Characterization of a learning curve for robotic cystectomy with intracorporeal urinary diversion at two institutions using the cumulative sum (CUSUM) method

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Introduction: *Robotic cystectomy with intracorporeal urinary diversion (RCID) is a technically challenging procedure. It is understood that this approach has a learning curve; however, limited studies have characterized this learning curve. The cumulative sum (CUSUM) method plots the learning curve. The aim of this study was to use the CUSUM approach to investigate the number of cases required to reach a consistent, desired performance level for RCID.*

Materials and methods: *Retrospective study of the first 27 and 28 RCID cases performed by two new fellowship trained faculty at two separate institutions from November 2014 to January 2018. Total operating time was calculated and the CUSUM method was used to describe the learning curve, the number of cases needed for a consistent performance level.*

Results: *Twenty-seven and 28 patients were reviewed from two institutions (A and B), with 8 and 7 females, 19 and 21 males and an average age of 66.7 and 67.6 years, respectively. Twelve and ten cases, respectively, had final pathology of stage T3 bladder cancer or higher. The CUSUM curve demonstrated a learning curve of 10 and 11 cases, respectively, when the curve transitioned from steady improvement in OR times (upward slope of curve) to a relative steady state of OR times (plateau of curve). The average lymph node yield, rate of ureteral stricture, and positive margins were also examined with no learning curve noted.*

Conclusion: *In RCID, approximately 10 cases were required by robotically trained new faculty to reach a steady-state level of performance.*

Key Words: cystectomy, urinary diversion, learning curve, bladder cancer, robotic surgery

Introduction

Open radical cystectomy with bilateral pelvic lymphadenectomy and urinary diversion has long been accepted as standard management for patients with invasive and high-risk bladder cancer. This procedure is associated with significant morbidity and mortality despite improvements in oncological outcomes.[1] A laparoscopic approach to radical cystectomy was first described in 1992 but was fraught with technical difficulties and never fully adopted.[2] The introduction of robot-assisted laparoscopic surgery has provided a viable alternative to open cystectomy.

It is widely understood that robot assisted radical cystectomy with intracorporeal urinary diversion (RCID) has an inherent learning curve; however, limited studies have characterized this learning curve well.[3] Robotic surgery necessitates unique skills such as reliance on visual cues to determine tension, learning to manipulate tissue without tactile feedback, and understanding spatial relationship of robotic instruments to maximize range of motion and minimize external clash of robotic arms.[4] Understanding the learning process associated with mastering this

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surgery can reduce frustration and provide realistic expectations. With the advent of minimally invasive surgery, the cumulative sum (CUSUM) method was adopted by the medical profession in the 1970s to analyze surgical procedures.[5] The CUSUM method is a trend curve analysis, which plots motor learning and evolution through training and allows characterization of the length of the learning curve. Rather than setting a predetermined number of procedures or direct observations by a tutor, a learning curve allows for individualized and quantitative monitoring of performance throughout the learning process.

Studies comparing open and robotic approaches to cystectomy for bladder cancer report that while there is no significant difference in overall complication rate between open and robotic cystectomies, the robotic approach has several perioperative advantages such as decreased time to flatus and bowel movement, and decreased inpatient morphine use.[6] Furthermore, they found no compromise in oncologic outcomes such as lymph node yield and margin status.[7] Studies in the literature report mean operative time for robot assisted radical cystectomies ranging from 5.67 hours to 10.67 hours.[8-11] Given these operative times, we hypothesized that it would take 10 cases before a fellowship trained urologist can perform a RCID at a level of proficiency defined as a total operative time of 8 hours or less.

Materials and methods

We performed a retrospective study of the first 27 and 28 RCID and bilateral pelvic lymph node dissection performed by two fellowship trained surgeons from November 2014 to January 2018. Patients who underwent open radical cystectomy or robotic-assisted radical cystectomy with open urinary diversion were excluded. IRB approvals were obtained for these retrospective reviews at the University of Maryland Medical Center and Robert Wood Johnson University Hospital. Total operative time, defined as time from incision to closing, was calculated and proficient performance defined as 8 hours or less, based on mean operative times from available literature. The primary aim was to compare the two surgeons using the CUSUM method to determine the number of cases required to reach a plateau level of proficiency. The CUSUM method plots each successive case in which the surgeon takes longer than the target time (reflected by upward deviation of the line) or takes less than the target (reflected by downward deviation of the line). Each consecutive surgery was plotted and the learning phase was identified by the inflection point from constant upward deviation (underperformance due to long operative time) to a flattened or downward deviation of the curve.

As a secondary aim, we examined if a learning curve exists for lymph node yield, which has been suggested as a surrogate for quality of surgical resection.[12] While the extent of lymph node dissection is a powerful prognostic factor for oncologic outcome, the optimal boundaries of the dissection and minimal lymph node yield continues to be an area of controversy. On average, the standard pelvic lymph node dissection yields 8-14 nodes and an extended dissection, which entails harvesting up to the bifurcation of the external iliac, yields 25-45 nodes.[13,14] Data from the SEER program report that despite variabilities in patient population, surgical technique, and protocols for pathology evaluation, a minimum of 10 to 14 nodes was shown to have survival benefits.[12] The mean lymph node yield in studies on robotic cystectomies performed at University of North Carolina and Roswell Park Cancer Institute were 19 and 21, respectively.[6,9]

We further compared patients in two distinct subgroups with the first subgroup consisting of the learning phases cases, which were performed before plateauing of the operative time, and the second consisting of cases once the operative time of 8 hours was reached consistently. We compared variables such as margin positivity, lymph node yield, and hospital length of stay for surgical quality. The average operative times from different patient groups are expressed as the mean ± SD. Statistical comparisons were made using Student's t test. A two-sided $p < 0.05$ was considered statistically significant.

Results

From institution A, a total of 27 RCID and bilateral pelvic lymph node dissection were reviewed in 8 females and 19 males. The mean age of the cohort was 66.7 years (range 59-81). The average age in the first 10 cases was 66.2 years and 67.1 years in the subsequent 17 cases. Advanced disease, defined as pT3 or higher disease, was identified in 12 patients. In the first 10 cases, 3 (30%) patients had advanced disease while 9 (53%) patients had advanced disease in the following 17 cases. The cohort from institution B consisted of 28 RCID and bilateral pelvic lymph node dissection, 21 male and 7 female patients. The average age was 65 years in the first 11 cases and 69.2 years in the subsequent 17 cases. The mean age of patients was 67.6 years (range 56-87). Ten patients had advanced disease of which 4 (36%) were in the first 11 cases and 6 (35%) were in the subsequent 17 cases. There was no significant difference between

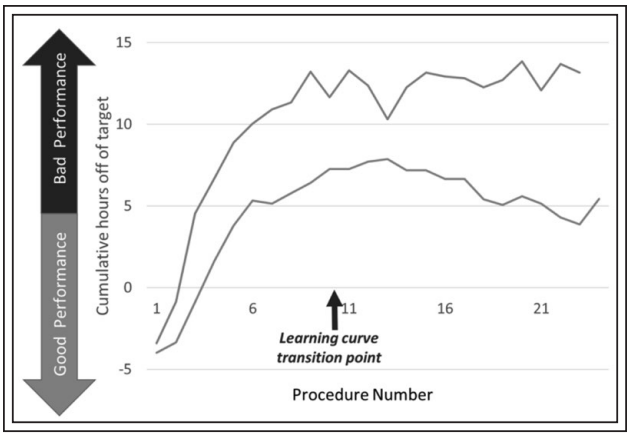

Figure 1. Learning curve for robotic cystectomy with intracorporeal diversion. A transition point was identified around 10 cases at which point the target total OR time was reached consistent. Subsequent cases were performed either at the target 8 hours or less, as demonstrated by flattening and downward trending curves.

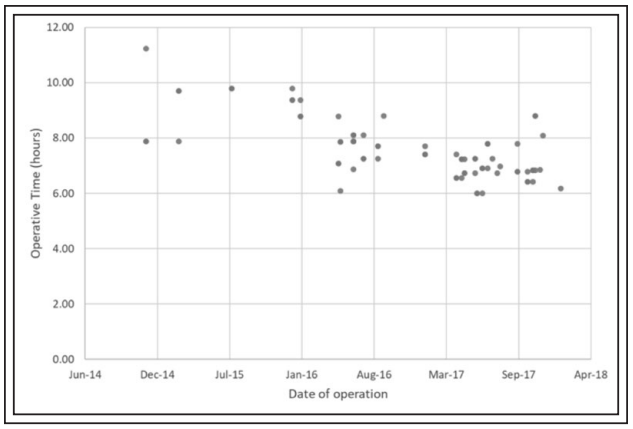

Figure 2. Operative times over time. A scatter plot of operative times over time demonstrate steady decrease in overall operative time as well as variability in operative times.

institutions in rate of neoadjuvant chemotherapy given or body mass index (BMI), Table 1.

The mean total operative time for the cases from institution A was 8.7 hours (range 5.9 to 13.4 hours). The mean operative time was 8.58 hours in men and 9 hours in females (p = 0.85). Baseline characteristics for the two institutional cohorts are listed in Table 1. The CUSUM curve demonstrated a learning curve of 10 cases, Figure 1. As seen in Figure 1, the curve transitioned from consistent OR time of over 8 hours (upward slope of curve in cases 1-10) to a relative steady state of OR times around 8 hours (plateau of curve after case 10). Figure 2 similarly demonstrates a steady improvement of operative times over time. There was a statistically significant difference in operative time observed between the learning phase and the plateau phase, 9.83 hours versus 8.03 hours, respectively, Table 2. For institution B, the mean total operative time was 7.5 hours, (range 6.1 to 11.2 hours), Table 2. The mean OR time in men was 7.32 and women was 8.13 (p = 0.28). The CUSUM curve exhibited that after 11 cases, a consistent OR time of 8 hours or less was achieved. Again, a statistically significant difference between learning and plateau phases was observed, with mean operative times of 8.37 hours and 6.97 hours, respectively, Table 2.

TABLE 1. **Patient characteristics**

	Institution A (27 total)	**Institution B (28 total)**	**p value**
Sex			0.7
Male (%)	19 (70.4%)	21 (75%)	
Female (%)	8 (29.6%)	7 (25%)	
Age			0.2
50-59	2 (7.4%)	6 (21.4%)	
60-69	14 (51.8%)	10 (35.7%)	
70-75	10 (37%)	8 (28.6%)	
Over 75	1 (3.7%)	4 (14%)	
Mean age (SD)	66.7 (6.59)	67.6 (8.69)	
Median age (range)	65 (59-81)	66 (56-87)	
Neoadjuvant chemo (%)	21 (75%)	18 (67%)	0.5
Body mass index (SD)	27.6 (4.5)	27.5 (3.6)	0.9

TABLE 2. **Perioperative variables stratified by performance phase**

	Learning phase	**Plateau phase**	**p value**
Operative time (hrs)			
Institution A mean	9.83	8.03	0.01
Institution B mean	8.37	6.97	0.01
Length of stay (days)			
Institution A mean	10.2	7.64	0.3
Institution B mean	7	5.35	0.3
Lymph nodes (number)			
Institution A mean	22.8	24	0.3
Institution B mean	18.3	21	0.5
Neoadjuvant chemo given			
Institution A percent	50%	76%	0.2
Institution B percent	90%	67%	0.2
Body mass index			
Institution A mean	27.0	27.9	0.6
Institution B mean	28.4	27.1	0.5

TABLE 3. **Pathology characteristics**

Pathology characteristics	**Institution A**	**Institution B**	**p value**
TNM classification			0.1
Stage 0/is			
pT0	2 (7.4%)	9 (32.1%)	
pTis	7 (25.9%)	7 (25%)	
Stage I			
pT1	2 (7.4%)		
Stage II			
pT2a	4 (14.8%)	1 (3.6%)	
pT2b		1 (3.6%)	
Stage III			
pT3a	9 (33.3%)	9 (32.1%)	
pT3b		1 (3.6%)	
Stage IV			
pT4a	3 (11.1%)		
pT4b			
pN stage (%)			0.3
N0	19 (70%)	23 (82.1%)	
N+	8 (30%)	5 (17.9%)	
Lymph node yield			0.7
≤ 10	5 (18.5%)	4 (14.3%)	
> 10	22 (81.5%)	24 (85.7%)	
Lymph node yield mean (SD)	23.6 (16.4)	19.9 (10.4)	0.4
Lymph node yield median (range)	19 (17-67)	18 (2-45)	
Positive margins (%)	3 (11%)	0	0.1

There was no significant difference in BMI or rate of neoadjuvant chemotherapy between the learning and plateau phase in both institutions. In RCID, the desired level of performance, as demonstrated by plateauing of the learning curve, was reached by 10 cases and 11 cases at institutions A and B, respectively.

For institution A, 12 cases had final pathology of stage T3 bladder cancer or higher versus 15 cases of stage T2 or lower with mean operative times of 8.58 versus 8.80 hours, respectively ($p = 0.37$). Pathology characteristics are listed in Table 3. A total of 3 patients (11%) had positive margins, and each of these patients had pT3a or higher disease on final pathology. The mean nodal yield was 23.6 nodes, with an average yield of 22.8 nodes in the first 10 cases and 24 nodes in the next 17 cases ($p = 0.3$). At institution B, the mean operative times were 7.26 and 7.98 hours for the 18 cases of stage T2 or lower disease and 10 cases of stage T3 or higher disease respectively. None of the patients from this cohort had positive margins. The mean lymph node yield was 19.9 nodes, with an average yield of 18.3 in the first 11 cases and 21 in the following 17 cases ($p = 0.5$). No learning curve was appreciated for the lymph node yield or margin status in either cohort.

The mean hospital length of stay (LOS) was 8.59 days for institution A with a maximum stay of 35 days due to bowel obstruction requiring lysis of adhesions, and a minimum stay of 5 days. LOS decreased from an average of 10.2 days in the first 10 cases to 7.64 days in the following 17 cases ($p = 0.3$). The mean hospital stay at institution B was 6 days, ranging from 4 days to 21 days. LOS decreased from an average of 7 days in the first 11 cases to 5.35 days in the subsequent 17 cases ($p = 0.3$).

Discussion

Robot assisted radical cystectomy is a technically challenging case with high morbidity. As more surgeons are performing robotic cystectomies, it is important to describe the learning curve for this advanced procedure so clear expectations are available to surgeons, as well as institutions, departments, and patients. The CUSUM learning curve has been widely used for robotic-assisted laparoscopic colorectal surgery, hysterectomies, endoscopic retrograde pancreatography, stereotaxic core needle breast biopsy, and thyroidectomy.[15] In urology, learning curves have been devised to study operative time and surgical outcomes for pediatric robotic-assisted laparoscopic pyeloplasty, robotic-assisted laparoscopic prostatectomy, and laparoscopic nephrectomy.[16] Ahlering et al reported that 12 robotic prostatectomies were required before a surgeon could reach a 4 hour proficiency and Atug et al reported 30 cases before noting a decrease in the rate of positive surgical margins.[1,17]

Multiple reports on the surgical outcomes of robotic-assisted laparoscopic radical cystectomy (RARC) have been published, but to our knowledge none have used the CUSUM methodology to analyze the learning curve.[3] The International Robotic Cystectomy Consortium evaluated 496 patients who underwent RARC performed by 21 surgeons at 14 institutions.[18] They used a logistic mixed model to create learning curves for rate margin positivity and Poisson mixed model for lymph node yield. As for operative time, they created a model to fit the assumption that surgical time would follow a negative exponential model. This study found that a total operating time of 6.5 hours could be reached after 21 cases.[18] The data is difficult to interpret given the variable methods of diversion, including a high prevalence of open diversion, and extent of pelvic lymph node dissection. They reported 30 cases were necessary before a mean lymph node yield of 18 and positive margin rate of < 5% were achieved.[18] Our study is unique in that we applied the CUSUM approach and successfully devised an operative time learning curve for two surgeons, which reduces confounding due to variations in technique of pelvic lymph node dissection and urinary diversion.

The mean operative time in multiple retrospective studies of RARCs with intracorporeal urinary diversion was between 5.67 hours to 10.67 hours; therefore, we set our targeted OR time of proficiency to be roughly a median 8 hours or less.[8,11] Of particular note, our goal was proficiency and not necessarily excellence as there are certainly talented surgeons nationally who can consistently perform this surgery much faster than 8 hours. A plateau of 8 hours for total OR time was achieved after 10 and 11 cases in the two institutions in our study. In order to evaluate surgical quality of the cystectomy, we examined lymph node yield and margin positivity as they are significant prognostic factors. With 10 lymph nodes set as the minimum level of proficiency, we did not appreciate a learning curve for lymph node yield. As the total operative time reached a consistent plateau, we also observed a decrease in the hospital length of stay with an average length of stay of 7.6 days and 5.3 days in Institutions A and B, respectively.

Initial arguments against RARC include concern for oncological outcomes, extended time in Trendelenburg position, and risk of associated complications. Tyritzis et al's experience with RARC and intracorporeal ileal neobladder formation included 70 patients and demonstrated negative margins in 98.6% of cases, with median follow up of 30.3 months.[11] At 24 months, they found the cancer-specific and overall survival rates to both be 88.9%.[11] Ultimately, it is important

to have a dedicated team when undertaking this complex procedure with a significant learning curve. A dedicated robotic team including bedside assistants and scrub team in addition to the surgeon is needed to ensure shortened operative time and minimize complications and conversion rates.

This study has some limitations. An important consideration in interpreting our data is that this curve is devised from the experience of fellowship-trained surgeons with extensive experience in robot-assisted radical prostatectomy and cystectomy prior to starting independent faculty positions. Furthermore; we are unable to account for differences in the robotic experience each attending had during fellowship training. Grantcharov et al described how different learning curves existed depending on surgeon experience.[19] Hence, robot-naïve surgeons may require more procedures before reaching a level of competency in RARC. Other limitations include the retrospective nature of this study and possible selection bias as not every cystectomy performed by either surgeon was robotic. There is a possibility that the selection criteria changed as time progress with both surgeons such that more straightforward cases were initially performed, and more challenging, complex cases included later in the learning curve. It is difficult to predict the effect such inclusion would have on the overall learning curve.

Conclusion

CUSUM analysis is a valuable tool for the analysis of surgical learning. In this study, we used the CUSUM method to devise a learning curve for RCID. By setting a total operating time of 8 hours as a proficient level of performance, our study suggests that 10 to 11 robotic cystectomies are required in order to reach a consistent level. With regards to oncological outcomes such as lymph node yield and margin positivity, we found comparable and adequate results between cases performed during the learning phase and plateau phase once proficiency was achieved. Larger, multi-institutional studies are warranted to further define robotic surgical learning curves and enhance the power of the CUSUM method in this regard. □

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