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Effects of the learning curve on operative time and lymph node harvesting during robotic gastrectomy

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Abstract

Background: Gastric cancer is the fifth most frequent cancer globally. The introduction of minimally invasive surgery for gastric cancer aimed at reducing postoperative morbidity and hospital length of stay. Although the role of laparoscopic gastrectomy has been established, robotic gastric surgery has only recently gained popularity. The purpose of this study was to evaluate, with a multidimensional analysis, the learning curve of a single surgeon with extensive experience in laparoscopic gastrectomy.

Methods: We prospectively collected data from 104 gastric cancer patients who underwent surgery with a robotic approach from June 2015 to June 2019 by a single surgeon. We performed 21 total gastrectomies (TGs) and 83 subtotal gastrectomies (STGs). A D2 lymphadenectomy was performed in all the patients. Proximal and distal resection margins were tumoour-free in all patients. There were no intraoperative complications, and no conversions occurred.

Results: The plateau of the learning curve based on harvesting lymph nodes and operative time was not reached for TG. The learning curve of operative time for STG could be divided into three different phases: an early or learning phase from 1 to 27 cases, an intermediate or proficiency phase from 28 to 48 cases, and a late or mastery phase from 49 to 83 cases. The learning curve for harvesting lymph nodes was achieved after 41 cases in the STG group.

Conclusion: This study shows that robotic gastrectomy is a complex procedure with a significant multiphasic learning curve. Nevertheless, the robotic learning curve seems to be more rapid than that of conventional laparoscopy. Most importantly, our results suggest that the robotic technique can provide oncological adequacy in terms of lymph node harvesting even in the very first phase of the learning curve.

KEYWORDS

gastric cancer, learning curve, minimally invasive surgery, robotic gastrectomy

1 | INTRODUCTION

Gastric cancer is the fifth most common and third most deadly malignancy worldwide.[1] Surgical resection, with or without (neo) adjuvant therapy, is the mainstay of curative treatment. Minimally invasive surgery for gastric cancer was implemented to decrease post-operative pain, morbidity, and hospital length of stay, allowing for a rapid return to normal daily activities.[2]

Although the role of laparoscopic gastrectomy has been clearly established,[3,4] robotic gastric surgery has only recently gained popularity. This is primarily because it is assumed that robotic technology can address some of the technical limitations of conventional laparoscopic gastrectomy in critical surgical steps, such as anastomosis and lymphadenectomy.[5] Indeed, the operative field during robotic surgery is magnified tenfold and allows the surgeon better optical control through the high-definition 3-D views from a mounted, stabilised surgeon-controlled camera reducing reliance on an assistant surgeon. The improved surgical dexterity and ergonomics provided by the robot system result from the instruments' 7 degrees of freedom, 90° articulation, and 540° rotation, permitting the optimal manipulation within small spaces. Many studies have investigated the potential benefits of robotic versus laparoscopic gastrectomy.[6–8] In particular, a faster surgeon's learning curve has been demonstrated for robotic gastrectomy when compared with conventional laparoscopy.[9,10] Operation time, conversion rate, and oncological adequacy are the most widely used parameters to assess the learning curve of robotic gastrectomy through a multidimensional analysis.[11] To our knowledge, no published studies have addressed the effect of the learning curve on lymph node harvesting during robotic surgery for gastric cancer.

The purpose of the present study was to evaluate, with a multidimensional analysis, the learning curve on lymph node harvesting of a single surgeon with extensive experience in laparoscopic gastrectomy over 104 robot-assisted gastrectomy procedures.

2 | MATERIAL AND METHODS

We analysed and prospectively collected data from 104 gastric cancer patients who underwent surgery with a robotic approach from June 2015 to June 2019 by a single surgeon at the Digestive Surgery Unit, Careggi University Hospital, Florence, Italy. All patients had a diagnostic and preoperative staging work-up that included upper digestive endoscopy with gastric biopsy and computed tomography of the abdomen and chest. Patients with distant metastases or pre- or intraoperative T4 lesions (i.e., local invasion of other organs such as the spleen, pancreas, or peritoneum) were excluded from the study. All patients underwent a preoperative multidisciplinary evaluation, including a nutritional risk assessment: patients with clinical T3 and/or N+ tumours were scheduled for perioperative chemotherapy (usually fluorouracil leucovorin oxaliplatin docetaxel regimen) and those with severe malnutrition were scheduled for a pre-or intraoperative position of a jejunostomy. Patients undergoing more procedures within the same surgery were excluded for the infeasibility of distinguishing surgical times for each specific procedure. The D2 lymph node dissection was performed in accordance with the Japanese Gastric Cancer Association's lymph node classification.[12] Tumours were staged according to the eighth edition of the American Joint Committee on Cancer (AJCC) tumour staging.[13] All the robotic gastrectomies were performed by a single surgeon already proficient in laparoscopic gastrectomy before initiating robotic surgery. All the procedures were performed with Xi or Si daVinci surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA). Patient demographic characteristics are summarised in Table 1. In accordance with the Helsinki Declaration, all patients were fully informed about the study and provided written consent for the investigation. The ethical committee of our University Hospital, Azienda Ospedaliero-Universitaria Careggi, reviewed and approved the present study (Approval No. 10780).

The patient was positioned in a supine, reverse Trendelenburg position with legs abducted under general anaesthesia. A nasogastric tube was positioned in all patients. The camera port was inserted with a 12-mm trocar through a left para-umbilical incision. Three 8-mm trocars for the robotic arms were inserted after pneumoperitoneum was established: one in the upper-right quadrant along the anterior axillar line, one in the upper-right quadrant along the emiclavear line, and one in the upper-left quadrant along the anterior axillar line. An auxiliary 12 mm trocar was inserted in the lower left quadrant (Figure 1). The first robotic arm, located on the patient's left side, was holding either a hook or a monopolar shear. An advanced bipolar energy device (i.e. Vessel sealer) was used for sealing and cutting short gastric vessels. A Maryland bipolar forceps and a Cadiere forceps were held in the second and third arms, respectively, on the patient's right side. Motion scaling was set at 3:1 in all patients. We used a laparoscopic linear stapler in all operations.

2.1 | Subtotal gastrectomy

The operative strategy involved 11 steps: (1) partial dissection of the left greater omentum (until the gastric short vessels) and the lymph nodes along the left gastroepiploic vessels (station n. 4sb); (2) dissection of the right omentum and the lymph nodes along the right gastroepiploic vessels (station n. 4d); (3) exposure of Henle's trunk and division of the right gastroepiploic vein and artery for dissection of infrapyloric nodes (station n. 6) (Figure 2); (4) transection of the duodenum with an articulable linear stapler (blue cartridge) just distal to the pyloric ring, followed by reinforcement of the stump with a barbed running suture; (5) division of the right gastric artery and dissection of the suprapyloric nodes (station n. 5) and nodes along the proper hepatic artery (station n. 12a) (Figure 3); (6) dissection of the nodes along the common hepatic artery (stations n. 8a and 8p) (Figures 4 and 5) as well as the proximal splenic artery (station n. 11p) (Figure 6); (7) division of the left gastric vein and artery and dissection of the nodes surrounding these vessels (station n. 7) (Figures 7 and 8) and the celiac trunk (station n. 9); (8) dissection of

TABLE 1 Clinicopathological characteristics and operative outcomes of the total and subtotal gastrectomy groups.

	Total gastrectomies $n = 21$	Subtotal gastrectomies $n = 83$
Gender (%)		
Male	15 (71.4)	45 (54.2)
Female	6 (28.6)	38 (45.8)
Age (years, mean ± SD)	72.0 ± 7.5	72.5 ± 9.0
BMI (kg/m^2, mean ± SD)	23 (±2.7)	23.5 (±2.9)
Comorbidity (%)	5 (23.8)	28 (33.7)
Perioperative chemotherapy (%)	7 (33.3)	11 (13.2)
ASA (%)		
Class I	4 (19.0)	14 (16.9)
Class II	11 (52.4)	42 (50.6)
Class III	6 (28.6)	27 (32.5)
Previous abdominal surgery (%)	1 (4.7)	7 (8.4)
Tumour location (%)		
Lower third	0 (0)	43 (51.8)
Middle third	9 (42.9)	40 (48.2)
Upper third	12 (57.1)	0 (0)
Operation time (min, mean ± SD)	360 ± 59.0	283 ± 54.2
Intraoperative complication (%)	0 (0)	0 (0)
Conversion (%)	0 (0)	0 (0)
Mortality (%)	0 (0)	0 (0)
Stage (%)		
I	4 (19.0)	36 (43.4)
II	6 (28.6)	15 (18.0)
III	11 (52.4)	32 (38.6)
No. of harvested lymph nodes (mean ± SD)	43.7 ± 21.8	48.2 ± 17.9

Abbreviations: ASA, American society of anesthesiologist score; BMI, body mass index.

the lymph nodes along the lesser curvature (station n. 3) and the right cardiac nodes (station n. 1) (Figure 9); (9) transection of the stomach on the upper third at least 5 cm above the tumour (10) mechanical intracorporeal gastrojejunal anastomosis, either Billroth II (performed in patients older than 75 years) or Roux-en-Y procedure; and (11) mechanical intracorporeal jejunal–jejunal anastomosis. The enterotomy after these two anastomoses was closed with a barbed suture. One drain was placed in the sovrapancreatic region close to the resected duodenum. The specimen was placed in a polyethylene endobag and extracted from the peritoneal cavity via the umbilical port, which was lengthened to 4–6 cm (Figure 5).

Total Gastrectomy (total gastrectomie (TG)). During TG, we completed the dissection of the left greater omentum by dividing the short gastric vessel and dissecting the station n. 4a lymph nodes. The surgical steps were then similar to those of the robotic Subtotal gastrectomy (STG) with the exception of the dissection of lymph nodes along the splenic artery (station n. 11d) (Figure 10) and the dissection of the left cardiac lymph nodes (station n. 2). A linear stapler was used to transect the distal oesophagus, and a Roux-en-Y intracorporeal side-to-side esophagogastomosis was performed. The jejunum-jejunal anastomosis was then performed either extra or intracorporeally. The enterotomy after these two anastomoses was closed with a barbed suture. One drain was placed close to the resected duodenum and another close to the esophagojejunal anastomosis. A jejunostomy was placed in those patients with severe malnutrition.

In this study, we tried to apply as many items as possible of the Enhanced Recovery After Surgery (ERAS) programme established for gastric surgery. Patients with major comorbidities were monitored in the Intensive Care Unit after surgery. In the first postoperative day, a liquid diet was started in STGs, while enteral nutrition via jejunostomy was adopted in malnourished patients. On post operative day

(POD) 3, the nasogastric tube was removed after control with oral contrast-enhanced X-ray transit or endoscopic control of the anastomosis with nasal gastroscope in TGs. In the absence of anastomotic leakage, oral intake was resumed. We used the visual analogue scale for the assessment of postoperative pain. The analgesic therapy consisted of continuous epidural infusion of Bupivacaine combined with Paracetamol i.v. The epidural infusion was interrupted at most in POD 3. Ketorolac 30 mg i.v. was used as rescue therapy. After discharge, the patients were re-evaluated 1 month later by the nutritionist and were taken into charge by the oncologist for the follow-up or postoperative chemotherapy.

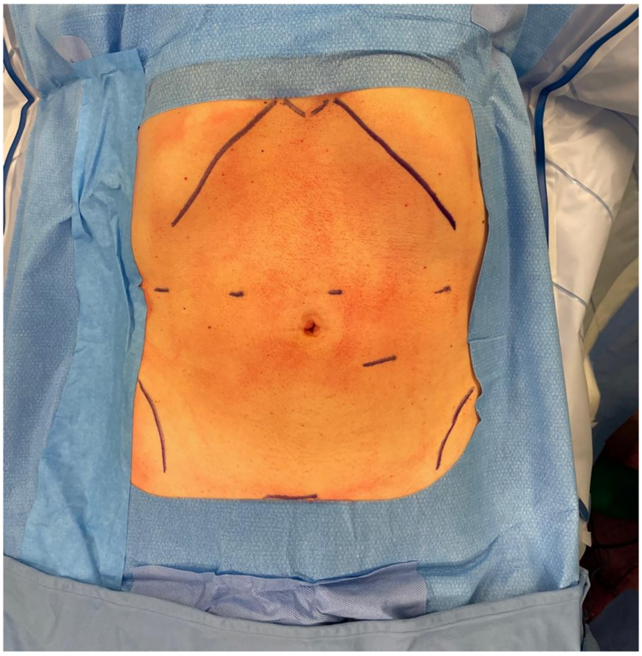

FIGURE 1 The position of the robotic trocars.

2.2 | Data collection

Data on preoperative patients' characteristics, intraoperative details, early clinical outcomes, pathological findings, and follow-up were collected and inserted in a prospectively maintained database. Surgical specimens were evaluated by dedicated pathologists experienced in digestive tract oncology. Our cohort of study includes our first experience with robotic gastrectomies at our Institution.

2.3 | Statistical analysis

The statistical analysis was carried out using R 4.1.1 (RStudio Team 2020: Integrated Development for R). Continuous variables were presented as mean ± standard deviation and range; categorical variables were described as frequency (%). A one-tailed ANOVA was used for the analysis of parametric data. A $p < 0.05$ was considered statistically significant. The cumulative sum method (CUSUM) is powerful and valuable in the early detection of trends in data.[14] We use the CUSUM plots for analysing the robotic gastrectomy learning curve according to the operative time. A polynomial regression analysis was performed to fit the number of D2 lymph nodes

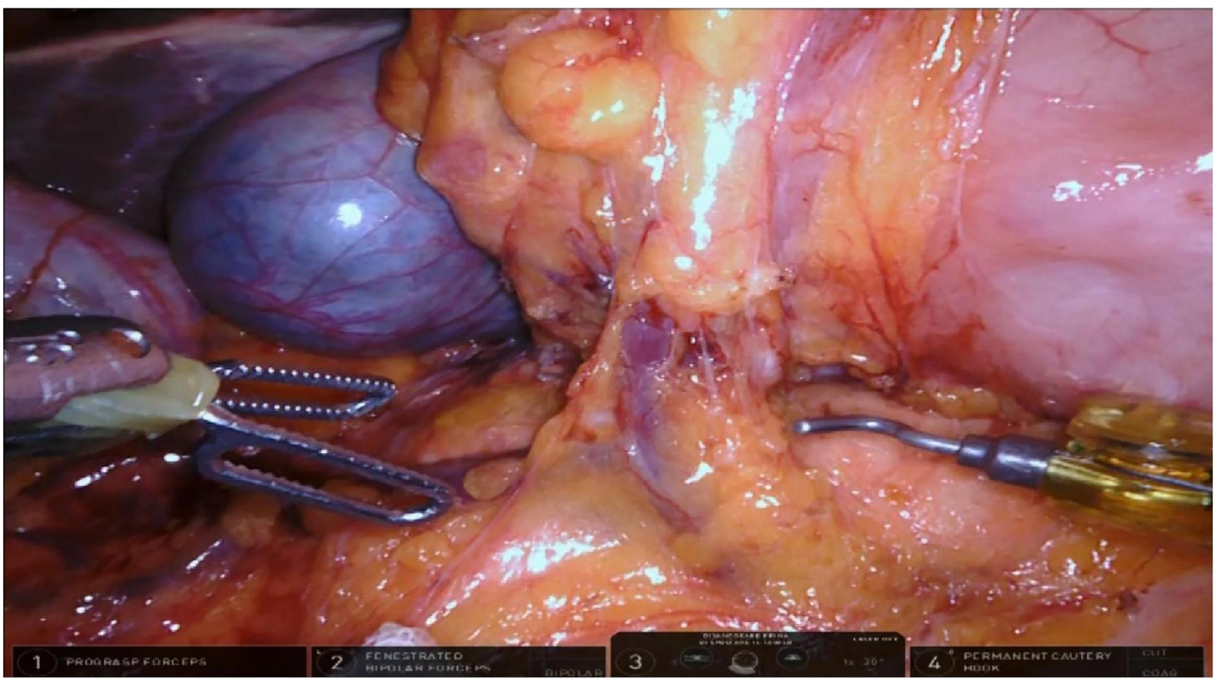

FIGURE 2 Dissection of lymph node station n. 6.

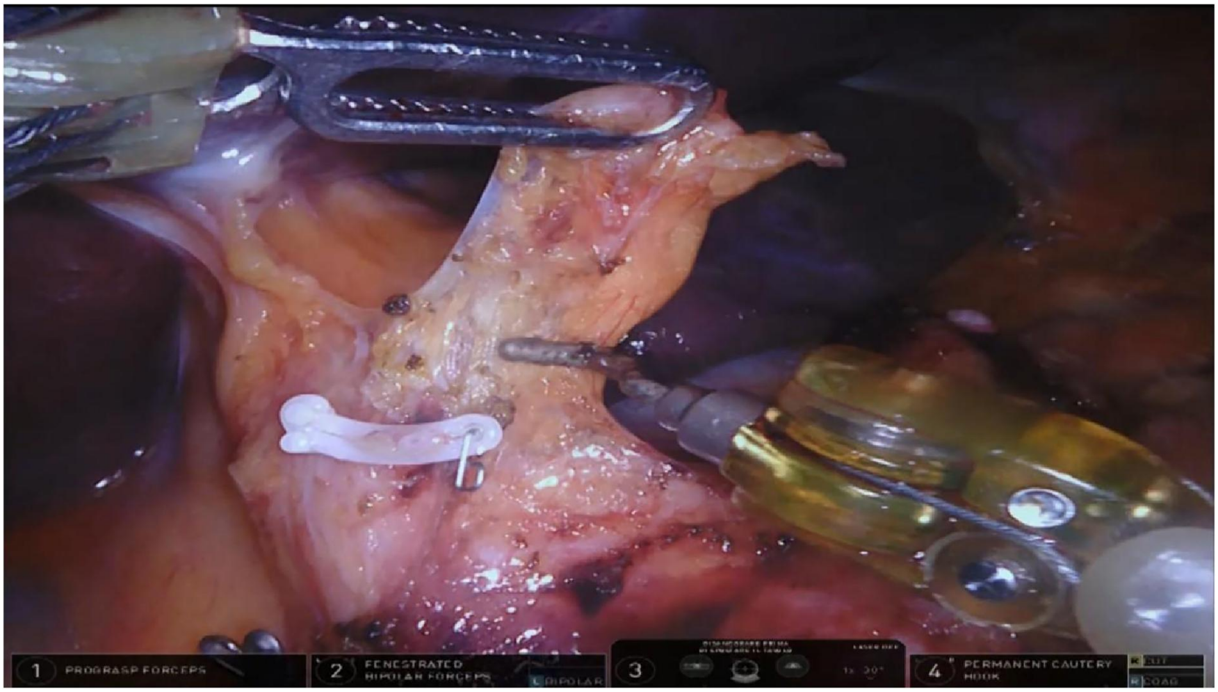

FIGURE 3 Dissection of lymph node section n. 5 and 12a.

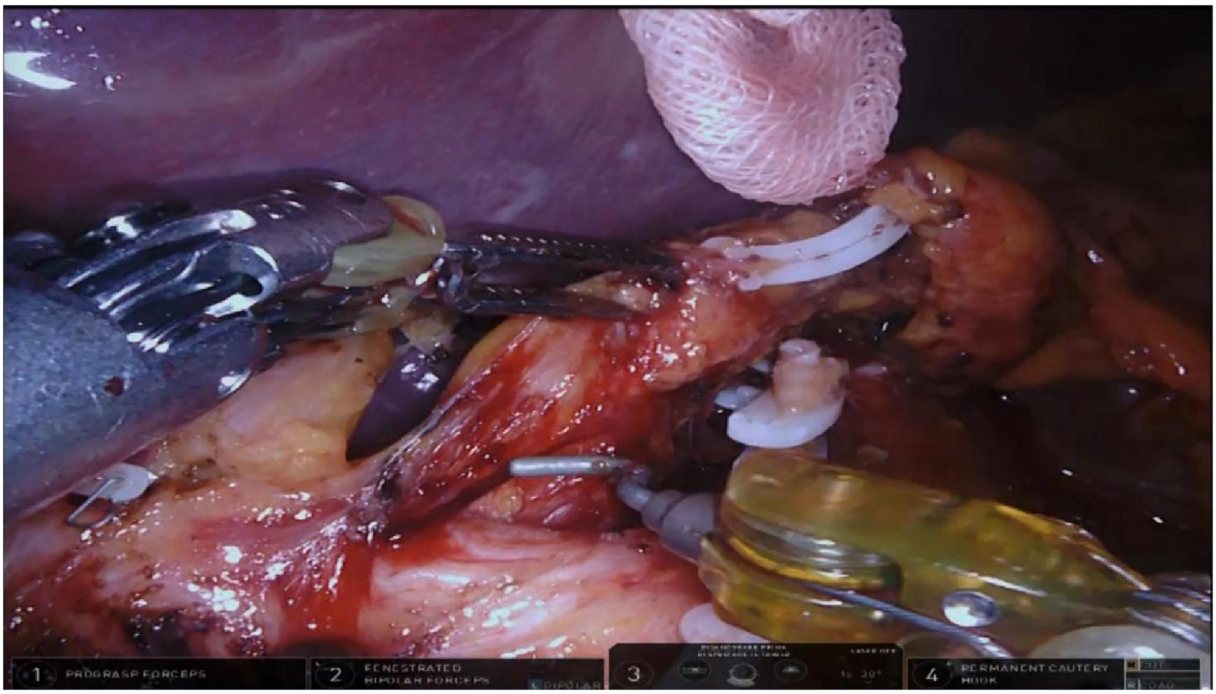

FIGURE 4 Dissection of lymph node station n. 8a.

removed during the succession. Polynomial regression describes a pattern in data that breaks from a straight linear trend. We choose the best polynomial fit based on R^2 and methicillin resistant staphylococcus epidermodis values

$$\mathrm{CUSUM}_{OPtime} = \sum_{i=1}^{n} (x_i - \mu)$$

3 | RESULTS

We performed 21 TGs and 83 STGs. A D2 lymphadenectomy was performed in all the patients. Proximal and distal resection margins were tumour-free in all patients. There were no intraoperative complications and no conversions to laparoscopic or open surgery occurred.

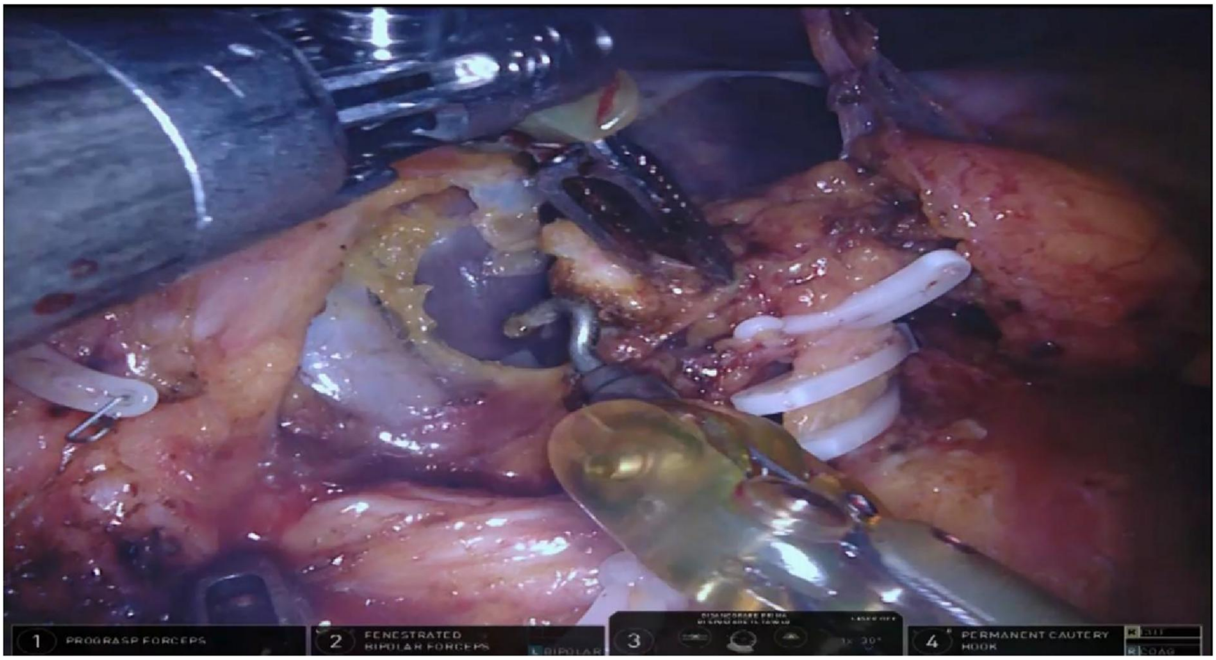

FIGURE 5 Dissection of lymph node station n. 8p.

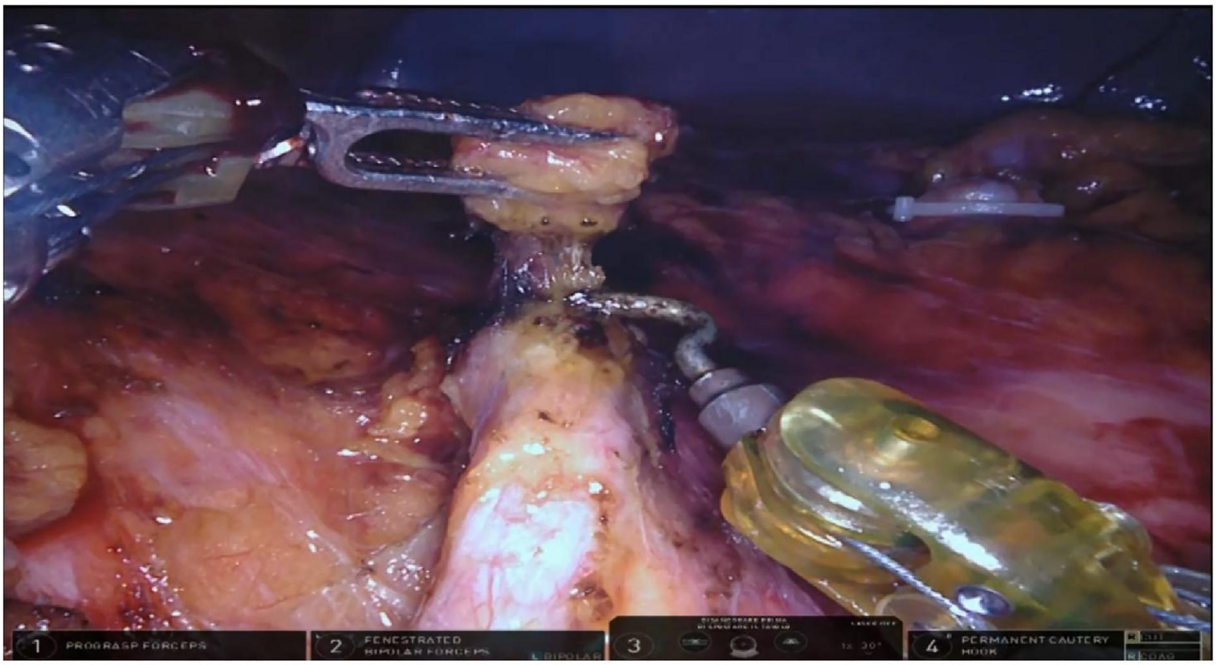

FIGURE 6 Dissection of lymph node station n. 11p.

3.1 | Total gastrectomy group

There were 15 (71%) males and 6 (29%) females. The median age was 72 years (SD, ±7.5; range, 57–85). Tumours were staged as follows: 4 (19%) were stage I, 6 (29%) were stage II, and 11 (52%) were stage III. The mean operative time was 360 min (SD, ±59.0; range, 250–500). The mean total number of harvested lymph nodes was 43.7 (SD, ±21.8; range, 14–110). Clinicopathological characteristics and operative outcomes are summarised in Table 1. We adopted a CUSUM analysis (Figure 11) that highlights an initial but constant decline in the operative time (from case 1 to case 16) without reaching a plateau. An increase in the operative time was observed from cases 17 to 21. At the same time, a second degree function described a progressive increase of harvested lymph nodes, corresponding to a linear trend without reaching a plateau (Figure 12).

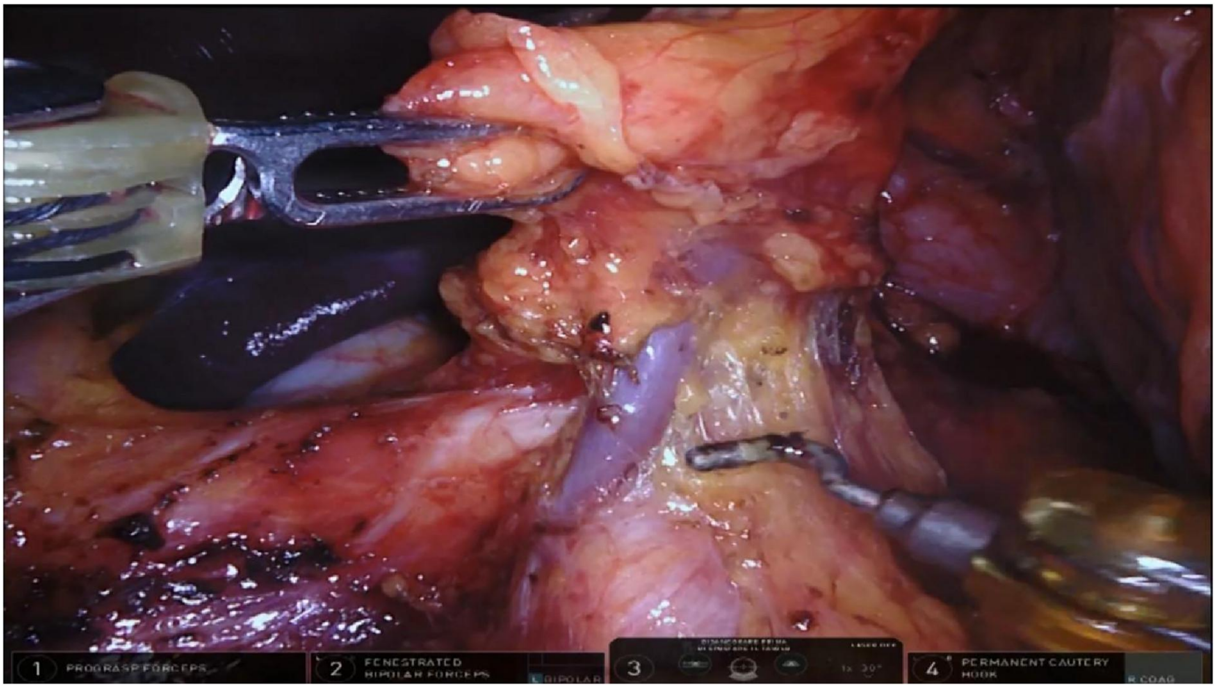

FIGURE 7 Dissection of lymph node station n. 7 (left gastric vein).

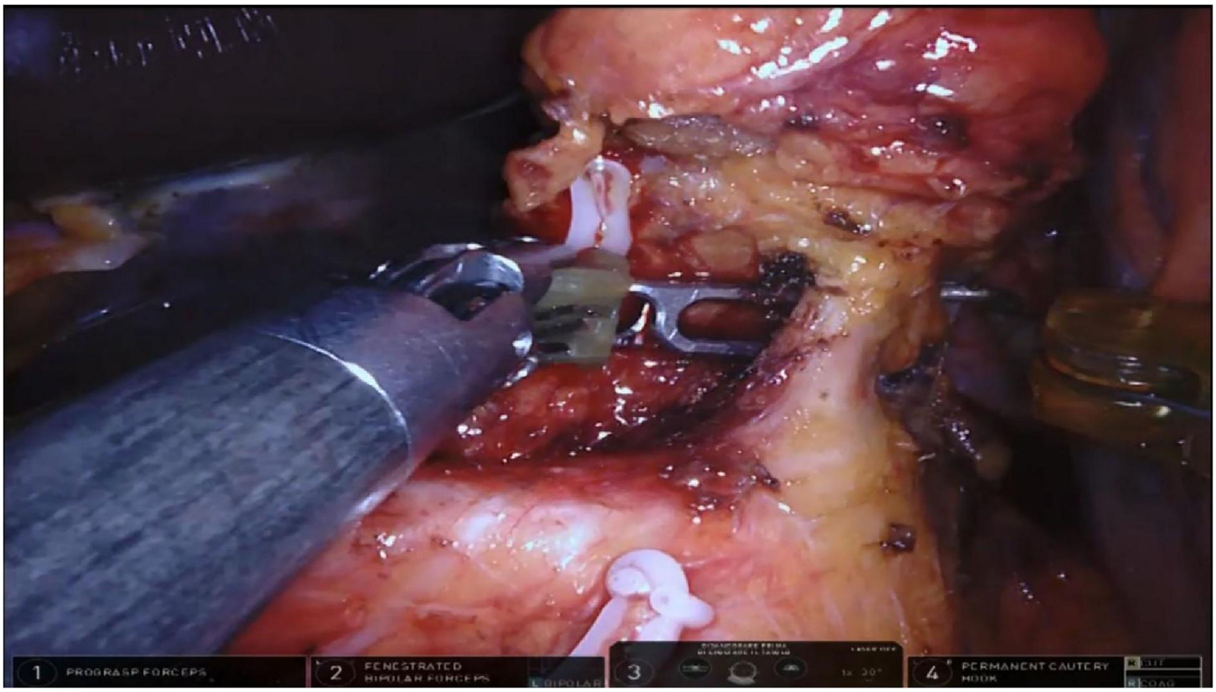

FIGURE 8 Dissection of lymph node station n. 7 (left gastric artery).

3.2 | Subtotal gastrectomy group

There were 45 (54%) males and 38 (46%) females. The median age was 72.5 years (SD, ±9.0; range, 44–90). Tumours were staged as follows: 36 (43%) were stage I, 15 (18%) were stage II, and 32 (39%) were stage III. The mean operative time was 283 min (SD, ±54.2; range, 155–420). The mean total number of harvested lymph nodes was 48.2 (SD, ±17.9; range, 18–93). Clinicopathological characteristics and operative outcomes are summarised in Table 1. The effect of the learning curve on the operative time was evaluated with a CUSUM analysis (Figure 13). At case 27, a peak is reached, after which an important time reduction occurs with a subsequent ascent phase up to case 48. After this, a progressive decrease of the curve until reaching a plateau was

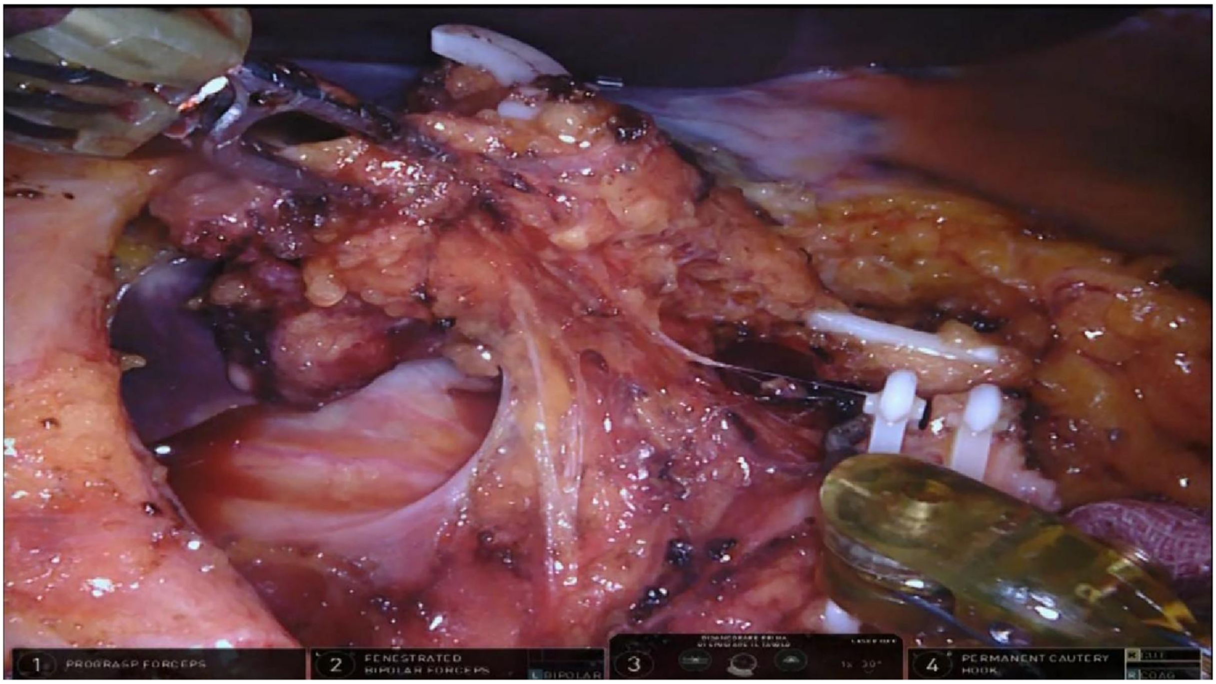

FIGURE 9 Dissection of lymph node stations n. 1 and 3.

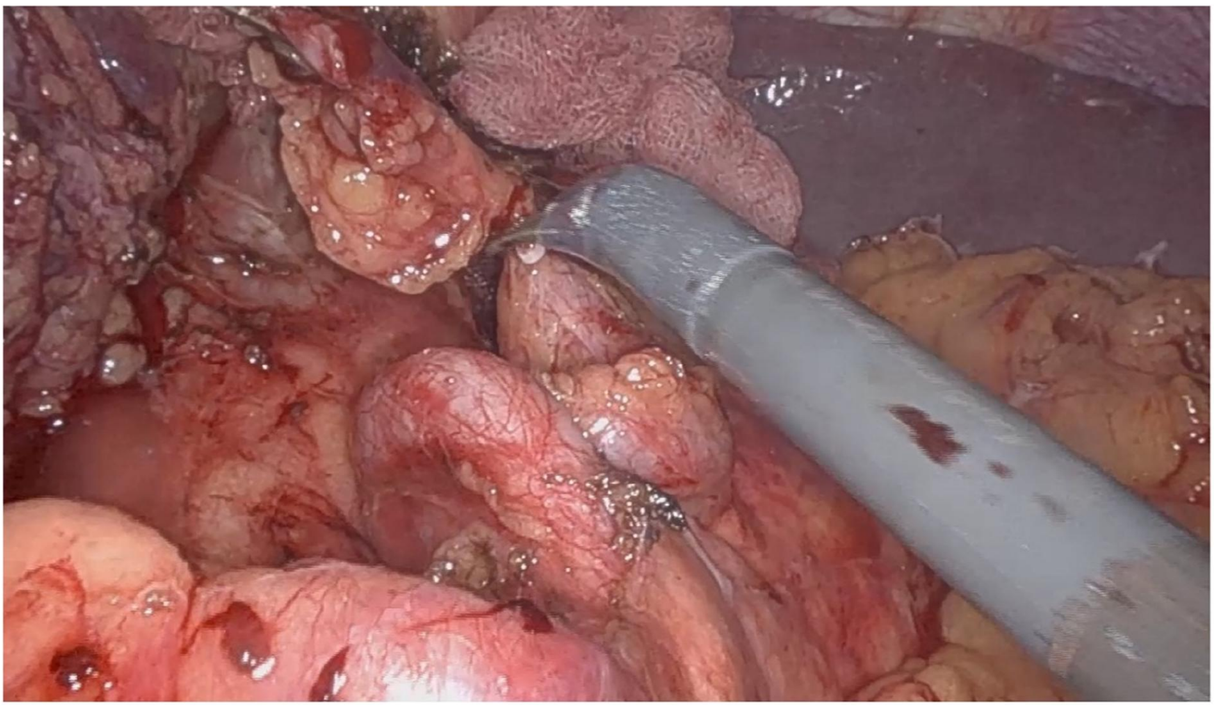

FIGURE 10 Dissection of lymph node stations n. 11d.

observed. The learning curve of operative time for STG can be divided into three different phases: an early or learning phase from 1 to 27 cases, an intermediate or proficiency phase from 28 to 48 cases, and a late or mastery phase from 49 to 83 cases. The mean operative time was 314 min (SD, ±56.7, range, 200–420) in the learning phase, 279 min (SD, ±46.9, range, 180–360) in the proficiency phase, and 263 min (SD, ±48.7, range, 155–347) in the mastery phase. A significant reduction of the mean operative time between the learning and the mastery phases (−16.3%) was observed (Figure 14). Given that body mass index (BMI) might influence the operative time, we compared the BMI values of patients operated during the learning, proficiency, and mastery phases and did not find any significant differences (23.9, 22.2 and 23.5 kg/m^2, respectively; p = nodal stations).

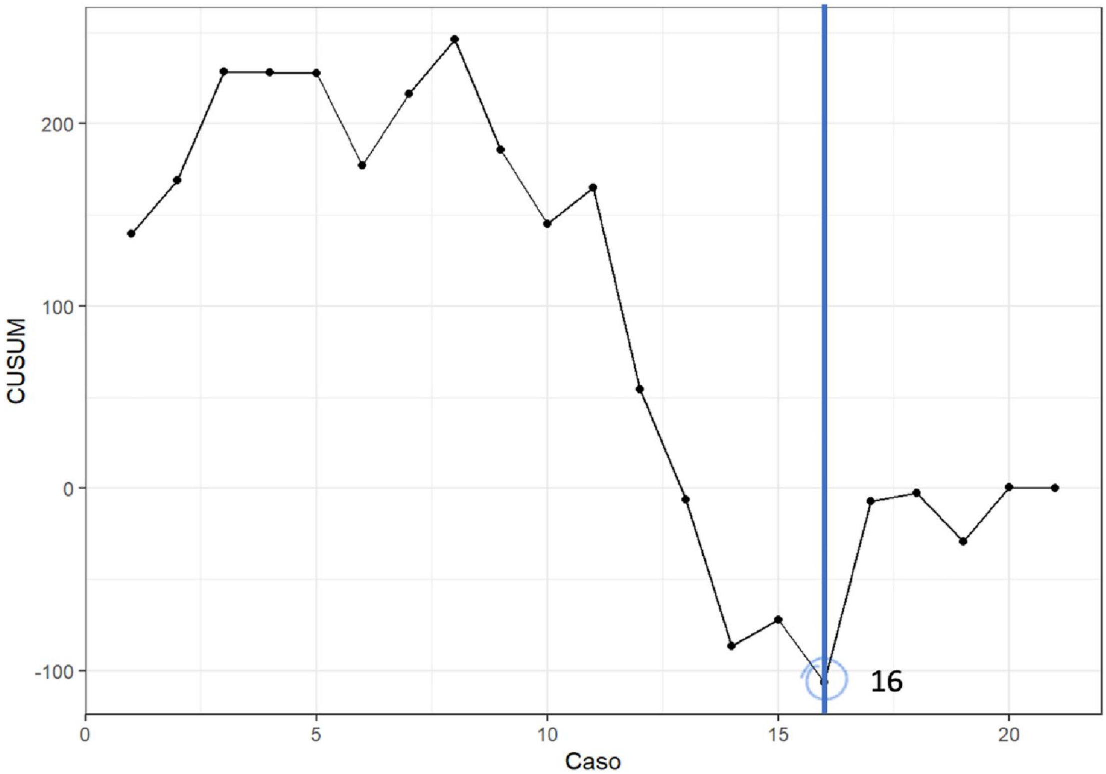

FIGURE 11 Cumulative sum method (CUSUM) analysis for total gastrectomy operative time. The vertical line located in the turning point of curvature indicates the point at which a surgeon transitions from one phase to another.

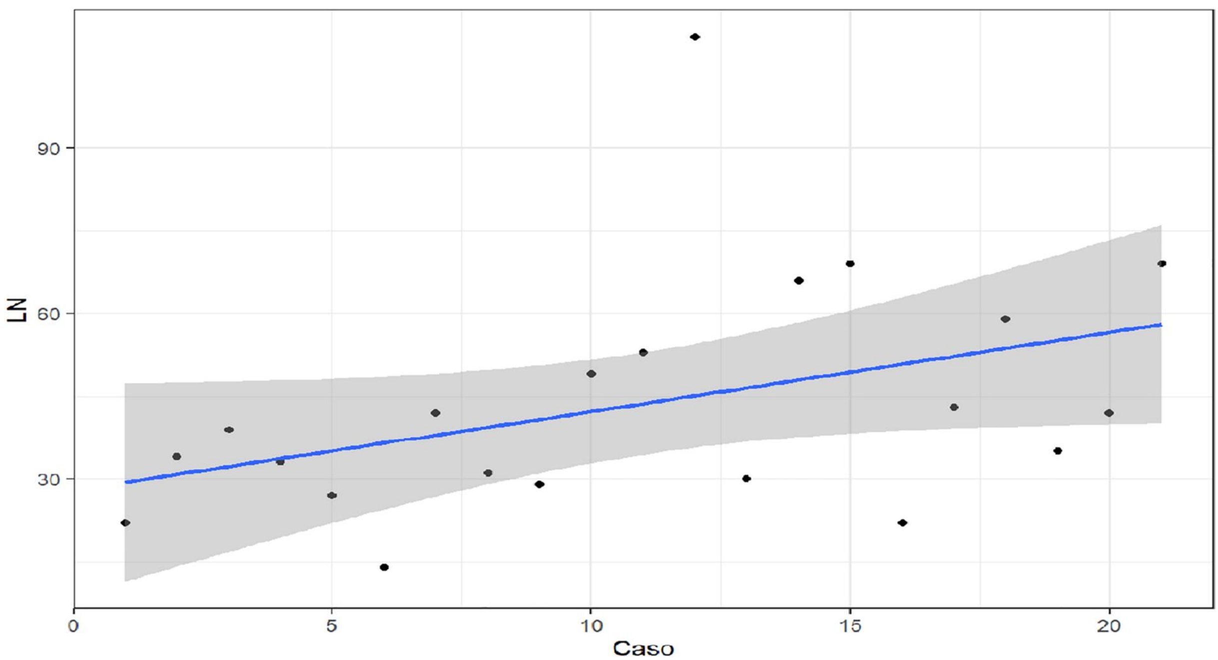

FIGURE 12 Second-degree polynomial function of harvested lymph nodes in total gastrectomy.

A third-degree polynomial function was employed to analyse the effect of the learning curve on the number of lymph nodes harvested during STG (Figure 15). We observed a progressive increase in the number of harvested lymph nodes up to case 41 and then a plateau was reached. We identified in the first phase from 1 to 41 cases a mean of 41.8 (SD, ±16.7, range, 18–92) harvested lymph nodes

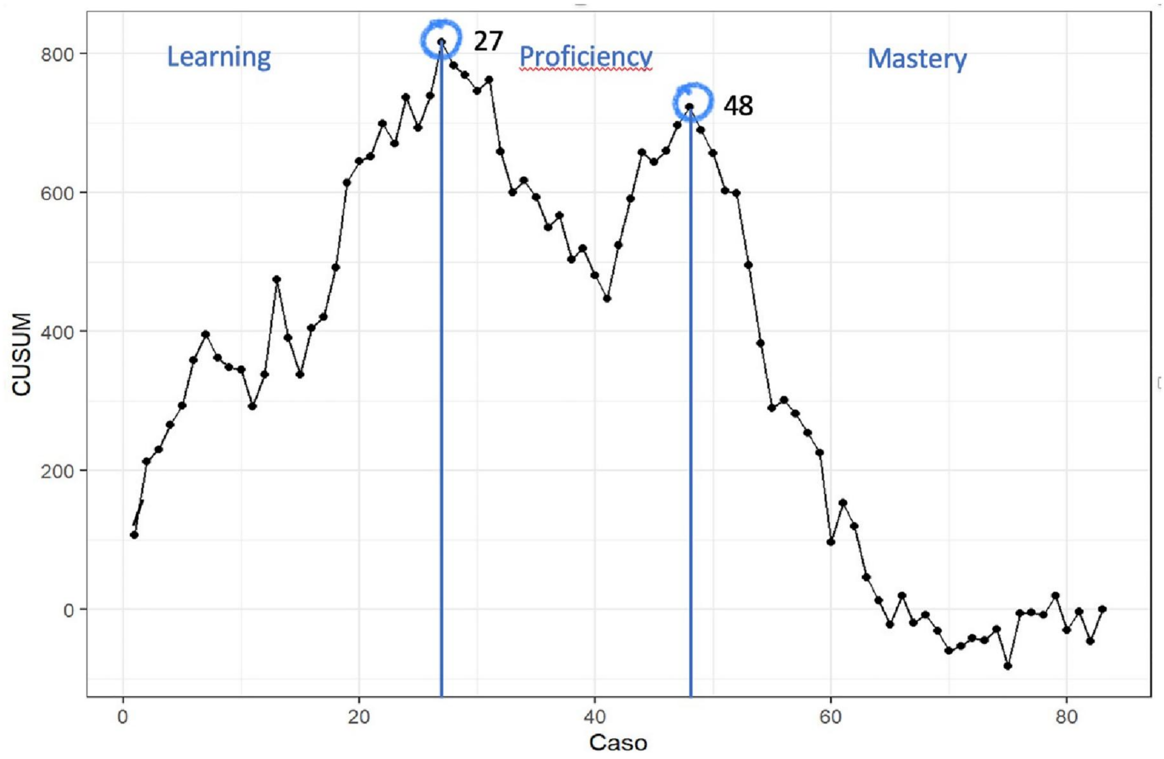

FIGURE 13 Cumulative sum method (CUSUM) analysis for subtotal gastrectomies operative time. Vertical lines located in the turning point of curvature indicate the point at which a surgeon transitions from learning to proficiency and from proficiency to mastery phases.

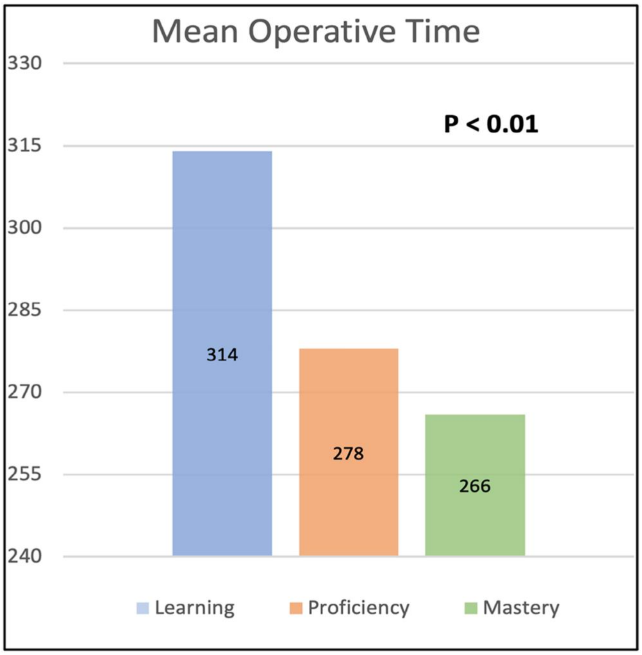

FIGURE 14 Mean subtotal gastrectomy operative time (minutes) in the learning, proficiency and mastery phases.

compared to the second phase from 42 onwards with a mean of 52.8 (SD, ±18.4, range, 25–93) harvested lymph nodes. A relative increase of mean harvested lymph nodes between the two phases of +25.6% was recorded.

4 | DISCUSSION

Laparoscopic gastric surgery is still regarded as a technically difficult procedure. Indeed, the technical threshold for performing an adequate D2 lymph node dissection remains high and needs a steep learning curve.[15,16] The robotic platform provides some technical advantages, such as an improved 3D vision, wristed instrument, tremor filtration system, and motion scaling, that can help surgeons easily perform precise lymphadenectomy and thus rapidly overcome the corresponding learning curve. Several studies have compared the learning curves of laparoscopic and robotic gastrectomy based on the operative time.[17–19] Huang et al.[20] have shown a significant reduction in the operative time after the initial 25 cases in the robotic group compared to laparoscopic groups, which seems to be in the learning curve period after 64 cases. Park et al.[21] have shown that three surgeons with sufficient experience in laparoscopic gastrectomy can quickly overcome the operative time learning curve for robotic gastrectomy, and high-quality surgery is achievable even after a small number of cases. A stable operation time was reached at 9.6 cases by surgeon A, 18.1 cases by surgeon B, and 6 cases by surgeon C.

Even Song et al.[22] have shown that experienced laparoscopic surgeons could perform robotic gastrectomy with a certain level of skill even after an initial series of only 20 consecutive cases. Kang et al.[23] have reviewed data from 100 consecutive patients who had undergone robotic gastrectomy; they conclude that robotic gastrectomy can be considered a safe and feasible procedure after 20 initial cases. In contrast with the results of the previously mentioned

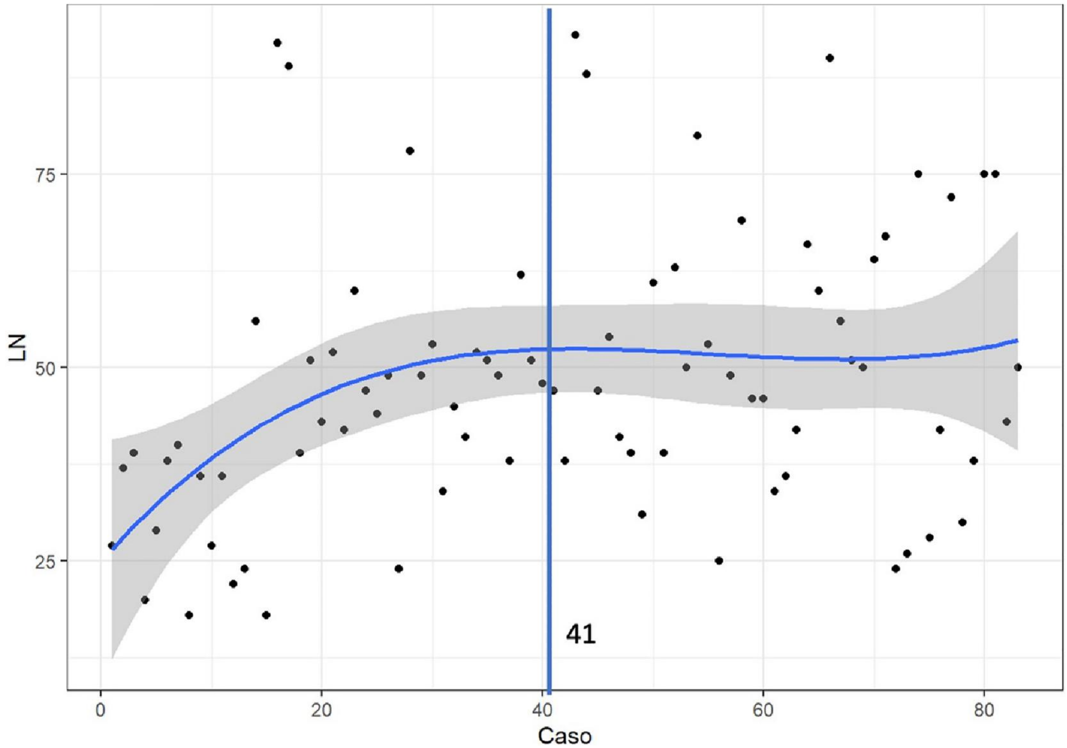

FIGURE 15 A third-degree polynomial function of harvested lymph nodes after robotic subtotal gastrectomy. A vertical line located in the turning point of curvature indicates the point at which the surgeon achieves proficiency in harvesting lymph nodes.

studies, Kim et al.[24] have found that a stable operative time during robotic gastrectomy can be reached only after 95 cases. Recently, a multicentric prospective study by Kim et al.[25] evaluated complications and operative time as dependent variables for the learning curve analysis of 502 robotic gastrectomies. The authors identified four distinct phases during the learning curve: the initial learning phase (cases 1–25), the proficiency phase (cases 26–65), the transitional or rebound phase (cases 66–88), and the mastery phase (cases 89–125). The authors have found a progressive decrease in the operative time and incidence of complications through these four phases except for the transitional or rebound one; the paradoxical increase in the complication rate in this phase has been attributed to the extension of indications and increased attempts of technically demanding procedures, such as TGs.

Our findings are in part similar to those reported by Kim et al.[25]; indeed, the CUSUM analysis of our operative time learning curve in the STG group could identify three different phases: an early phase from 1 to 27 cases; a second intermediate phase from 28 to 48 cases; and a third late phase from 49 to 83 cases. As shown in Figure 13, the early phase represented the true learning phase, as suggested by the line with a positive slope, which most probably involves those cases required for the adaptation to a new surgical system. In the proficiency phase, we found a second peak in the operative time that might be explained by some technical difficulties occurring during operations within this phase. In particular, we found and preserved an aberrant left hepatic artery arising in the left gastric artery in three patients, and the time it takes to perform the lymph node dissection along the main trunk of the left gastric artery led to a lengthening of the operative time. The third or mastery phase was most probably achieved when the surgeon demonstrated to surpass the proficiency level in terms of the ability to manage high-complexity cases and/or more technically more demanding procedures, such as a more extensive lymphadenectomy.

The analysis of the operative time learning curve in the TG group showed a progressive decline in the operative time without reaching a plateau. The minimum positive slope observed in the last cases within the TG group might be explained by a recent evolution in our esophagojejunal anastomotic technique together with a progressive increase in lymph node harvesting, in particular in the splenic hilar station. Moreover, likely, the low number of patients in this group might not permit us to draw definitive conclusions.

Lymphadenectomy is an important step in gastric cancer surgery because removing an adequate number of lymph nodes has been shown to improve staging accuracy and regional disease control.[26] The 15-year update of a Dutch trial[27] has definitively shown the superiority of D2 when compared to D1 dissection in terms of long-term survival. Evidence-based medicine and practical surgical experience now seem to move towards an international agreement. Nowadays, D2 procedure is recommended as the standard lymphadenectomy for gastric cancer treatment by the Italian[26] and European Society for Medical Oncology[28] and National Comprehensive Cancer Network[29] guidelines. Several studies have shown that the estimated learning curves to achieve proficiency for laparoscopic

STG and TG with D2 lymphadenectomy were 60–90 and 100 cases, respectively.[30–32] Recent meta-analyses comparing open, robotic, and laparoscopic gastrectomy showed no inferiority of robotic surgery in the number of retrieved lymph nodes.[33,34] Interestingly, a recent large meta-analysis on 17 712 patients by Guerrini et al.[35] has shown a significantly higher mean number of retrieved lymph nodes after robotic gastrectomy when compared to the laparoscopic approach.

To our knowledge, this is the first study to evaluate the number of harvested lymph nodes as a dependent variable for learning curve analysis in the field of robotic gastrectomy. In the STG group, the estimated proficiency in lymph node harvesting was achieved after 41 cases. Indeed, the mean number of lymph nodes retrieved in the first phase (52.8; SD, 18.4) was higher than in the second (41.8; SD, 16.7). Interestingly, the mean value in the first phase was much higher than the suggested number (i.e., 25)[36–38] for adequate D2 lymphadenectomy, demonstrating that the learning curve of robotic STG has no effect on the procedure's oncological adequacy. Unfortunately, the plateau of the learning curve based on harvested lymph nodes was not reached in the TG group, and this is most likely due to the small sample analysed.

The present study has the main limitation of having been based on the experience of only one surgeon skilled in laparoscopic gastrectomy. Our results should be validated by other studies preferably involving surgeons without long-standing experience in laparoscopic gastric surgery.

In conclusion, this study suggests that robotic gastrectomy is a complex procedure with a significant multiphasic learning curve. Technical immaturity is likely to affect the surgical outcome in terms of operative time even if the robotic learning curve seems to be more rapid than that of conventional laparoscopy. Most importantly, our results suggested that the robotic technique can provide oncological adequacy in terms of lymph node harvesting even in the very first phase of the learning curve.

AUTHOR CONTRIBUTIONS

Fabio Staderini and Fabio Cianchi designed the study; Giuseppe Barbato, Andrea Bottari, and Laura Fortuna wrote the manuscript. Francesco Coratti, Fabio Staderini, and Fabio Cianchi collected the data. Edda Russo edited the manuscript. Lorenzo Stacchini and Edda Russo performed the statistical analysis. Francesco Giudici and Giampiero Indennitate revised the manuscript. Edda Russo, Francesco Giudici, and Fabio Cianchi provided funding acquisition.

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The authors have nothing to report.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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