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Learning curve of robotic-assisted transabdominal preperitoneal repair (rTAPP) for inguinal hernias

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Abstract
Background Learning curves describe the rate of performance improvements according to the surgeon's caseload, followed by a plateau where limited additional improvements are observed. The aim of this study was to evaluate the learning curve for robotic-assisted transabdominal preperitoneal repair (rTAPP) for inguinal hernias in surgeons already experienced in laparoscopic TAPP.
Methods The study was approved by local ethic committee. Male patients undergoing rTAPP for inguinal hernia from October 2017 to December 2019 at the Bellinzona Regional Hospital were selected from a prospective database. Demographic and clinical data, including operative time, conversion to laparoscopic or open surgery, intra- and postoperative complications were collected and analyzed.
Results Over the study period, 170 rTAPP were performed by three surgeons in 132 patients, and mean age was 60.1 ± 13.7 years. The cumulative summation (CUSUM) test showed a significant operative time reduction after the 43rd operation, once the 90% proficiency on the logarithmic tendency line was achieved. The corrected operative time resulted 71.1 ± 22.0 vs. 60.8 ± 13.5 min during and after the learning curve ($p = 0.011$). Only one intraoperative complication occurred during the learning curve and required an orchiectomy. Postoperatively, three complications (one seroma, one hematoma, and one mesh infection) required invasive interventions during the learning curve, while no cases were recorded after it ($p = 0.312$).
Conclusion Our study shows that the rTAPP, performed by experienced laparoscopists, has a learning curve which requires 43 inguinal hernia repairs to achieve 90% proficiency and to significantly reduce the operative time.

Keywords Robotic · Inguinal · Hernia · Groin · Learning curve · TAPP

The learning curve (LC) can be applied in medicine to describe the rate of progress in gaining experience or new skills [1]. Surgeons typically exhibit improvements in performance over time, followed by a plateau where minimal/limited additional improvements are observed [1]. Generally, surgical LCs are measured as a change in an operative variable (which can be considered a surrogate of surgeons' performance) over a series of procedures. Studies investigating LCs for surgical procedures are of utmost importance, as LCs have substantial impact on surgical metrics, clinical outcomes, surgical teaching, and cost–benefit decisions [2, 3].

New techniques in minimally invasive hernia surgery have shown to be promising and, nowadays, many abdominal wall hernias are approached robotically [4–7]. Waite et al. [8] published a smaller series of robotic transabdominal preperitoneal repair (rTAPP) vs. laparoscopic transabdominal preperitoneal repair (lapTAPP) that showed improved postoperative pain and a longer operating time in the robotic group, while costs resulted similar.

The aim of this study was to assess the LC and to predict the number of cases required by expert surgeons in lapTAPP to become proficient in rTAPP.

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Materials and methods

Written consents were administered to all patients and the local ethic committee approved the study (Comitato Etico Cantonale Ticino n. 2019-01132 CE3495).

Patient's selection, clinical data, and follow-up

From December 2017 to December 2019, male patients who underwent rTAPP for symptomatic inguinal hernias were selected from a prospectively collected database on robotic-assisted surgery at Bellinzona Regional Hospital, a tertiary teaching center. Patients treated as an emergency and those with femoral hernias were excluded. Data included demographic and clinical characteristics, operative time (OT), conversion rate to laparoscopic or open surgery, operating surgeon, intra- and postoperative complications (according to Clavien–Dindo classification [9]).

The operating surgeons were considered expert in lap-TAPP with a caseload of more than 150 cases. In addition, before starting with rTAPP they attended specific robotic surgery training programs and performed exercises on the robotic surgery virtual simulator available at our institution (Mimic dV-Trainer—Mimic Technologies, Inc., Seattle, WA).

All patients were followed up at 10 and 30 days after surgery and contacted by telephone during the long-term follow-up to fill up a questionnaire to determine the incurring of later complications as recurrence or chronic pain and the time needed to return to daily activities.

The primary outcome was the assessment of the LC in rTAPP, i.e., the number of operations required to achieve 90% proficiency in obtaining a significant reduction in OTs. The latter was defined as the time required from the first skin incision to skin suture. Secondary outcomes were differences during and after the LC of intra- and postoperative complications, rate of conversion, time to return to daily activities, chronic pain, and recurrence.

Surgical technique

From study begin to October 2019, we used the Da Vinci® Si (Intuitive Surgical) to perform the rTAPPs, while from November 2019 we used the Xi system. The Si system was docked from the patient's legs and the Xi system from the right side. Access to the peritoneal space was obtained with a mini-open technique at the umbilical level. After the abdomen was inflated with CO_2, additional two robotic trocars were placed bilaterally on the pararectal line at umbilical level. After the incision of the peritoneum at least 5 cm above the hernia defect, the preperitoneal space was dissected, the spermatic cord identified and preserved and the hernia reduced. Afterward, a light-weight mesh was laid and fixed laterally and medially with absorbable stitches. In case of bilateral hernias, the procedure is repeated contralaterally. The peritoneum closed with a running suture and the robot undocked.

Statistical analysis

As statistical software, we used MedCalc Statistical Software version 19.3.1 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2020). Descriptive statistics were presented as absolute frequencies for categorical variables and mean with standard deviation (SD) for continuous variables. The comparisons of dichotomous values were performed with the chi-squared test, while continuous variables between groups were compared with Student t-test. The OT was estimated dividing bilateral hernias by 2 and subtracting 25.5 min to unilateral hernias (corresponding to mean time difference from unilateral and bilateral hernias estimation). OTs were calculated for each surgeon and a logarithmic tendency line was used to estimate the OT trend as a function of the performed surgical cases. The cumulative summation (CUSUM) test was used to assess the LC according to seniors' OT mean and as benchmark [10]. Finally, OTs during and after the LC were compared to validate the logarithmic tendency line and CUSUM results.

Results

At our institution, three surgeons performed 170 consecutive rTAPPs in 132 patients. All patients were male and mean age was 60.1 ± 13.7 years. Patients' characteristics are reported in Table 1. The comparison between groups during and after the LC showed that they were comparable in terms of preoperative characteristics.

The CUSUM analysis (Fig. 1) showed an OT reduction after the 43rd operation. Similarly, the logarithmic tendency line showed that 90% proficiency in OTs was reached after the 43rd operation (Fig. 2), being 71.1 ± 22.0 vs. 60.8 ± 13.5 min the corrected OT during and after the LC ($p = 0.011$). OT for unilateral rTAPP was significantly shorter after the LC phase (102.8 ± 36.2 vs. 86.3 ± 20.0, $p = 0.028$), while in case of bilateral hernias only a slight OT improvement was noted (147.5 ± 28.9 vs. 136.1 ± 22.5, $p = 0.309$). After exclusion of bilateral rTAPP, the CUSUM analysis for unilateral rTAPP only showed an OT reduction after the 25th operation and 19 min improvement in OT was noted (103.9 ± 23.9 vs. 84.9 ± 11.9 min before and after the LC, $p = 0.011$).

Intraoperatively, only one complication occurred. During an inguinoscrotal hernia reduction, testicular vessels have

Table 1 Patients' characteristics

Hernias	Learning curve $n=97$ $n=129$	After learning curve $n=35$ $n=41$	p
Age, years (SD)	60.1 (14.1)	60.1 (12.9)	0.989
Body mass index, kg/m^2 (SD)	26.3 (3.0)	25.4 (3.0)	0.134
Comorbidities			
Arterial hypertension, *n* (%)	32 (33.0)	8 (22.9)	0.265
Cardiac disease, *n* (%)	17 (17.6)	7 (20.0)	0.746
Pulmonary disease, *n* (%)	5 (5.2)	1 (2.9)	0.597
Diabetes mellitus, *n* (%)	6 (6.2)	1 (2.9)	0.453
Recurrent hernia, *n* (%)	6 (6.2)	5 (14.3)	0.139

Dichotomous variables are expressed as number with percentage. Continuous variables are expressed as mean with standard deviation (SD)

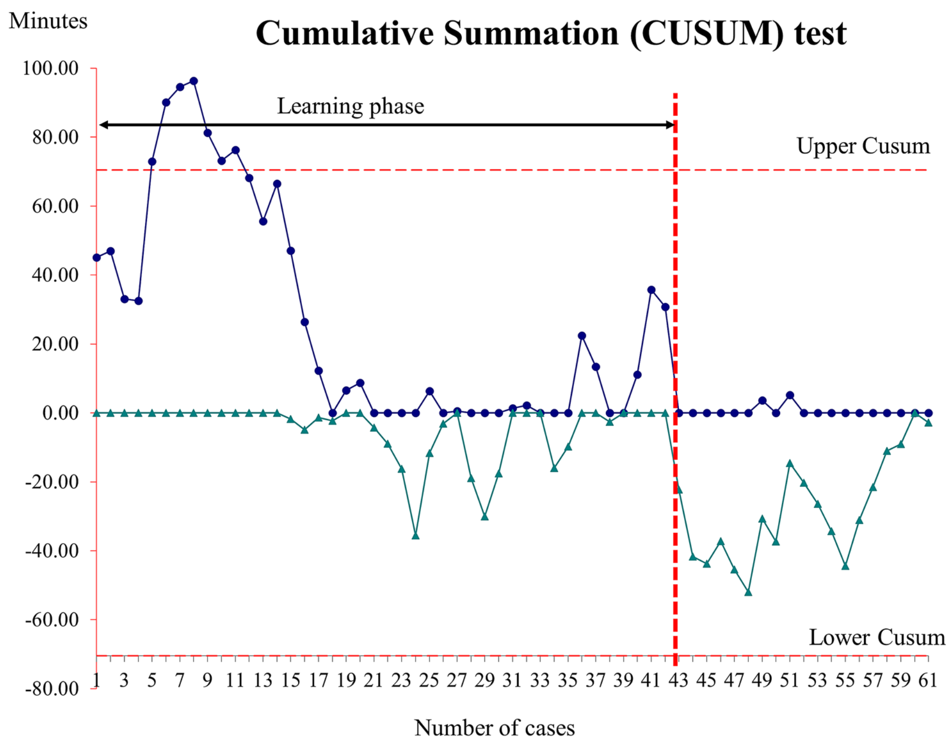

Fig. 1 CUSUM analysis showing the operative time reduction after the learning phase (Color figure online)

been injured and an orchiectomy had to be performed. No cases of conversion to open surgery or laparoscopy were recorded.

Postoperatively, three complications Clavien–Dindo III–IV occurred, all during the LC. One case of seroma and one hematoma were radiologically drained and a case of mesh infection required a surgical revision and the mesh was removed. Twelve complications Clavien–Dindo I–II occurred during the LC and five thereafter ($p=0.800$). In particular, one case of seroma, five bleedings/hematomas, two urinary retention, one surgical site infection, and three cases of chronic pain were recorded during the LC, while after it one case of hematoma, two urinary retention, one surgical site infection, and one case of chronic pain were noted.

A mean follow-up of 11.7 months was available for 119 (90%) patients, 14.3 ± 5.0 months and 4.2 ± 1.6 months during and after the LC, respectively. No cases of recurrence have been documented. Chronic pain incidence and return to daily activities did not differ among groups. Details are reported in Table 2.

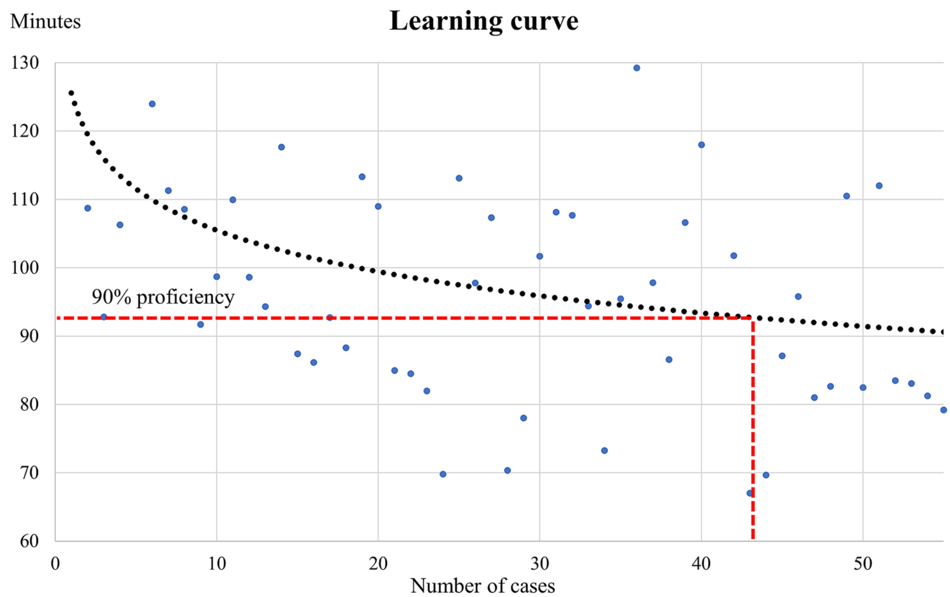

Fig. 2 Distribution of operative times according to the number of cases. The logarithmic regression line identifies the 90% proficiency at 43 cases (Color figure online)

Table 2 Intra- and postoperative results

Hernias	Learning curve $n=97$ $n=129$	After learning curve $n=35$ $n=41$	p
Corrected OT, min (SD)	71.1 (22.0)	60.8 (13.5)	0.011
OT for unilateral hernias, min (SD)	102.8 (36.2)	86.3 (20.0)	0.028
OT for bilateral hernias, min (SD)	147.5 (28.9)	136.1 (22.5)	0.309
Intraoperative complications	1 (1.0)	0	0.548
Conversion to open surgery or laparoscopy	0	0	1.000
Postoperative complications	16 (16.5)	5 (14.3)	0.839
Grade I–II Clavien–Dindo, *n* (%)	12 (12.4)	5 (14.3)	0.800
Grade III–IV Clavien–Dindo, *n* (%)	3 (3.1)	0	0.312
Seroma, *n* (%)	2 (2.1)	0	0.389
Bleeding/hematoma, *n* (%)	6 (6.2)	1 (2.9)	0.473
Surgical site infections, *n* (%)	2 (2.1)	1 (2.9)	0.792
Urinary retention, *n* (%)	2 (2.1)	2 (5.7)	0.300
Chronic pain, *n* (%)	4 (4.1)	1 (2 .9)	0.746
Recurrence, *n* (%)	0	0	1.000
Return to daily activities, days (SD)	2.5 (5.9)	2.3 (2.5)	0.901

Dichotomous variables are expressed as number with percentage. Continuous variables are expressed as mean with standard deviation (SD). Operative time (OT)

Discussion

To the best of our knowledge, this is the first report on the LC in rTAPP performed by surgeons already skilled in lap-TAPP. In our study, a significant performance in reducing OTs is reached after performing 43 cases.

The concept of ‘learning curve’ was introduced in aircraft manufacturing by Theodore Paul Wright in 1936 [11], who described a theory for costing the airplane production. In the 1980s, this term was introduced to healthcare sector, after the beginning of minimally invasive surgery era. The surgical LC can be defined as ‘The time taken and/or the number of procedures an average surgeon needs to be able to perform a procedure independently with a reasonable outcome’ [12], such as OT, recurrence incidence, or time to daily activities. The LC can be influenced by several factors, such as the background knowledge of anatomy, surgeon’s manual dexterity, teaching program and many other [13]. Training on surgical inanimate models and animal tissue has been shown to help and facilitate the learning process [13].

In surgery, the introduction of new techniques and instrumentation can have a relevant influence on patients' safety, surgical training, and hospital costs. Therefore, analyzing the surgical LC of a specific robotic procedure is a matter of interest not only from a clinical and educational point of view, but from a financial one as well. In fact, economic considerations are unavoidable, giving the high costs associated with robot-assisted surgery and the increased financial pressure on hospitals [4–8].

However, defining and measuring a LC is difficult because of multiple confounders related to the examined surgeons, to the operated patients, to the specific procedures, and to the institution where the surgery takes place [14].

In addition, the proper LC outcomes have to be identified. In their systematic review of LC in robot-assisted surgery, Soomro et al. found time-based metrics as assessment tool for the LC in 42 of the 49 studies [2]. In another review, Kassite et al. analyzed 166 studies with 46 endpoints reported, among which the total operating time and the total robotic times were used as outcomes in 21 and 2 studies, respectively.

We found it appropriate to measure the LC using the OT as primary outcome and the conversion rate to open surgery, intra- and postoperative complications, chronic pain and recurrence as secondary ones.

While the LC of rTAPP has been so far not investigated, plenty is described about the LC of laparo-endoscopic inguinal hernia repair, as lapTAPP and especially TEP are considered more difficult to learn than the open approach because of a limited working space and different appreciation of the usual anatomic landmarks seen through an anterior approach [9, 15, 16]. This is thought to influence the caseload needed to overcome the LC [3].

Achieving the LC in laparoscopic inguinal hernia repair depends on several intra- and postoperative factors such as OT, conversion rate, and number of complications [17, 18]. The LC for lapTAPP is a controversial topic and many authors described a highly variable number of cases to be performed before considering completed the LC. The International Endohernia Society (IEHS) guidelines are unclear on this topic [19–21] and stated that the LC for lapTAPP may range from 13 to more than 200 cases. This high variability may depend on heterogeneity and the context in which studies were carried out, in particular, the number of hernia repairs performed per year, patient selection, standardization of the technique, and the training program itself [22, 23].

In our experience, 43 cases were demonstrated by the CUSUM analysis to be necessary to complete the LC and to achieve 90% proficiency on OTs. Taking into account unilateral rTAPP only, 25 cases were necessary to complete the LC. However, this result may be influenced by the caseload of bilateral rTAPP within this learning phase. In fact, the skills acquired while performing bilateral rTAPPs are plausibly expected to directly improve the performance in unilateral rTAPP, so that we believe that 43 cases may more reliably reflect the actual learning caseload. In unilateral rTAPP, a mean 16.5 min improvement after the LC was noted and resulted significant. On the contrary, the 11.4 min improvement in bilateral rTAPP resulted not significant. The reason should be sought in the relatively small amount of bilateral rTAPP after the LC (eight cases) in our series. After having completed the LC, in our experience OTs seem to be comparable to other series published in the literature. In particular, Gamagami R et al. [24] reported 74.0 ± 30.1 min, Dickens EO et al. [25] reported 71.8 ± 30.0 min, and Charles EJ et al. [26] reported 105 ± 17.5 min in rTAPP. However, in our series a significant amount of OT can be justified by the use of light-weight non-self-fixating mesh that were fixated with re-adsorbable stitches to keep the mesh in place. The incidence of complications did not vary during and after the LC, though numbers were relatively low and a tendence, even not significant, in having more complications during the LC was noted. Similarly, return to daily activities, chronic pain and recurrence did not differ between groups.

In our study, the number of procedures needed to complete the learning time was relatively low compared to other studies involving inexperienced surgeons. This is understandable, as we considered surgeons who already mastered the standard lapTAPPs and were at the beginning of the LC of robotic surgery, so benefiting from the advantages of a good knowledge of anatomy, landmarks, and surgical steps.

This study has some limitations. We performed a retrospective analysis of a prospectively collected database with a limited number of patients. As some studies described a significant improvement in inguinal hernia surgery after up to 200 cases, one may argue that 170 hernia repairs in male patients for three operators is not enough. Nevertheless, an OT improvement can be demonstrated after 43 cases already, and, according to the logarithmic transformation and the CUSUM analysis, minimal reduction on OTs should be expected as the caseload dramatically increases, putting the cutoff of cases not far from 43. The three surgeons participating the study were considered expert in laparoscopic TAPP, having performed much more than the 65 cases needed for the LC [23]. The low surgeon's year caseload may also represent a limitation; however, Köckerling et al. [27] defined small caseload as less than 25 laparoscopic inguinal hernia repair per year. Authors reported a slightly higher recurrence rate and pain on exertion in patients operated on by surgeons with small caseload, while other postoperative outcomes resulted comparable. Similarly, Maneck M et al. [28] reported higher recurrence rate in low-volume hospitals (up to 75 inguinal hernia repairs per year) as compared to high-volume hospitals (≥ 126 inguinal hernia repairs per year), while no other outcomes seemed to be affected. In our series all surgeons overcome the reported cutoff of 25 cases per year and altogether more than 200 inguinal hernias are treated yearly in our center, making these limitations unlikely. A comparison with lapTAPP cases would be interesting to analyze the impact of introducing rTAPP, though unavailable data on the three surgeons' historical cases makes this analysis not performable.

Patients' characteristics, which may also represent a source of bias as they influence postoperative outcomes, resulted comparable among groups. Another limitation is the lack of IEHS classification [5], which considers the hernia anatomic localization and dimension. Large hernias are expected to require more OT and a homogeneous distribution during and after the LC is desirable to validate our results. Even missing, we do not expect that the IEHS classification would substantially influence our primary endpoint and we believe that our series reliably reflects a real-life surgical setting. Another procedure-related confounder is represented by the inclusion of unilateral and bilateral hernias requires an OT correction and is, therefore, artificial. The absolute number of minutes required for a rTAPP does not correspond to a real OT, however, it is of utmost importance for statistical analysis. Another source of bias is represented by the level of competence of the table assistant and operating room nurses that, of course, has an influence on some components of the OT (i.e., docking and instruments' exchange times). It would have also been interesting to analyze docking time separately in order to assess how surgical steps improve during the LC.

Then, the number of surgeons involved was limited; a larger analysis would be desirable to confirm our findings. This seems to be a generalized bias in the articles on LC of robot-assisted surgery. In the review of Soomro et al. [2], most of the 49 considered studies included < 5 robotic surgeons.

Finally, further surgeon-related confounders have to be considered. In fact, our three surgeons had previous proper surgical experience in both open hernia surgery and lapTAPP and were unexperienced in robotic surgery. However, they had all taken part in a robotic surgery training program sponsored by Intuitive Surgical before the started to perform rTAPP. In addition, a robotic surgery virtual simulator is available at our institution (Mimic dV-Trainer—Mimic Technologies, Inc., Seattle, WA) and was used for training sessions from our three surgeons.

In conclusion, our study shows that the rTAPP, performed by experienced laparoscopists, has a LC which requires 43 inguinal hernia repairs to achieve 90% proficiency and to significantly reduce the operative time.

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Compliance with ethical standards

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