8%; 95% C.I.: 5.6%, 25.4%).

In order to address whether changes in the laparoscopic learning curve were due to profession-wide changes in technique, we included the starting year of each surgeon's career in the model; it was not an independent predictor of recurrence ($p = 0.20$).

Sensitivity analysis

It is plausible that the apparent learning curve resulted from better technique of surgeons who conducted a large number of procedures, compared to surgeons who did not reach a high level of experience in this data set. To address this point, we restricted analysis to the five surgeons who conducted at least 250 surgeries. We observed a learning curve in these surgeons ($p < 0.001$) that was similar in shape to the overall learning curve. The change in outcome with experience was greater than for the group as a whole (risk difference 10 vs. 750 prior surgeries of 18.6%; 95% C.I. 13.1%, 24.9%) likely because four of the five most experienced laparoscopic surgeons had previously conducted open surgery, with consequently poorer outcome.

When year of treatment was added to the model as a sensitivity analysis, it was itself non-significant ($p = 0.12$), but led to surgeon experience losing statistical significance ($p = 0.58$); when we then added whether surgeons had performed prior open radical prostatectomy, which is correlated with year and a strong predictor of outcome, cumulative experience ($p = 0.0061$) but not year ($p = 0.29$) was a predictor of outcome. This suggests that our findings are not due to unmeasured temporal changes in tumor characteristics.

Prior open experience was added as a covariate in subsequent sensitivity analyses due to its strong association with recurrence. To account for unmeasured differences in casemix, we restricted the analysis to patients who were at low risk of recurrence (defined as those with organ-confined cancer, Gleason grade 6 or lower, and a PSA level lower than 10 ng/mL), as clinically meaningful differences in prognosis are unlikely in this homogenous group. Although this was an underpowered analysis (only 59 events), and the p value for experience missed statistical significance ($p = 0.075$), results from this low risk subgroup were comparable to our main analysis, with greater experience associated with lower probability of recurrence (risk of recurrence with 10, 250 or 750 prior procedures of 11.7%, 7.5% and 2.9%, respectively).

We saw no difference when restricting the analysis to the four institutions who used a rising PSA > 0.2ng/ml as to the definition for BCR definition. The risk of recurrence at five years decreased from 16.0% to 15.5% to 8.2% for a patient treated by a surgeon with 10, 250 and 750 prior laparoscopic procedures, respectively ($p<0.001$). Our results were similarly unaffected if we excluded the single surgeon who moved between institutions; five year recurrence probabilities decreased from 16.3% to 11.0% to 7.1% for a patient treated by a surgeon with 10, 250 and 750 prior laparoscopic procedures, respectively ($p=0.038$).

Discussion

The probability of recurrence after laparoscopic radical prostatectomy decreases with increasing experience of the operating surgeon. As well as replicating the radical prostatectomy learning curve on an independent data set, our data allows us to compare learning curves between open and laparoscopic approaches. Outcome appears to improve more slowly for laparoscopic than for open surgery. There are several possible explanations for this observation.

First, laparoscopic radical prostatectomy may be inherently more difficult to learn. Laparoscopy requires learning how to operate in a two-dimensional space without a direct view of the surgical field, with longer instruments and diminished haptic feedback. Second, the laparoscopic learning curve may reflect, in addition to the increasing experience of the individual surgeon, profession-wide modifications to the technique. Open radical prostatectomy is a relatively mature procedure.(7,8) In contrast, laparoscopy is a much more recently developed surgical technique(9); indeed, our data set includes the very first patient on whom a laparoscopic radical prostatectomy was performed. That said, we did not see any evidence of temporal changes in our laparoscopic learning curve.

Several other possible explanations for the difference in learning curves appear unlikely. It seems implausible that slower learning is a function of the institutions at which laparoscopy is performed, especially given that the laparoscopic learning curve was slower than that for open surgery when comparing only institutions contributing to both data sets (data not shown). It also seems unlikely that differential learning curves could result from unmeasured confounding. In a longitudinal study such as this, the unmeasured confounders would need to vary systematically over the course of each individual surgeon's career, and to explain the differences in the open and laparoscopic learning curves, such unmeasured confounding would have to differ between the respective cohorts. In addition, it is difficult to think of confounders that have a substantive impact on biochemical recurrence after radical prostatectomy, let alone those that might explain the ~50% relative risk reduction that we report here, or our previously reported ~15% absolute risk difference in organ-confined disease.(4)

We also report that prior open experience leads to poorer outcomes. One possible explanation is that it takes time to understand that the pelvic anatomy differs subtly between open and laparoscopic procedures. Surgeons may inappropriately adapt what is observed through the laparoscope to a mental representation based on their open experience. Other possible, though less plausible, explanations include that surgeons with prior open experience have a greater emphasis on functional outcomes, or that any small differences in the age of these surgeons would affect learning. If replicated, our findings may have important implications for surgical practice, suggesting that surgeons should not switch between open and laparoscopic procedures without a compelling reason.

Our results cannot be used directly to compare the value of open and laparoscopic radical prostatectomy. This is due to the different definitions of recurrence in each data set and the limited power to compare results higher up the learning curve due to the moderate number of patients receiving treatment from the most experienced surgeons. Moreover, we have no

comparative data on functional outcomes. Our results should also not be taken as suggesting that experience is deterministic of outcome: it seems plausible that two surgeons with similar levels of experience and treating similar patients might have different results due to variations in surgical technique.

Our data may be taken to suggest that there is little learning before 250 procedures. However, the confidence interval around the learning curve is relatively wide, and is thus consistent with various different shaped curves, including faster initial learning. We can be confident that there is a learning curve for laparoscopic radical prostatectomy, and that this is slower than for open surgery; the precise shape of the learning curve is less certain.

Surgical learning curves, especially those indicating that a high level of experience is required before good results are achieved, have obvious implications for clinical practice: the only way to minimize the number of surgeons on the early part of the learning curve is to restrict the number of surgeons who conduct a particular operation, a policy generally known as “regionalization”.(10,11) Nonetheless, even with regionalization, new surgeons will need to start operating until they develop sufficient surgical experience. Accordingly, the surgical community should consider educational interventions to shorten the learning curve. This would likely require a shift from theoretical, classroom-based, continuing medical education to more practical training, based in laboratories or operating rooms. Structured training including surgical simulation has already been described for laparoscopic radical prostatectomy, and consideration should be given as to whether such programs should be made more widely available(12). There is also a clear need for empirical research to determine what aspects of surgical technique improve with experience and to investigate whether these might be taught to surgeons at an early stage of their careers. It would also be critical to determine whether robotic-assisted laparoscopic radical prostatectomy accelerates the learning curve.

In sum, we have replicated, using an independent, international cohort, our finding that a patients’ probability of recurrence after radical prostatectomy is strongly influenced by the experience of his surgeon. The size of the learning curve effect is similar between the laparoscopic and open cohorts and is of clear clinical relevance, an absolute risk difference of approximately 10% for biochemical recurrence at 5 years between the most and least experienced surgeons. We have shown, furthermore, that outcomes seem to improve more slowly for laparoscopic radical prostatectomy, and that having prior open experience leads to poorer laparoscopic results. Clinical, educational and research initiatives are required in order to moderate the negative effects of the learning curve on clinical care.

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Appendix

A permutation test was used to compare the open and laparoscopic learning curves, as follows:

1. Denote as y_{ij} the probability of an event for a given level of experience i ($i=0, 1, \dots, n$) and approach j ($j=0, 1$). For our analysis, $n=1000$ as this was the highest level of experience for surgeons using the laparoscopic approach; $j=0$ for the laparoscopic approach and $j=1$ for the open approach (although identical results are obtained if

these values were reversed); the event was recurrence within 5-years; probability was calculated using a multivariable model as described in the main body of the text.

2. A measure of the difference in the shape of the learning curves between approaches can be constructed by comparing the slopes of the learning curves over various levels of experience using bins of size b . The observed test statistic is given by:

$$t_{obs} = \sum_{i=1}^{n/b} |(y_{bi,1} - y_{bi-b,1}) - (y_{bi,0} - y_{bi-b,0})|$$

That is, for each approach separately we calculate the change in adjusted 5-year predicted probability of recurrence between one level of experience and another b units higher, take the absolute value of the difference between approaches, and sum over all units 0 to b , b to $2b$, $2b$ to $3b$... $n-b$ to n . Note that n should be adjusted so that it is divisible by b . For our analysis, $b=10$, although b can be as small or large as the data set permits; smaller values of b are preferred but are more computationally intensive.

3. By randomly permuting j , the indicator for surgical approach, we obtain a test statistic t^* under the null hypothesis that the learning curves are equivalent.
4. We repeat step 3 a total of R times. For our analysis, $R=5000$.
5. The p-value is given by the proportion of t^* that equals or exceeds t_{obs}

$$p = \frac{\sum_{r=1}^R t_r^* \geq t_{obs}}{R}$$

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Number at risk					
250+	2352	912	281	5	0
100-249	946	416	203	118	0
50-99	611	279	111	56	1
<50	793	424	174	81	16

Figure 1.
Kaplan Meier Curve.

Figure 2. Learning curve for recurrence after laparoscopic radical prostatectomy. Probabilities are for a patient with typical cancer severity. Dashed lines represent 95% confidence intervals.

Figure 3. Learning curve for recurrence after open radical prostatectomy. Probabilities are for a patient with typical cancer severity and is restricted to those treated after 1995. Dashed lines represent 95% confidence intervals.

Table 1

Distribution of lifetime number of laparoscopic and open radical prostatectomies performed by surgeons

Total lifetime number of laparoscopic procedures performed	Number of surgeons (%)
< 50	12 (41%)
50–99	2 (7%)
100–249	10 (34%)
≥ 250	5 (17%)
Total	29
Number of open procedures before first laparoscopic procedure	Number of surgeons (%)
0	13 (45%)
1 – 10	3 (10%)
11 – 99	5 (17%)
100 – 249	5 (17%)
≥ 250	3 (10%)
Total	29

Table 2

Characteristics by surgeon experience

	Surgeon experience (no. of procedures before the incident procedure)				P*
	< 50	50–99	100–249	250–1100	
Number of patients	793	611	946	2352	
Patients followed and event free at:					
3 years	238	242	278	500	
5 years	103	87	158	122	
Patient or tumor characteristic					
Median preoperative PSA level, ng/mL (IQR)	6.9 (5.0, 10.0)	6.8 (5.0, 9.8)	7 (5.1, 10.3)	5.9 (4.3, 8.5)	0.11
Median age, yr (IQR)	64 (59, 68)	64 (59, 68)	63 (58, 68)	61 (56, 66)	0.036
Number of operations performed by time period (%)					0.005
1998–2002	283 (36%)	204 (33%)	351 (37%)	369 (16%)	
2003	126 (16%)	76 (12%)	121 (13%)	426 (18%)	
2004	145 (18%)	91 (15%)	173 (18%)	517 (22%)	
2005	197 (25%)	150 (25%)	122 (13%)	543 (23%)	
2006–2007	42 (5%)	90 (15%)	179 (19%)	497 (21%)	
Gleason grade, no. (%)					0.39
≤6	365 (46%)	255 (42%)	439 (46%)	1024 (44%)	
7	375 (47%)	311 (51%)	423 (45%)	1180 (50%)	
≥8	53 (7%)	45 (7%)	84 (9%)	148 (6%)	
Extracapsular extension	243 (31%)	198 (32%)	296 (31%)	593 (25%)	0.34
Seminal vesicle invasion	61 (8%)	58 (9%)	95 (10%)	174 (7%)	0.73
Lymph node involvement (n=number of patients with lymph nodes removed)	9 (1%) (n=337)	16 (3%) (n=302)	19 (2%) (n=411)	37 (2%) (n=1188)	0.47
Non-organ confined cancer [‡]	247 (31%)	205 (34%)	304 (32%)	612 (26%)	0.31
Unadjusted Outcomes					
Five-year recurrence-free probability (95% CI)	79% (74%, 83%)	78% (71%, 83%)	80% (76%, 84%)	87% (84%, 90%)	
Positive surgical margin	193 (24%)	141 (23%)	220 (23%)	456 (19%)	

* Linear, logistic or ordinal regression with number of prior procedures included as a continuous variable

[‡] Extracapsular extension, seminal vesicle invasion or lymph node involvement