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The learning curve for reducing complications of robotic-assisted laparoscopic radical prostatectomy by a single surgeon

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What's known on the subject? and What does the study add?
Between December 2005 and January 2010, 200 consecutive patients with prostate cancer received RALP performed by a single surgeon. Only one case with Clavien grade II complication due to gouty arthritis. The complication rate was 1%. We suggested that patient with history of gouty arthritis need to prescribe preventive colchicine.

OBJECTIVE

- To analyse the learning curve for reducing complications of robotic-assisted laparoscopic radical prostatectomy (RALP) performed by a single surgeon in Taiwan.

PATIENTS AND METHODS

- Complication rates were prospectively assessed in 200 consecutive patients undergoing RALP (Group I: cases 1–50; Group II: cases 51–100; Group III: cases 101–150 and Group IV: cases 151–200).
- Complications were classified using the Clavien system: grade I: deviation normal postoperative course without treatment; grade II: drug or bedside treatment; grade III: endoscopic or surgical intervention; grade IV: life-threatening problem; and grade V: death.
- Operative parameters and peri-operative complications were evaluated, including operative and console time, blood loss and transfusion rate, Gleason scores, positive surgical margin (PSM) rate, specimen volume, tumour size, tumour percentage, node positive rate and intra- and postoperative complications.

RESULTS

- RALP console time was gradually lowered from Group I to Group IV ($P < 0.05$). Significantly less blood loss occurred after every 50 cases of RALP (Group I 275 mL, Group II 179 mL, Group III 145 mL, Group IV 102 mL, $P < 0.001$).
- Blood transfusion incidence was 8%, 4%, 2% and 0% in Groups I, II, III and IV, respectively.
- Complication rates were 18%, 12%, 18% and 0% in Groups I, II, III and IV, respectively.
- Major complications (grade III–IV) were 6%, 2%, 4% and 0% in Groups I, II, III and IV, respectively.
- Bowel injury occurred in three cases (Group II: 1; Group III: 2); one received intra-operative repair without sequelae and two received a transient colostomy and later colostomy closure.

CONCLUSIONS

- The learning curve for every 50 cases of RALP showed significantly less blood loss and blood transfusion rate.
- The learning curve for significantly decreasing complications is 150 cases.

KEYWORDS

complications, laparoscopy, prostate cancer, radical prostatectomy, robotics

INTRODUCTION

Prostate cancer is the second most common cancer among men in the USA. Only skin cancer is more common. It's also the 2nd ranked cancer that results in death in the USA next to lung cancer. In Asia and Taiwan the incidence of clinical prostate cancer is low, however, it has increased in recent years [1]. Prostate cancer is currently the 5th most common cancer and the 7th ranked cancer that results in death among men in Taiwan [1]. Since 1980, when retropubic radical prostatectomy (RRP) was adopted by Walsh *et al.* [2], the procedure has remained the gold standard for surgical treatment of localized prostate cancer. After the introduction of the da Vinci robotic surgery system in urology in 1999, urology surgeries have had the advantage of three-dimensional magnified vision, enhanced ergonomics, computer filtration of tremors and scaled-down movement with the use of an endo-wrist instrument with seven degrees of freedom of

range of motion and improved manual dexterity. The first robotic-assisted laparoscopic radical prostatectomy (RALP) was performed by Binder and Kramer in Frankfurt in May 2000 [3]. Less than a decade after its introduction, RALP was used in 75% to 85% of RP performed in the United States in 2008 [4,5]. Patients are attracted by commercial and health provider websites where they learn that RALP is minimally invasive and that outcomes are superior to other approaches [6,7]. Excellent oncological and functional results have been reported by high-volume surgeons and institutions [8–12]. RALP is still in its infancy in Taiwan. For the safety and quality of patient care, decreasing morbidity and complications is a paramount goal. Although the disparity in the quality of surgical complications reported in urological oncology makes it almost impossible to compare the morbidity of surgical techniques and outcomes [13]. The trend towards the use of validated classification systems such as the Clavien classification for reporting complications allows better comparison [14]. Since 2005, early references bringing the Clavien system into peri-operative morbidities of laparoscopic and robotic RP were reported in several institutes [15–17]. The Clavien system for reporting complications has been adopted in several RALP series [8,18–24]. In the present study, the Clavien classification was used to prospectively evaluate and manage peri-operative complications of RALP by a single surgeon in Taiwan. We further analysed the learning curve for reducing complications of RALP.

PATIENTS AND METHODS

SURGICAL PARAMETERS

Before the introduction of the robotic programme, the console surgeon and experienced clinical fellows performed open RRP, laparoscopic radical prostatectomy (LRP) and laparoscopic urological procedures collaboratively. The robotic team includes a console surgeon, two clinical fellows, one circulating nurse, two scrub nurses and an Intuitive Surgical Taiwan representative. Between December 2005 and January 2010, 200 consecutive patients with prostate cancer received RALP performed by a single surgeon at Taichung Veterans General Hospital. An IRB-approved, prospective database was collected by investigators and the study coordinator. The patients were classified into four groups: 1–50 cases (Group I), 51–100 (Group II), 101–150 (Group III) and 151–200 (Group IV). Preoperative clinical characteristics were prospectively recorded, including age, body mass index (BMI), American Society of Anesthesiologists anesthetic/surgical risks class (ASA), PSA levels, PSA density, biopsy percentage, biopsy Gleason score and clinical stage (using the 2002 American Joint Committee on Cancer, AJCC, staging). Preoperative risk was determined by D'Amico classification [25]: low-risk patients were defined as having T1c or T2a, PSA levels <10 ng/mL or a Gleason score <7; intermediate-risk patients had T2b, PSA levels of 10–20 ng/mL or a Gleason score of 7; and high-risk patients had T2c, PSA levels >20 ng/mL or a Gleason score of 8–10. We performed RALP as previously described [26], using Patel's technique with minor modifications [27]. We used a three-arm approach with five trocars (cases 7–134) and a four-arm approach with six trocars (cases 1–6 and cases 135–200). Dissection of the bilateral pelvic lymph nodes (BPLND) was usually performed. Neurovascular bundle (NVB) preservation procedures were performed according to preoperative tumour status and patient's preference. Preservation of NVB was done using the Vattikuti Institute Prostatectomy technique [28]. From case 61, posterior reconstruction of rhabdosphincter was done [29]. Urethrovesical anastomosis using two 18-cm 3-0 Monocryl continuous stitches was done [26]. An 18-French silicon Foley catheter with a 10-mL balloon was used. Next, the intra-operative urinary bladder was injected with 200 mL normal saline to confirm watertight anastomosis. Parameters recorded for each surgery included whether BPLND was used, whether NVB preservation was done, surgeon's console time, vesicourethral anastomosis time, estimated blood loss (EBL) and transfusion rate. Console time was defined as the time when the surgeon was at the console using the daVinci instrument from beginning to finishing the procedure. Specimens were fixed, coated with Indian ink and cut into systemic stepwise sections at 4-mm intervals [26]. The Gleason score, positive surgical margin (PSM) rate, specimen volume, tumour volume, tumour percentage and node positive rate were recorded. Patients were encouraged to ambulate on the first postoperative day (POD). Patients were allowed to have water and then resumed a regular diet on POD 1–2. The drainage tube was removed and i.v. fluid discontinued on POD 1–3. Patients were discharged POD 2–5 and Foley's catheter removed on POD 7–14. Patients received cystograms before removal of Foley's catheter from case 1 to case 13 for patients' safety. Two cases in Group II and two cases in Group III were checked using cystogram as a result of mild urine leakage postoperatively. Cystogram was not needed for other patients. Patients were ask to follow-up at our office 6 weeks, 3 and 6 months postoperatively. The peri-operative complications including intra-operative events and up to 180 POD events were recorded by the surgeon, team member and study nurse coordinator, defined and graded according to the Clavien system [14]. Specifically, grade 0 identified the absence of any complication; grade I identified the presence of any deviation from the normal postoperative course, including the need for pharmacological treatment other than antiemetics, antipyretics, analgesics, diuretics, electrolytes, or physiotherapy; grade II identified complications needing only the use of i.v. medications, total parenteral nutrition, enteral nutrition or blood transfusion; grade III identified complications needing surgical, endoscopic, or radiological intervention, grade IIIa intervention not under general anaesthesia, grade IIIb intervention under general anaesthesia; grade IV identified life-threatening complications requiring intensive care/intensive care unit (ICU) management, grade IVa single organ dysfunction, grade IVb multiorgan dysfunction; and grade V identified complications causing the death of the patient. Minor complications were defined as grade I to grade II and major complications were defined as grade III to grade V. Urine leakage was defined as persistent urine drainage of more than 100 mL at POD 4. Lymphocele was defined as persistent lymph fluid drainage of more than 100 mL at POD 4. Ileus was defined as requiring nasogastric tube placement as a result of an inability to resume a normal diet at POD 4.

STATISTICAL ANALYSIS

All data are expressed as mean ± SD SPSS 10.0 for Windows (SPSS, Inc., Chicago, IL, USA) was used for statistical calculations. Statistical analysis was performed using the non-parametric Mann–Whitney *U* test, Fisher's exact test and Yate's correction of the contingency test as appropriate. A *P* value <0.05 was considered statistically significant.

RESULTS

As shown in Table 1, preoperative clinical characteristics were similar between the four groups except for a higher incidence (24%) of ASA III in Group I than in the other Groups II–IV ($P < 0.001$). Operative parameters are shown in Table 2. Both console time ($P < 0.001$) and anastomosis time ($P < 0.001$) were significantly reduced from Group I to Group IV. The incidence of performing BPLND was higher in Groups II–IV than in Group I ($P < 0.01$).

The Incidence of NVB preservation was similar between the four groups. Table 3 shows that the incidence of complications was significantly reduced in Group IV than in Groups I–III. The complications were classified using the Clavien system (I to IV) or minor/major, and the complication rate was also significantly reduced in Group IV than Groups I–III. Trends of reducing blood transfusion, rectal injury and medical complications were also noted in Group IV. Table 4 detailed the types of complications. A total of 24 patients had 29 complications. Twenty patients had only one event. One patient had three events, including blood transfusion, bladder injury and urine leakage. Three patients had two events, including minor urine leakage and wound infection in one patient, umbilical wound infection and gouty arthritis attacks in another patient, and blood transfusion and urine leakage needing percutaneous nephrostomy drainage in the third patient. Management of intra-operative complications included intra-operative repair of rectal injury and bladder injury. The principle management of urine leakage was prolonged catheterization; only one patient needed to receive percutaneous nephrostomy drainage for 1 week. Medical complications including UTI, gouty arthritis and deep vein thromobus were treated with medication. Clavien III complications, including minor vesicourethral anastomosis and urethral meatal stricture, needed to receive cystoscopic urethral sounding. Intestinal injuries were noted in three patients: one had intra-operative repair of a rectal injury without sequlae, and the other patient that needed intra-operative repair of a rectal injury developed a rectourethral fistula requiring a transient colostomy then readmission for transperineal closure of rectourethral fistula; the colostomy was closed later. Another patient sustained an unrecognized sigmoid colon injury with presentation of abdominal distention fullness and pelvic abscess formation at POD 14. An exploratory laparotomy was done with segmental resection of a sigmoid colostomy and transverse colostomy. The colostomy was closed 3 months later. The mean postoperative hospital stay was 3.76 for all patients. The mean postoperative hospital stay was 5.66, 6.46 and 5 with complications of Clavien I, II and III, respectively. The mean post-operative hospital stay for RALP in two Clavien IV patients was 23 days. These two patients needed second and/or third admissions for further operations, so the

TABLE 1 Comparison of preoperative clinical characteristics of robotic-assisted laparoscopic radical prostatectomy (RALP) by a single surgeon

Clinical data	Group I: 1–50	Group II: 51–100	Group III: 101–150	Group IV: 151–200	*P* value
Age (years)	65.9 ± 6.3	65.0 ± 7.3	64.5 ± 6.9	64.8 ± 7.0	0.726
BMI	24.6 ± 3.0	24.4 ± 2.8	25.0 ± 2.7	24.3 ± 3.1	0.618
ASA, I/II/III	13/24/12	13/33/1	7/39/3	7/41/2	<0.001
PSA level (ng/mL)	17.2 ± 17.9	18.0 ± 17.3	22.3 ± 23.2	13.8 ± 9.7	0.673
Biopsy Gleason score 2–4/5–7/8–10	2/39/9	0/40/10	0/44/6	0/44/6	0.228
Clinical stage T1/T2/T3	23/26/1	21/24/5	21/24/5	15/33/2	0.346

BMI, body mass index; PSA density, PSA/prostate volume by transrectal sonography; ASA, American Society of Anesthesiologists anesthetic/surgical risks class.

TABLE 2 Comparison of operation parameters of robotic-assisted laparoscopic radical prostatectomy (RALP) by a single surgeon

Factors	Group I: 1–50	Group II: 51–100	Group III: 101–150	Group IV: 151–200	*P* value
Console time (h)	207.7 ± 80.8	184.1 ± 32.9	168.1 ± 33.0	145.9 ± 28.3	<0.001
BPLND	34/50 (68%)	48/50 (96%)	46/50 (92%)	49/50 (98%)	<0.001
NVB preserving	23/50 (46%)	18/50 (36%)	21/50 (42%)	21/50 (42%)	0.789
Anastomosis time (min)	40.5 ± 14.4	27.8 ± 7.4	26.9 ± 8.5	25.9 ± 5.1	<0.001
Blood loss (mL)	275.3 ± 242.6	179.4 ± 168.2	145.5 ± 127.7	102.6 ± 72.8	<0.001

BPLND, bilateral pelvic lymph node dissection; NVB, neurovascular bundle.

TABLE 3 Comparison of complication rates of 200 cases of robotic-assisted laparoscopic radical prostatectomy (RALP) by a single surgeon

Complication rate	Group I: 1–50	Group II: 51–100	Group III: 101–150	Group IV: 151–200	*P* value
Total	9 (18%)	6 (12%)	9 (18%)	0	0.017
I/II/III/IV	1/6/2/0	3/2/1/0	2/5/0/2	0	<0.001
Minor/major	7 (14%)/2 (4%)	5 (10%)/1 (2%)	7 (14%)/2 (4%)	0	0.017
Blood transfusion	4 (8%)	2 (4%)	1 (2%)	0	0.159
Rectal injury	0	1	2	0	0.302
Medical	2	0	3	0	0.352

Clavien system, grade I: deviate from the normal post-operative course without treatment, grade II: drug or bedside treatment, grade III: endoscopic (IIIa) or surgical intervention (IIIb), grade IV: life-threatening problem, single organ (IVa) or multiorgan (IVb), grade V: death; Minor: I-II, Major: III-V.

TABLE 4 Complications of 200 cases of robotic-assisted laparoscopic radical prostatectomy (RALP) using the Clavien classification system

	Number a (by event)	Detail
Clavien I	11	Umbilical wound infection (2), intra-operative bladder injury (2), rectal injury (1), urine leakage (4), ileus (1), lymphocele (1)
Clavien II	13	Blood transfusion(7), gouty arthritis (3), urine leakage with PCN drainage (1), UTI with stone formation(1), DVT (1)
Clavien III	3	Anastomosis stricture (2), urethral stricture (1)
Clavien IV	2	Unrecognized sigmoid colon injury (1), rectourethral fistula (1)

In all, 24 patients had 29 complications, 1 patient had 3 events, 3 patients had 2 events and another 20 patients had 1 event; PCN: percutaneous nephrostomy, UTI: urinary tract infection, DVT: deep vein thrombosis.

mean total post-operative hospital stay was 37 days.

DISCUSSION

A 'learning curve' refers to characterizing the diminishing amount of time required to perform a specific repeated task [30]. No consensus of standard definition has been accepted. The surgical learning curve is typically defined as the number of cases a surgeon needs in order to perform a particular procedure to achieve acceptable operative times, reasonable outcomes and for the surgeon to reach a comfort zone [31,32]. In a review article, the learning curve for RALP assesses the trifecta outcomes (i.e. continence rate, coitus and cancer control) and complication rate [33]. In the present study, we report on the learning curve for decreasing complications in 200 consecutive cases of RALP performed by a single surgeon. Most series do not use a standardized reporting system, and complications are not clearly defined, leading to wide discrepancy in complication rates ranging from 4.4% to 26% between centres that use a Clavien classification system and those that do not [22].

We compared complication rates using the Clavien classification system in several series (Table 5). No routine PSA screening is performed in Taiwan, which is why our surgical population has higher PSA results (18.5 ng/mL) than other series (4.9–7.2 ng/mL) and a higher incidence of a high-risk population (47%) than other series (6.5–13.25%). However, the complication rate is within average when compared with other series using the Clavien classification system for complications (range 5.08% to 26%). This can be interpreted and explained in several ways. First, we transferred surgical skills with reduced morbidity from open and LRP to a robotic environment. Knowledge of surgical anatomy and familiarity with the technique from previous RRP and LRP experiences and teamwork were instrumental in shortening the learning curve with RALP. Second, we created a dedicated robotic team and attended urological robotic symposia and workshops. Third, we have learned from experts; Dr Patel has contributed substantially to the establishment of the robotic programme since our da Vinci robotic training course was completed at Ohio State University, Ohio, USA, in October 2005. We have learned from Dr Kawachi that the patient's position placement, da Vinci system set up, trocar insertion and doing first procedure of seminal vesicle and vas deference dissection from cul de sac [34]. Dr Tewari defined the athermal technique of prostatic fascia preservation (veil of Aphrodite), which appears to enhance the quality of nerve preservation, avoiding neurovascular injury during and after robotic prostatectomy [28]. Fourth, preoperative discussion with team members and postoperative review of operative videos for pitfalls and tips helped our team progress step by step and case by case while gaining experience. Therefore, our learning curve was rapid and progressed steadily. Lastly, from the beginning we have dealt with high-risk patients with a larger tumour size and greater adhesion of the periprostate plane. After climbing the learning curve, we have gained experience in performing challenging surgical cases with reduced morbidity.

The learning curving for reducing complications of RALP varied as a result of different criteria, different populations, different technique and different centres. This series had only a single surgeon, which reduces bias when compared with other series that had 2 to 3 surgeons except Coelho's series (Table 5). We found that during cases 100–150, we still had grade IV complications as a result of extending the indications for RALP to include difficult patients who may have, for example, larger tumour size, clinical stage T3a and previous TURP. Several groups found a statistically significant reduction in minor and major comparisons after 200 personal interventions of a console surgeon [11,19]. The learning curve for decreasing complications was usually 200 cases. Drs. Herrell and Smith reported that RALP results similar to those obtained routinely with RRP were not achieved until >150 procedures [31]. Surgeon comfort and confidence similar to that with RRP did not occur until 250 RALP procedures [31]. In our experience, the learning curve of every 50 cases of RALP showed significantly less blood loss and a lower blood transfusion rate. The console time and anastomosis time became gradually shorter with every 50 cases experience from Group I to Group IV. Zorn *et al.* [12] reported that the learning curve for achieving an operation time of less than 4 h was 120 RALP cases. In our series, after experience with 150 RALP cases, the transfusion rate was significantly reduced and complications were reduced to zero.

This series had a lower urine leakage rate (2.5%) than other series (1.4–7.5%) as a result of posterior reconstruction of the rhabdosphicter, watertight urethrovesical anastomosis testing with 200 mL normal saline and longer mean duration of Foley catheter (9 days) for anastomosis healing. Marcos *et al.* [20] reported filling the bladder with 120 mL sterile water to check for anastomotic leakage. Patel *et al.* [11] reported 1500 cases experience with 6.3 days of catheter removal. Radiological leakage

TABLE 5 Peri-operative complications after robotic-assisted laparoscopic radical prostatectomy (RALP) using the Clavien system in world series

Author	Year	No.	Surgeons	Mean or median PSA level (ng/mL)	Risk group (%) low/intermediate/high	Overall complications (%)	>Grade 3	Blood transfusion (%)	Urine leak	Bowel injury	Anastomotic stricture	Lymphocele
Hu *et al.* [18]	2006	322	3	N/R	53.5/35.6/10.9	14.6	1.8	1.6	7.5	0.6	0.6	0.9
Badani *et al.* [19]	2007	2766	3	6.43	69.1/22.7/8.2	12.2	0.51	1.5	N/R	N/R	N/R	N/R
Fischer *et al.* [20]	2008	210	2	7.2	N/R	26	8.5	1.0	6.5	1.5	0.5	3.3
Murphy *et al.* [21]	2009	400	2	7.0	36.5/50.25/13.25	15.75	5.23	2.5	4.5	1.25	3.7	N/R
Novara *et al.* [22]	2010	415	2	6.4	69.4/24.1/6.5	21.6	3.2	5.3	6.7	1.2	N/R	1.2
Lasser *et al.* [23]	2010	239	3	5.42	N/R	19.6	5.0*	4.2	3.3	0.4	N/R	2.5
Coelho *et al.* [24]	2010	2500	1	4.9	N/R	5.08	0.96	0.48	1.4	0.08	0.12	0.36
Present study	2010	200	1	18.5	21.5/31.5/47	12	2.5	3.5	2.5	1.5	1	0.5

**Lasser et al. [23] reported one (0.4%) grade V complication: mortality as a result of a postoperative pulmonary embolism, no mortality was reported in other series. N/R, not reported.*

(1.46%) requiring prolonged catheterization has decreased and/or disappeared accordingly with increased experience. In Patel's series with 2500 RALPs, in a large-volume centre and a single surgeon had low complication rates of 5.08% [24]. He concluded that proficiency is only accomplished with consistent surgical volume; complication rates demonstrated a tendency to decrease as the surgeon's experience increased [24].

In conclusion, we prospectively assessed the complications of an initial 200 patients with prostate cancer who received RALP performed by a single surgeon. Although the technique is still in its early stages, the learning curve was steady with every 50 cases experience. We conclude that the learning curve for a single surgeon to achieve significant decreases in complications is 150 cases.

CONFLICT OF INTEREST

None declared.

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Abbreviations: **RALP**, robotic-assisted laparoscopic radical prostatectomy; **PSM**, positive surgical margin; **RRP**, retropubic radical prostatectomy; **LRP**, laparoscopic radical prostatectomyl; **BPLND**, bilateral pelvic lymph nodes; **NVB**, neurovascular bundle; **EBL**, estimated blood loss; **POD**, postoperative day.