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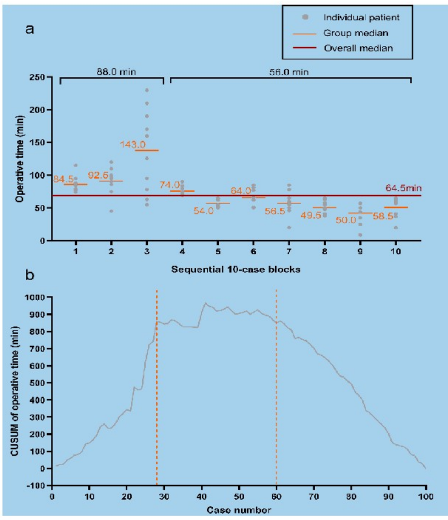
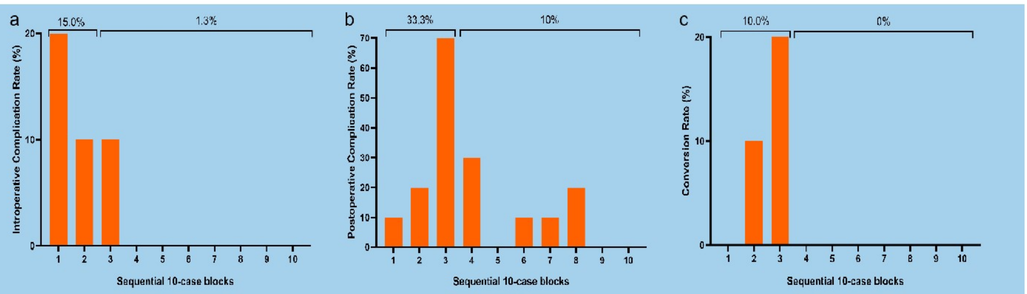
[Learning Curve for Endoscopic Resection of Gastric Gastrointestinal Stromal Tumors: A Single-center Experience]





Operative outcomes for 100 consecutive endoscopic resection of gastric gastrointestinal stromal tumors demonstrating decrease in outcomes. a) Introperative complication rate after 20 cases (P=0.025). b) Postoperative complication rate after 30 cases (P=0.004). c) Conversion rate after 30 cases (P=0.025)

Control chart of operative time in sequential 10-case blocks: The operative time decreased significantly after 30 cases (P < 0.001). b) Cumulative sum control chart (CUSUM) of the operative time: The data increased dramatically before about 30 cases (phase 1) and decreased after 60 cases (phase 3), with relatively stable in the middle 30 cases (phase 2)

[The LC for ER of gGISTs is approximately **60** cases]

[Around **30** cases are enough to reduce complications and conversion rate during ER procedure by acquiring the necessary skills]

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Learning curve for endoscopic resection of gastric gastrointestinal stromal tumors: a single-center experience

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Author contributions: Luoiie Liu and Xiaodan Xu contributed equally to this work.

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ABSTRACT

Background: endoscopic resection (ER) is widely used in the treatment of gastric gastrointestinal stromal tumors (gGISTs). However, no studies have previously described the learning curve (LC) for ER of gGISTs. This study aimed to evaluate the LC based on multifarious operative outcomes.

Methods: one hundred consecutive patients who underwent ER of gGISTs by a single endoscopist from January 2017 to December 2022 were included. Patients were analyzed in groups of ten to minimize demographic differences, and operative time (OT), conversion rate, intraoperative and postoperative complication were assessed to evaluate the LC. Meanwhile, for the OT, the LC was further analyzed using the cumulative sum (CUSUM) method and patients were organized chronologically in three phases.

Result: there was a statistically significant decrease in OT, conversion to laparoscopic surgery, and postoperative complication after 30 cases (median 80.0 min *vs* 56.0 min, $p < 0.001$; 10.0 % *vs* 0 %, $p = 0.025$; 33.3 % *vs* 10.0 %, $p = 0.004$), rate of intraoperative complications after 20 cases (15.0 % *vs* 1.3 %, $p = 0.025$). CUSUM chart demonstrated that OT increased dramatically before around 30 cases (phase 1) and decreased after 60 cases (phase 3), with a plateau phase in the middle 30 cases (phase 2). Among the three phases, the R0 resection and conversion rate were not significantly different. However, OT, intraoperative and postoperative complications were gradually decreased ($p < 0.05$).

Conclusions: the LC of ER of gGISTs is approximately 60 cases. However, about 30 cases were sufficient to acquire skills to reduce complications and conversion rate during the ER procedure.

Keywords: Gastrointestinal stromal tumors. Learning curve. Endoscopic resection.

INTRODUCTION

Gastric gastrointestinal stromal tumors (gGISTs) are the most commonly found submucosal tumors (SMTs) in the upper digestive tract (1). The primary treatment for gGISTs used to be open resection. Nevertheless, open resection of gGISTs has the disadvantages of significant trauma, long postoperative hospital stay and slow recovery. Minimally invasive techniques, such as laparoscopic gastric wedge resection and endoscopic resection (ER), are now used to remove gGISTs (2-4). Compared with laparoscopic wedge resection, ER was associated with more rapid postoperative recovery, shorter hospital stays and lower cost (5,6). However, ER of gGISTs requires superior endoscopic skills. Hence, it is important to develop guidelines to obtain proficiency in gGISTs ER. To date, no previous study has analyzed the LC for ER of gGISTs. In light of this, the present study aimed to evaluate the LC for ER of gGISTs based on multifarious operative outcomes.

MATERIAL AND METHODS

Patients

One hundred consecutive gGISTs ER procedures at the First Affiliated Hospital of Soochow University, China, from January 2017 to December 2022 were analyzed. All cases were performed by a single endoscopist (W.D.Y.) who had limited experience in ER of gGISTs, but had performed approximately 100 colonic endoscopic mucosal resections and 20 gastric endoscopic submucosal dissection (ESD). Demographic and perioperative outcomes were retrospectively collected. The general indications for ER of gGISTs in this study were tumors less than 5.0 cm in size without lymph nodes and distant metastasis. The study protocol was approved by the Ethics Committee of our hospital. All patients signed a written informed consent for the procedure.

Main outcome parameters and analysis

The main outcomes evaluated included OT, intraoperative complication, postoperative complication, R0 resection and conversion rate. The OT was defined from the start of submucosal injection to completion of the closure of the defect. Intraoperative complications mainly refer to severe intraoperative bleeding, which was defined as repeated endoscopic hemostasis with a postoperative hemoglobin drop of > 2 g/dl or a requirement for surgical assistance (7). Postoperative complications included delayed bleeding, delayed perforation and postoperative infection. Delayed bleeding was confirmed by emergency endoscopy and delayed perforation was confirmed by X-ray or computed tomography. Postoperative infection was defined as postoperative body temperature exceeding 37.5 °C, accompanied by an increase in inflammatory indicators such as blood routine, C-reactive protein (CRP) or calcitonin (8). R0 resection was defined by histological examination suggestive of no residual tumor at the lateral and vertical margins (9).

Outcomes were analyzed in groups of ten cases to minimize the impact of demographic differences and to optimize the distribution of normal status. The results were plotted on control charts, allowing visualization of outliers for each cohort as well as the entire study period.

Cumulative sum analysis

The cumulative sum (CUSUM) method was applied to the quantitative evaluation of the LC for multiple endoscopic procedures (10,11). In the present study, in view of the OT, the CUSUM method was further used to analyze the LC of ER of gGISTs. The calculation formula was as follows, where Xi represents the OT for each patient, u represents the average OT for all patients and n represents the patient serial number.

$$\mathrm{CUSUM} = \sum_{i=1}^{n}(Xi - u)$$

Endoscopic resection procedures and equipment

Two types of ER techniques were used: ESD and endoscopic full-thickness resection (EFTR). ESD was used for gGISTs originating from the muscularis mucosae (MM) or muscularis propria (MP) and protruding into the lumen. EFTR was used for gGISTs originating from deep MP with extraneous growth, or gGIST in which the tumor is found to be tightly adherent to the serous layer and cannot be separated during ESD. The ER procedure was performed in accordance with previous reports (12,13). A single channel endoscope (GIF-Q260J, Olympus, Japan) was used. Other equipment included: insulated-tip knives (ERBE Germany), dual knives (KD-611L, Olympus, Japan), high-frequency generator device (ERBE VIO® 200D), carbon dioxide insufflator, hot biopsy forceps, injection needles, metallic clips and nylon loops.

Statistical analysis

Categorical variables were expressed as frequencies and percentages, and analyzed using Chi-squared or Fisher's exact tests. Continuous variables consistent with a normal distribution were expressed as mean ± standard deviation, and compared using t test or ANOVA. Variables not consistent with a normal distribution were expressed as median and interquartile ranges, and compared using Mann-Whitney U test or Kruskal-Wallis rank sum test. A p value < 0.05 was considered as statistically

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significant. All analyses were performed using SPSS version 26 (Chicago, IL, USA).

RESULTS

Patient demographics and outcomes

One hundred consecutive patients were enrolled in the study. Table 1 shows the demographics and operative outcomes for ER of gGISTs. The median (IQR) OT was 64.5 (50.0,84.0) and conversion to laparoscopic surgery was required for three patients (3.0 %). The rates of intraoperative and postoperative complication were 4.0 % and 17.0 %, respectively. A total of 86 patients (86.0 %) had an R0 resection. The ten groups were comparable in terms of baseline characteristics (Table 2).

Comparison of operative outcomes

Intraoperative complication rate decreased after 20 cases ($p = 0.025$) (Fig. 1A). Postoperative complication rate decreased after 30 cases ($p = 0.004$) (Fig. 1B). The rate of conversion decreased after 30 cases ($p = 0.025$) (Fig. 1C). After 30 procedures, the OT had improved significantly (median 80.0 min for cases 1-30 *vs* 56.0 min for cases 31-100, $p < 0.001$) (Fig. 2A). In the latter group, a progressive but significant shortening of the OT was also observed between 31 to 60 cases and 61 to 100 cases (median 69.5 min for cases 31-60 *vs* 50.0 min for cases 61-100, $p < 0.001$).

Learning curve analysis

To visualize the trend of OT, a CUSUM chart was constructed demonstrating a dramatical increase in OT before 30 cases and decrease after 60 cases, with a plateau in the middle 30 cases (Fig. 2B). Based on the CUSUM chart, patients were organized chronologically in three phases: phase 1 (1-30 cases), phase 2 (31-60 cases) and phase 3 (61-100 cases). Comparisons of patient demographics and operative outcomes of the three phases are presented in table 3. Patients in the three phases had different body mass index (BMI) (mean 23.5 *vs* 21.3 *vs* 22.7 kg/m^2, $p = 0.017$). With the increase in the number of surgical cases, the OT was gradually shortened (median 88.0 min *vs* 69.5 min *vs* 50.0 min, $p < 0.001$). The rate of intraoperative and postoperative complications also showed a decreasing trend

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(13.3 % *vs* 0 % *vs* 0 %, p = 0.014; 33.3 % *vs* 13.3 % *vs* 7.5 %, p = 0.014). Otherwise, no statistical differences were found in conversion and R0 resection rate of the three phases.

DISCUSSION

European and Japanese guidelines recommend surgical resection once diagnosis of a GIST is confirmed histopathologically, regardless of diameter due to the malignant potential of gGISTs (14,15). With the rapid development of endoscopic technology, ER of gGISTs has gradually replaced laparoscopic surgery as a common method for the treatment of gGISTs, due to its advantages such as less trauma, short surgery time and quick recovery of postoperative gastrointestinal function. However, ER of gGISTs is more challenging and requires more substantial skills than ER of mucosal lesions. Therefore, it is necessary to evaluate the surgical skills of endoscopists according to the LC. To this end, some scholars have analyzed the LC of ER for the treatment of early gastric cancer and SMTs (16,17). Yet, these studies used OT as a sole parameter to determine the LC. The reduction in OT may not be sufficient to represent the completion of skill acquisition, as speed does not equal proficiency. Hence, we evaluated the LC using OT, intraoperative complication, postoperative complication, R0 resection and conversion rate.

Our results indicate that the rate of intraoperative complication was the first metric to show a stable surgical status (about 20 cases). Intraoperative bleeding is the most common complication in the ER (18). Endoscopists can also accumulate experience in handling intraoperative bleeding during other endoscopic surgeries, so they can master it quickly. After endoscopists mastered the treatment of intraoperative bleeding and defect clamping, other important indicators, such as postoperative complication and conversion rate were also improved at an early stage (approximately 30 cases). The OT was 88.0 minutes in the first 30 cases, which was even higher than the laparoscopic OT in some studies (19,20). Although the OT decreased after 30 cases (Fig. 2A), the CUSUM chart demonstrated that OT decreased after 60 cases, and was relatively stable in the middle 30 cases (Fig. 2B). In the plateau phase, the OT still fluctuates, and the technique of endoscopists is still unstable. Therefore, endoscopists can truly master this skill after completing 60 cases for ER of gGISTs. With the improvement of the endoscopist's skills, the OT was gradually shortened, and the incidence of intraoperative and postoperative complications was gradually decreased in the three phases ($p < 0.05$). However, no statistically significant difference was found in conversion and R0 resection rate of the three phases ($p > 0.05$). We postulate two reasons for this: first, when a novice was unable to handle severe intraoperative bleeding and to close the perforation, the surgery usually needs to be continued by a specialist, which reduces the incidence of conversion; second, the overall incidence of conversion was low, only 3 %.

Our study had some limitations. First, this is a learning experience from a single endoscopist. Different training backgrounds and advances in medical equipment may affect an individual's learning process. Second, there were no difficult cases in this study. With the improvement of the endoscopic technique of the operator, the ratio of challenging cases in the later stage will increase, and the OT may increase again, thus affecting the LC of the operator. However, this study can provide a reference for doctors conducting ER of gGISTs at an early stage. Third, the number of cases of intraoperative complications and conversions to surgery in this study was only four (4 %) and three (3 %), respectively. However, previous studies also showed that the incidence of intraoperative severe bleeding and conversions to surgery for ER of gGISTs was very low (5,7). Our study suggests that the incidence of intraoperative complications and conversion to surgery tends to decrease the more cases are performed.

In general, the LC of ER of gGISTs is approximately 60 cases. However, about 30 cases were sufficient to acquire skills to reduce complications and conversion rate during the ER procedure.

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Table 1. Patient demographics and operative outcomes

Age, years, mean ± SD	60.1 ± 8.9
Gender, male, n (%)	45 (45.9)
Tumor size, cm, median (IQR)	1.5 (1.0, 2.0)
BMI, kg/m², mean ± SD	22.5 ± 3.0
Location, n (%)	
Upper	68 (68.0)
Middle	25 (25.0)
Lower	7 (7.0)
Invasion depth, n (%)	
MM	19 (19.0)
MP	77 (77.0)
MP-ex	4 (4.0)
Modified NIH risk criteria, n (%)	
Very low	70 (70.0)
Low	22 (22.0)
Intermediate	8 (8.0)
High	0
Endoscopic technique, n (%)	
ESD	48 (48.0)
EFTR	52 (52.0)
Defect closing method, n (%)	
Metallic clips	98 (98.0)
Nylon loops	2 (2.0)
Procedure time, min, median (IQR)	64.5 (50.0, 84.0)
Intraoperative complications, n (%)	4 (4.0)
Postoperative complications, n (%)	17 (17.0)
Conversion rate, n (%)	3 (3.0)
R0 resection, n (%)	86 (86.0)
Postoperative hospitalization, days, median (IQR)	5.0 (5.0, 6.0)
Postoperative fasting, days, median (IQR)	3.0 (2.0, 3.0)

SD: standard deviation; IQR: interquartile ranges; BMI: body mass index; MM: muscularis mucosae; MP: muscularis propria; MP-ex: muscularis propria with exophytic growth; NIH: National Institute of Health; ESD: endoscopic submucosal dissection; EFTR: endoscopic full-thickness resection.

Table 2. Demographics of 100 consecutive patients who underwent endoscopic resection of gGISTs

	Group (case)										*p value*
	1 (1-10)	*2 (11-20)*	*3 (21-30)*	*4 (31-40)*	*5 (41-50)*	*6 (51-60)*	*7 (61-70)*	*8 (71-80)*	*9 (81-90)*	*10 (91-100)*	
Age, years, mean (SD)	53.2 (5.4)	59.5 (12.4)	58.7 (8.5)	62.3 (8.1)	59.2 (9.2)	65.4 (7.2)	61.7 (4.3)	63.2 (8.3)	61.0 (10.3)	56.9 (10.0)	0.132
Gender, male, n (%)	5 (50.0)	4 (40.0)	6 (60.0)	5 (50.0)	5 (50.0)	6 (60.0)	4 (40.0)	5 (50.0)	4 (40.0)	1 (10.0)	0.588
Tumor size, cm, median (IQR)	1.3 (0.5-2.3)	1.8 (1.0-2.6)	1.8 (1.0-2.0)	1.9 (1.0-2.6)	1.5 (0.7-2.1)	2.0 (1.5-2.3)	1.5 (1.0-2.0)	1.5 (1.0-2.1)	1.5 (0.7-1.9)	1.5 (1.0-2.0)	0.708
BMI, kg/m², mean (SD)	25.0 (2.0)	23.0 (3.2)	21.8 (2.6)	21.5 (2.1)	22.1 (2.5)	20.8 (2.8)	21.9 (2.1)	23.3 (4.3)	22.7 (4.2)	23.0 (2.9)	0.146
Location, n (%)											0.146
Upper	7 (70.0)	7 (70.0)	10 (100.0)	8 (80.0)	7 (70.0)	7 (70.0)	6 (60.0)	6 (60.0)	7 (70.0)	3 (30.0)	
Middle	2 (20.0)	3 (30.0)	0	2 (20.0)	1 (10.0)	3 (30.0)	3 (30.0)	4 (40.0)	3 (30.0)	4 (40.0)	
Lower	1 (10.0)	0	0	0	2 (20.0)	0	1 (10.0)	0	0	3 (30.0)	
Invasion depth, n (%)											0.616
MM	0	3 (30.0)	2 (20.0)	2 (20.0)	1 (10.0)	0	3 (30.0)	3 (30.0)	2 (20.0)	3 (30.0)	
MP	10 (100.0)	6 (60.0)	8 (80.0)	8 (80.0)	9 (90.0)	10 (100.0)	7 (70.0)	6 (60.0)	7 (70.0)	6 (60.0)	

MP-ex	0	1 (10.0)	0	0	0	0	0	1 (10.0)	1 (10.0)	1 (10.0)

SD: standard deviation; IQR: interquartile ranges; BMI: body mass index; MM: muscularis mucosae; MP: muscularis propria; MP-ex: muscularis propria with exophytic growth; gGISTs: gastric gastrointestinal stromal tumors.

Table 3. Patient demographics and operative outcomes of the three phases

	Phase 1 (n = 30)	*Phase 2 (n = 30)*	*Phase 3 (n = 40)*	*p value*
Age, years, mean ± SD	57.9 ± 10.0	61.5 ± 8.0	60.7 ± 8.6	0.260
Gender, male, n (%)	17 (56.7)	14 (46.7)	14 (35.0)	0.192
Tumor size, cm, median (IQR)	1.5 (1.0, 2.1)	1.9 (1.0, 2.1)	1.5 (1.0, 2.0)	0.343
BMI, kg/m², mean ± SD	23.5 ± 2.8	21.3 ± 2.4	22.7 ± 3.4	0.017
Location, n (%)				0.232
Upper	24 (80.0)	22 (73.3)	22 (55.0)	
Middle	5 (16.7)	6 (20.0)	14 (35.0)	
Lower	1 (3.3)	2 (6.7)	4 (10.0)	
Invasion depth, n (%)				0.148
MM	5 (16.7)	3 (10.0)	11 (27.5)	
MP	24 (80.0)	27 (90.0)	26 (65.0)	
MP-ex	1 (3.3)	0	3 (7.5)	
Modified NIH risk criteria, n (%)				0.820
Very low	17 (56.7)	19 (63.3)	25 (62.5)	
Low	8 (26.7)	9 (30.0)	10 (25.0)	
Intermediate	5 (16.7)	2 (6.7)	5 (12.5)	
High	0	0	0	
Endoscopic technique, n (%)				0.948
ESD	14 (46.7)	14 (46.7)	20 (50.0)	
EFTR	16 (53.3)	16 (53.3)	20 (50.0)	
Defect closing method, n (%)				0.333*
Metallic clips	30 (100.0)	30 (100.0)	38 (95.0)	
Nylon loops	0	0	2 (5.0)	
Procedure time, min, median (IQR)	88.0 (75.8, 102.5)	69.5 (51.8, 80.3)	50.0 (41.0, 60.0)	< 0.001
Intraoperative complications, n (%)	4 (13.3)	0	0	0.014*
Postoperative complications, n	10 (33.3)	4 (13.3)	3 (7.5)	0.014

(%)				
Conversion rate, n (%)	3 (10.0)	0	0	0.051*
R0 resection, n (%)	23 (76.7)	26 (86.7)	37 (92.5)	0.167
Postoperative hospitalization, days, median (IQR)	5.0 (5.0, 6.5)	5.0 (4.5, 6.0)	5.0 (5.0, 6.0)	0.432
Postoperative fasting, days, median (IQR)	3.0 (2.0, 3.0)	3.0 (2.0, 3.3)	3.0 (2.0, 3.0)	0.209

SD: standard deviation; IQR: interquartile ranges; BMI: body mass index; MM: muscularis mucosae; MP: muscularis propria; MP-ex: muscularis propria with exophytic growth; NIH: National Institute of Health; ESD: endoscopic submucosal dissection; EFTR: endoscopic full-thickness resection. *Fisher's exact test.

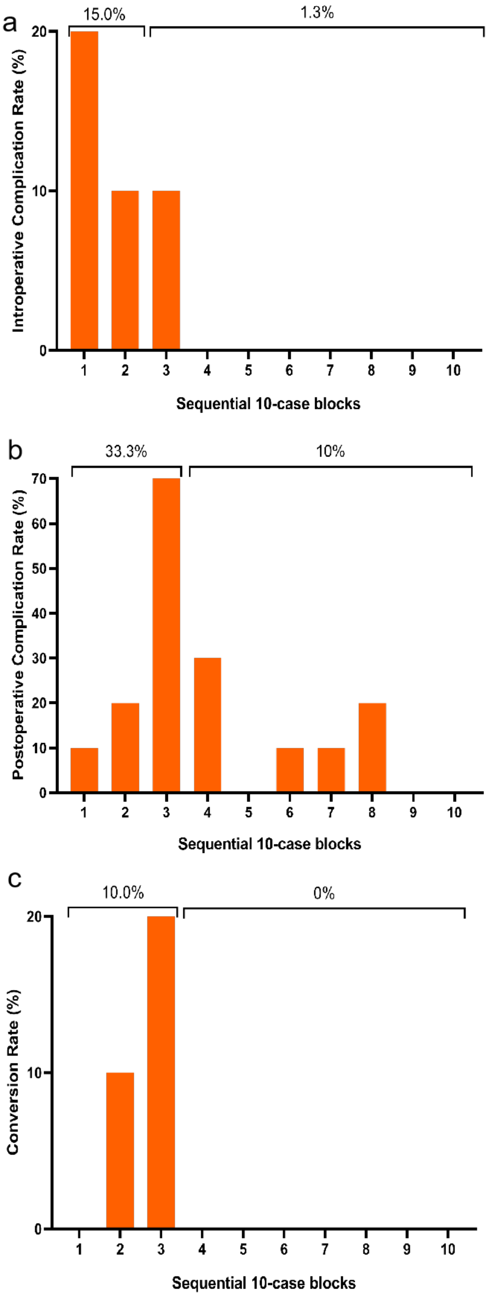

Fig. 1. Operative outcomes of 100 consecutive endoscopic resections of gastric gastrointestinal stromal tumors, demonstrating a decrease in outcomes. A. Intraoperative complication rate after 20 cases (p = 0.025). B. Postoperative complication rate after 30 cases (p = 0.004). C. Conversion rate after 30 cases (p = 0.025).

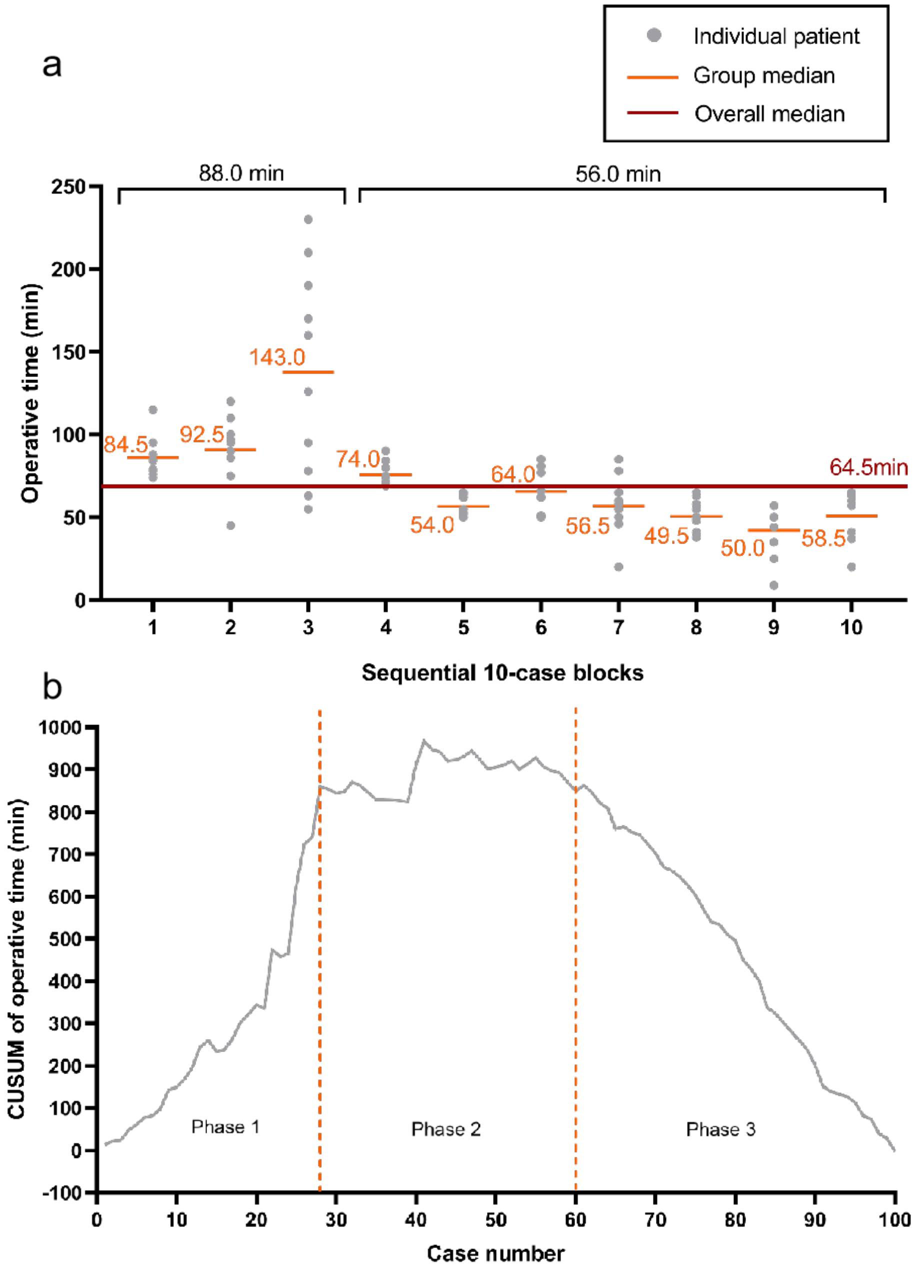

Fig. 2. A. Control chart of operative time in sequential 10-case blocks: the operative time decreased significantly after 30 cases ($p < 0.001$). B. Cumulative sum control chart (CUSUM) of the operative time: The data increased dramatically before about 30 cases (phase 1) and decreased after 60 cases (phase 3), and was relatively stable in the middle 30 cases (phase 2).