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Research Article

The Learning Curve of Robot-Assisted Rectal Surgery by Cumulative Sum Analysis in Binh Dan Hospital, Ho Chi Minh City, Vietnam - A Preliminary Study

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Abstract

Introduction: Robotic surgery is an innovative step in the treatment of rectal cancer. Robotic surgery has advantages to perform rectal cancer by its ergonomic designs and advanced technologies. However, it was uncertain whether these robotic technologies could shorten the learning curve.

Objective: To investigate the learning curve of robotic surgery in rectal cancer treatment at Binh Dan Hospital.

Materials and methods: A case series study of 77 cases of rectal cancer operated by Si generation da Vinci robots at Binh Dan Hospital from 11, 2016 to 02, 2020. The moving average method is used to determine the overall trend in surgery time. The Cumulative Sum (CUSUM) is used to determine the learning curve.

Results: According to CUSUM, the learning curve is divided into 3 phases: Stage 1 (initial learning phase (case 1st-32nd), n=32), phase 2 (additional experience phase (case 33rd-41st), n=9), and stage 3 (concluding phase (case 42nd-77th), n=36).

Conclusion: The learning curve in robotic surgery of rectal cancer consists of 3 phases: an initial learning phase, an additional experience phase, and a concluding phase. Mastering robotic surgery skills is achieved from case 42nd onwards. The laparoscopic rectal surgical experience may affect the learning curve process.

Keywords: Rectal cancer; Robotic surgery: Learning curve

Abbreviations

CUSUM: Cumulative Sum Method; RA-CUSUM: Risk-Adjusted CUSUM; AR: Anterior Resection; LAR: Low Anterior Resection; ULAR: Ultra-Low Anterior Resection; RP: Rectopexy; APR: Abdomino-Perineal Resection; ISR: Inter-Sphincteric Resection; TME: Total Mesorectal Excision; CAA: Coloanal Anastomosis

Introduction

Rectal cancer is still one of the most common and lethal cancers worldwide. Globocan 2020 shows that the new case number is over 700 thousand, ranks seventh after breast, lung, prostate, colon, stomach, and liver cancers. The mortality is over 300 thousand [1]. In Vietnam, these data are 9,399 new cases, ranks 5th after liver, lung, breast, and stomach cancers, and 4,758 deaths, respectively [1]. The mainstay of the treatment is surgery. With the development of robotic surgery, pelvic procedures were disposed of special advantage. Therefore, Total Mesorectal Excision (TME) is a great concern. The benefits and safety of robot systems such as high definition 3D view, wide range motion instruments, and decreasing tremors have been reported. The first robotic-assisted laparoscopic low anterior resection with TME for rectal cancer was performed in 2006 [2]. Multiple studies have demonstrated the good result of the procedure [3-5].

For a new operation, a surgeon should have to do it a certain number of times to master it. So it is very important to evaluate the learning curve, especially in robotic-assisted rectal surgery [6-12]. To detect the change in surgeon performance, the Cumulative Sum (CUSUM) analysis method is usually used in literature.

Binh Dan Hospital at Hochiminh City is the first surgical hospital in Vietnam to introduce robotic surgery for adults. To the best of our knowledge, Vietnam has not yet had any research on the learning curve for rectal cancer robotic surgery.

Materials and Methods

All patients diagnosed with rectal cancer underwent robotic surgery with Si da Vinci generation between November 2016 and February 2020, in Binh Dan Hospital, Hochiminh City, Vietnam (Table 1).

Inclusion criteria

- Patients with rectal tumors on colonoscopy (distance from anal margin ≤ 15 cm).
- Pathology was adenocarcinoma.

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- Patients had no contraindications to laparoscopic surgery and agree to participate in the study.

Exclusion criteria

- Patients did not agree to participate in the study.
- Patients had incomplete recordings of survey factors.
- Patients neither follow treatment regimens nor follow up after surgery.
- Patients had another secondary cancer attached simultaneously.

The preoperative status of patients was assessed by the American Society of Anesthesiologists (ASA) Classification. Tumor location was divided by the distance from the anal verge: low (0 cm-5 cm), mid (5.1 cm-10 cm), and upper rectal cancer (10.1 cm-15 cm). The conversion was defined as an unintended extension of a mini-laparotomy above 3 cm-4 cm during the operation (Table 1). The surgical techniques are described in the textbook [13,14]. The specimen was extracted through a midline mini-laparotomy (3 cm-4 cm) above the pubis.

Surgeon 1 (Chuc VH) had a 10-year of experience in laparoscopic surgery before performing robotic rectal surgery (34 cases). Surgeon 2 (Huu PN) had 8-years of laparoscopic surgery before practicing robot surgery (77 cases). The first 34 cases were performed by Surgeons 1 and Surgeon 2; the remaining 43 cases were only by Surgeon 2. Before their first robotic procedures, they were trained for a month by an experienced surgeon from Singapore. The first 20 cases were performed by hybrid technique (the robot is used only in the pelvic phase), and the remaining 57 cases by the totally robotic technique (the robot is used in both colonic and pelvic phase).

The total operation time was subdivided into the surgeon console time and the docking time. The total operation time was the time from the first incision to the abdominal closure. The surgeon console time was the actual operation time performed in the robotic console. Docking time was the time from moving robotic instruments to completely setting the robotic arms in the surgical field. In considering port placement and position, we used double-docking in the first 20 cases, then single-docking onward.

Statistical analysis

The statistical analysis was performed by R 3.6.2 Software. In this study, we analyzed the operation times to assess the learning curve using two statistical methods: the moving average method, and the Cumulative Sum (CUSUM) method.

Continuous variables will be tested for variables that comply with the normal distribution law, and variables that follow the normal distribution law will be presented as an average ± standard deviation. The continuous variables in each phase were tested based on the ANOVA method, the test has statistical significance when the value $p<0.05$. Each phase was compared with each other and tested by the Bonferroni calibration method, the test had statistical significance when the value $p <0.05$. We applied the moving average and CUSUM analytical method similar to that indicated by Park [12].

The moving average method is used to find the trend of the three types of time in rectal cancer robotic surgery. Data of time were arranged in order, and in turn, each group of 5 times values is grouped to calculate the moving average value according to the following formula:

$$MAx = \frac{1}{5}\sum_{i=n}^{n+4} x$$

The Cumulative Sum (CUSUM) is used to find the learning curve of time groups in rectal cancer robotic surgery. CUSUM is an analytical method used to find the difference between the data time of each case and the average value of the data. In this study, CUSUM is calculated using the following formula:

$$CUSUM = \sum_{i=1}^{n}(xi - \mu)$$

(MA: Moving Average; CUSUM: Cumulative Sum Chart; µ: Average Value of Data Set)

The study was approved by the Ethics Committee in Biomedical Research at the Binh Dan Hospital No. 267/ĐHYD-HĐĐĐ on June 6, 2018.

Results

We recorded 77 cases of rectal cancer robotic surgery. The characteristics of the study sample are shown in Table 1.

The docking time, console time, and total operating time are shown on the chart by the sliding average method as follows:

The learning curve is divided into 3 phases based on the CUSUM diagram. This determination is based on 2 steps.

Step 1: Identify overall trends

The overall trend of operating time is determined by the moving average method. The Graphs in Graph 1 and 2 show similar shapes with the two lowest peaks at the 34th (190 and 235 minutes) and 42nd (120 and 125 minutes) cases.

Step 2: Identify the learning curve

The learning curves are determined by the CUSUM graph. Regarding docking time (Graph 3), the line shows the peak at the 21st case (30 minutes). From the 32nd case onwards, the performance line declines, starting horizontally at the 44th case (5 minutes) until the 77th case. Regarding the time of robotic surgery (Graph 4), the performance line has 2 vertices in 32nd (300 minutes) and 41st (220 minutes) cases. In terms of total operating time (Graph 5), the performance line has 2 peaks in 32nd (350 minutes) and 39th (335 minutes) cases. Graphs 4, 5 have the same trend and the two highest peaks are quite similar.

Table 1: Characteristics of the study.

Characteristics	Value
Age (years)	61,97 ± 12,3
ASA(number of cases)	
I	25
II	46
III	6
Type of procedure (number of cases)	77
Anterior resection(AR)	7
Low anterior resection(LAR)	44
Ultra-low anterior resection(ULAR)	10
Abdominal perineal resection(APR)	16
Docking time(minutes)	14,17 ± 9,58
Console time(minutes)	156,69 ± 64,7
Total operating time (minutes)	202,79 ± 64,7
Intraoperative blood loss(ml)	78,66 ± 62,88
Length of stay (days)	8,15

We decided to choose the surgeon console time to be the main criterion for determining the learning curve because it is a characteristic of robotic surgery. The period in which surgeons try to adopt the robotic technique in abdominal and pelvic procedures is the key to robotic surgery.

Through the statistical analysis above, the learning curve is divided into 3 phases as follows:

- Phase 1 (initial learning period): from case number 1 to number 32.
- Phase 2 (competent period): from case number 33 to number 41.
- Phase 3 (challenging period): from case number 42 onwards.

In Table 2, docking time has a statistically significant difference between phases (p<0.001). This proved that surgeons gradually adapted to identify the location of the port to match the purpose of surgery. Regarding the console time, there was no difference between phases 1 and 2 (p=0.7281). However, we see a statistically significant difference between phases 2 and 3 (p<0.001), and between phases 3 and 1 (p<0.001).

Discussion

In our study, the learning curve of robotic surgery in rectal cancer was divided into 3 phases: the initial learning period (cases 1-32), the competent period (cases 33-41), and the challenging period (cases 42-77). The technical competence was achieved with the time: the docking times were reduced with statistically significant differences from phase I to phase III. However, the operating skills were only obtained after phase II: surgeons need more time to accomplish the robotic operating techniques (Table 2).

When surgeons develop a new technique, patient safety is put forward. The surgeon needs certain cases, under supervision or simulated setting, to achieve the safety and competence standards. The theory of LC could promote surgical training using data to plan the progress [15]. The LC knowledge is crucial in comparing new operations with conventional ones [16]. Multiple studies with LC analysis to get robotic competence are shown in Table 3.

Choosing the variables is a critical condition to estimate the LC. We choose the variables for measuring the surgical process (the total operative time to complete the procedure, the console time, the conversion rate from laparoscopic to open surgery) and the variables for measuring patient outcomes (the anastomotic leak, the CMR involvement, the length of hospital stay, intraoperative/postoperative complications, mortality) (Tables 3-6). However, not all variables are accurate for measuring the LC. The operating time alone might not be a good index [17]. The interaction between these variables may confound the LC analysis [16,18]. The experience of laparoscopic rectal cancer can affect the learning course but is inadequately defined [19]. The influence of the senior surgeon on the junior surgeon also cannot be evaluated. In this study, we do not know the inter-operator difference between Surgeon 1 (senior) and Surgeon 2 (junior), as well as the reciprocal action of the variables.

Similarly, the conversion rate seems to be improved with the progressive phase, with no conversion reported in phase III by any author. We have no conversion in any phase (Tables 4-6). We have 3 cases of complications with the anastomotic leak, all having an ileostomy. These cases were self-resolved after medical management (Clavian-Dildo classification 2).

Table 2: Comparison between phases of learning curves.

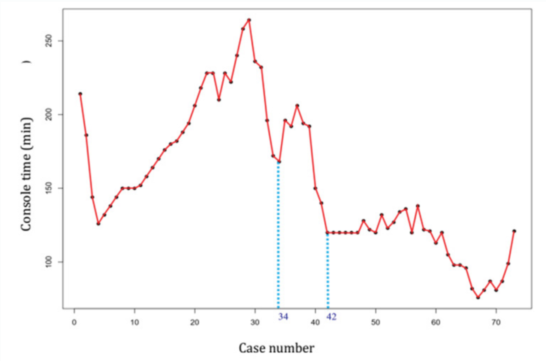
	phase 1 n=32	phase 2 n=9	phase 3 n=36	P^a value	P^b value (phase 1 *vs.* phase 2)	P^b value (phase 2 *vs.* phase 3)	P^b value (phase 3 *vs.* phase 1)
Docking time	21,41 ± 7,64	12,78 ± 5,65	8,72 ± 4,06	<0,001	<0,001	0,073	<0,001
Console time	195,31 ± 63,14	190,00 ± 58,95	114,03 ± 35,25	<0,001	<0,001	<0,001	<0,001
Total operating time	216,72 ± 62,24	202,78 ± 57,29	190,42 ± 62,01	0,085	1	1	0,26

a: ANOVA accreditation method; b: Bonferroni adjustment method

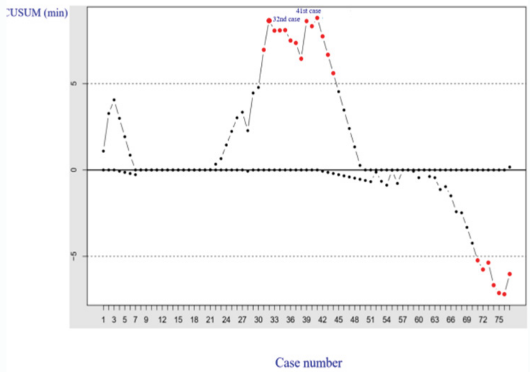
Table 3: Learning curve studies in robotic rectal surgery (modified from Jimenez-Rodriguez et al. [34]

Author & year	**Study design**	**No.of patient**	**Operation technique**	**Statistics**	**Learning curve**	**No. of surgeon**	**No. of phases**	**Procedures**
Bokhari et al. [7]	Case series	50	Hybrid	CUSUM	15	Single	3	AR 25; LAR 15; APR 6; RP 4
Sng et al. [10]	Case series	197	Totally	CUSUM	35	Single	3	AR 3; LAR 126; Ultra LAR 10; ISR 45; AP 13
Jimenez-Rodriguez et al. [6]	Case series	43	Totally	CUSUM, RA-CUSUM	21-23	Three	3	AR 36; APR 7
D'Anibale et al. [35]	Case series	50 *vs.* 50	Totally	CUSUM	22	Single	2	(Robotic = 50, Laparoscopic = 50) LAR (TME) 100
Kim et al. [21]	Case series	167	Totally	CUSUM	32	Single	3	LAR 102; CAA 65
Park et al. [11]	Case series	130	Hybrid	CUSUM, RA-CUSUM	44	Single	3	LAR 130
Park et al. [12]	Non-randomized case comparaison	89 *vs.* 89	Totally	CUSUM	44	Single	3	(robot = 89,laparoscopic=89) LAR 178
Yamaguchi et al. [9]	Case series	80	Totally	CUSUM	25	Single	3	AR 6; LAR 46; ISR 22; APR 6
Melich et al. [23]	Non-randomized case comparaison	92 *vs.* 106	Totally	CUSUM	31	Single	3	(robot=92, laparoscopic=106) LAR 198
Foo et al. [20]	Case series	39	Totally	CUSUM	8	Single	3	LAR 34; APR 4; 1 HARTMANN
Hung VT et al.	Case series	77	Hybrid (20) Totally (57)	CUSUM	32	Two	3	AR 7; LAR 44; ULAR 10; APR 16

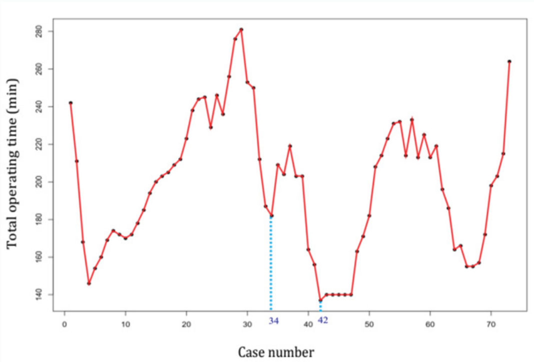
CUSUM: Cumulative Sum Method; RA-CUSUM: Risk-Adjusted CUSUM; AR: Anterior Resection; LAR: Low Anterior Resection; ULAR: Ultra-Low Anterior Resection; RP: Rectopexy; APR: Abdomino-Perineal Resection, ISR: Inter-Sphincteric Resection; TME: Total Mesorectal Excision; CAA: Coloanal Anastomosis



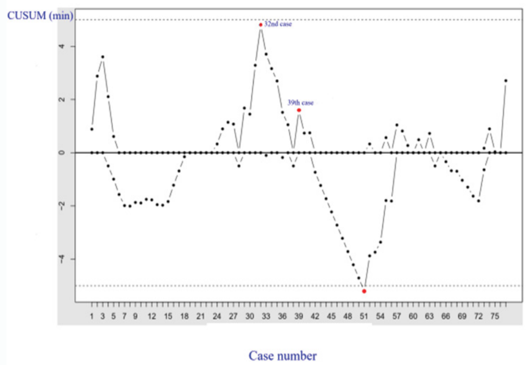
Graph 1: Moving average chart of console time.



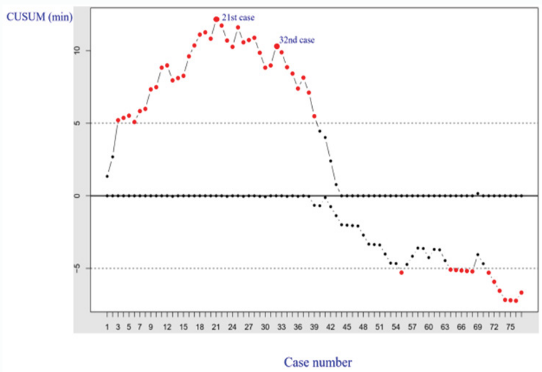
Graph 4: CUSUM of console time.



Graph 2: Moving average chart of total operating time.



Graph 5: CUSUM of total operating time.



Graph 3: CUSUM of docking time.

The CUSUM analysis reveals three differentiated phases. Multiple studies indicated the development of the skills with the cases [6,9-12,20-23]. Most studies are case series (Table 3). The most common procedure was the Low Anterior Resection (LAR) (Table 3). The number of cases varied according to the kinds of operations and the pathology of the tumors (Table 3). The inappropriate sample can lead to inaccurate conclusions. Our mean number of cases for phase I was 32, phase II was 9, and phase III was 36. In our study, the number of cases for phase I and phase III is consistent with other authors (Tables 4 and 6), but only 9 patients for phase II. These results may associate with previous experience of laparoscopic rectal surgery relating to 2 surgeons in the study. In addition, in the phase, we chose simple cases for the first steps to a new operation technique. We applied the hybrid technique in the first 20 cases. The first thirty-four cases were simultaneously operated by 2 surgeons. In phase II (9 cases), most cases (7 cases) were performed by 1 surgeon (Huu PN) with the totally robotic technique. In phase 3 (36 cases), all were done by only 1 surgeon (Huu PN) with the totally robotic technique. This might cause bias in LC [24].

All the above studies showed a progressive decrease in both total operative time and in console time. Our findings are consistent with these authors (Table 7).

Our study has factors that may cause bias or confounding. There are lots of factors we cannot analyze: the training of surgical assistants, operating nurses, anesthetists, and technical staff may influence the LC [25,26], the patient-related factors (gender, anatomical varieties, BMI…), pathology characteristics (tumor position, tumor staging…), sample selection (simple cases included) [25-27]… Most of these factors have not been defined clearly in studies (Tables 3-6) and may affect the outcome of the LC analysis [28-30].

The competence and the standard for LC measurement also are not defined due to the heterogeneity in the literature [31] (Table 3). Good reasoning should compose the above-needed variables with a multivariate analysis [32,33]. This study has limitations due to its retrospective nature, low case numbers, the cases are not equilateral between 2 surgeons, and the prior experience of 2 surgeons can not exactly be assessed. Preoperative and postoperative parameters are not comprehensively analyzed.

Despite the limitations of our study, our results suggest that the laparoscopic experience may influence the LC analysis, the challenging period (phase 3) can be achieved rapidly (after 9 cases), and the console time should be considered as one of the main variables in the LC research. Of course, we need more studies with good design

Table 4: Phase I (modified from Jimenez-Rodriguez et al. [34])

Authors	No. of cases	Total operative time (minutes)	Console time (minutes)	Conversion (cases)	Anastomotic leak(cases)	CMR non-involved (>1 mm)	Postoperative hospital stay (days)
Akmal et al. [22]	40	310 (180-540)	60 (25-130)	2	5	-	7.8 (2-230
Sng et al. [10]	35	265 (190-470)[a]	135 (60-244)[a]	0	2	-	8 (5-20)[a]
Jimenez-Rodriguez et al. [6]	9	246	160 ± 30	1	-	-	13.2
Kim et al. [21]	32	252 ± 42.1	112.3	2	6	29	9.8 ± 7.2
Parks et al. [11]	44	229.8 ± 48.5	75.2 ± 29.4	0	1	40	9 ± 3.3
Parks et al. [12]	44 *vs.* 41	299.8 ± 48.5 *vs.* 242.3 ± 80	75.2 ± 29.4	0 *vs.* 4	1 *vs.* 2	44 *vs.* 39	9 ± 3.3 *vs.* 10.2 ± 4.1
Foo et al. [20]	8	243 ± 38[a]	96.4 ± 25[a]	0	1	8	6.3 ± 2.4[a]
Melich et al. [23]	31 *vs.* 31	397 (373-420) *vs.* 308 (291-325)	297 *vs.* 261	1 *vs.* 3	1 *vs.* 2	-	9.5 *vs.* 12
Yamaguchi et al. [9]	25	415 (156-683)[a]	-	0	0	-	8 (7-12)[a]
Hung et al	32	216,7 ± 64.2	195,3 ± 63.1	0	1	23	8.09 (7-14)

[a]: Median with an interquartile range; all other continuous variables are described as the mean with a standard deviation.

Table 5: Phase II (modified from Jimenez-Rodriguez et al. [34])

Authors	No.of cases	Total operative time (minutes)	Console time (minutes)	Conversion (cases)	Anastomotic leak(cases)	CMR non-involved (>1mm)	Postoperative days
Akmal et al. [22]	40	297 (150-660)	64 (38-120)	2	1	-	7.3 (2-22)
Sng et al. [10]	93	285 (182-475)[a]	156 (65-367)[a]	0	11	-	9 (5-50)[a]
Jimenez-Rodriguez et al. [6]	12	279.9	201.6 ± 40.6	1	-	-	8.7
Kim et al. [21]	40	213.8 ± 44.5	90 ± 32.8	0	7	39	10.8 ± 7.3
Parks et al. [11]	34	189.4 ± 53,2	56.1 ± 23.2	0	0	32	8 ± 4.2
Parks et al. [12]	45 *vs.* 48	187.9 ± 53 *vs.* 168 ± 52	53.7 ± 23.2 *vs*-	0 *vs.* 1	0 *vs.* 3	43 *vs.* 40	7.9 ± 4.2 *vs.* 9.7 ± 7.7
Foo et al. [20]	17	540.9 ± 133.4[a]	136.6 ± 37.5[a]	0	2	17	9.2 ± 7.2[a]
Melich et al. [23]	31 *vs.* 31	252 (238-268) *vs.* 275 (263-288)	205 *vs.* 237	0 *vs.* 0	2 *vs.* 0	-	9.6 *vs.* 9.1
Yamaguchi et al. [9]	25	292 (157-509)[a]	-	0	0	-	7 (6-12)[a]
Hung et al	9	202 ± 57.3	190 ± 58.9	0	8	8	8.7 (6-16)

[a]: Median with an interquartile range; all other continuous variables are described as the mean with a standard deviation

Table 6: Phase III (modified from Jimenez-Rodriguez et al. [20])

Authors	No.of cases	Total operative time (minutes)	Console time (minutes)	Conversion (cases)	Anastomotic leak (cases)	CMR non-involved (>1mm)	Postoperative days
Akmal et al. [21]	-	-	-	-	-	-	-
Sng et al. [10]	69	250 (145-515)[a]	135 (60-244)[a]	0	6	-	10 (5-122)[a]
Jimenez-Rodriguez et al. [6]	22	210.4 ± 4	156.4	0	-	-	13.8
Kim et al. [22]	95	197 ± 47.1	68.4 ± 23.7	0	5	91	8.6 ± 5.3
Parks et al. [11]	52	181.6 ± 54	52.8 ± 25.7	0	5	49	8 ± 5.1
Parks et al. [12]	-	-	-	-	-	-	-
Foo et al. [23]	14	310.6 ± 164.5[a]	104.2 ± 35.5[a]	0	0	13	6.4 ± 1.6[a]
Melich et al. [24]	30 *vs.* 44	204 (196-211) *vs.* 220 (212-219)	155-183	0 vs. 0	4 *vs.* 2	-	9.9 *vs.* 9.1
Yamaguchi et al. [9]	30	196 (135-529)[a]	-	0	0	-	7 (6-15)[a]
Hung et al	36	190.4 ± 62	114 ± 35.2	0	2	23	8.0 (5-13)

[a]: Median with an interquartile range; all other continuous variables are described as the mean with a standard deviation

Table 7: The decrease of the operative and console time with increasing cases.

	Phase I		Phase II		Phase III	
	Literature	Hung et al.	Literature	Hung et al.	Literature	Hung et al.
Operating time (minutes)	299-415	216.7	168-540	202	196-310	190
Console time (minutes)	60-216	195	67-237	190	68-183	114

to approve them.

Conclusion

Rectal robotic surgery has a learning curve of three phases. In our study, phase 1 (the initial learning period, the primary technical competence) from the 1st case to the 32nd case. Phase 2 (the competent period, the technical completion to assure feasible perioperative clinical and pathological outcomes) lasts from the 33rd to the 41st case. Phase 3 (challenging period) is from the 42nd case onwards. This is comparable to surgeons who have already mastered the laparoscopic techniques. However, further studies with appropriate design, focusing on more specific parameters and homogenous data, are needed to assess the competency and make recommendations for rectal robotic surgery.

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Author Contributions

HVT and HVD were major contributors to writing the manuscript. HVT, HVD, and MPN were involved in the design of the study and the drafting of the manuscript. MPN, CVH, HPN, AKV, and PVP collected and analyzed data. HVT and HVD critically revised the manuscript till the final version was reached. All authors read and approved the final manuscript.

Declarations

Ethics approval and consent to participate. The study protocol and data collection were approved by the Ethics Committee in Biomedical Research at the Binh Dan Hospital No. 267/ĐHYD-HĐĐĐ on June 6, 2018, signed by Associate Professor Do Van Dung, University of Medicine and Pharmacy at Hochiminh City, the chairman of the committee. Written patient informed consent was obtained for study participation.

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