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Learning curve analysis

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AIM: *Totally extra-peritoneal (TEP) repair technique is one of the most used laparoscopic techniques for inguinal hernia repair. This study aimed to investigate the learning curve of technique and phases involved to help guiding novice learners.*
MATERIALS AND METHODS: *Box-Jenkinson method for time series analysis and moving average method for standard deviation (SD) analysis and were employed for group determination and learning curve evaluation. Three individual groups were created based on the statistical analysis results and each group has been evaluated to determine the accuracy of the learning phases.*
RESULTS: *The learning phases of the technique were classified as: (1) Phase 1 (1st-28th case), (2) Phase 2 (29th-98th case), and Phase 3 (after 99th case). Operation time was statistically different between each phase. In addition, the number of intra-operative incidents was also found to be statistically different between phase-1 and other phases, with phase-1 being unfavorable.*
CONCLUSION: *To our knowledge, this is the first study that describes phases of learning the TEP hernia repair and compares these phases in terms of complication and operative time. We recommend that novice surgeons take extra care in terms of the selection of their patients during their first 28 cases and broaden their patient spectrum after the 63rd case. The learning curve of the TEP technique has three phases and each step must be carefully considered for patient selection so that milestones can be achieved as smoothly as possible without any complications.*

KEY WORDS: Hernia, Laparoscopy, Learning curve, Moving average, TEP

Introduction

Inguinal hernia is one of the most diagnosed surgical pathologies in the world and surgery is the only option for treatment [1,2]. Following the first demonstration of anatomical repair by Bassini, the treatment options have changed significantly and advanced over time [3].
Especially, Lichtenstein and Stoppa popularized tension-free repair in the literature to solve early recurrence [4,5].

There are various available techniques described in the literature for the repair of an inguinal hernia. The open and laparoscopic techniques have been widely debated for this type repair. With the development of the laparoscopic-endoscopic surgery, Dulucq introduced a new technique called totally extraperitoneal repair technique (TEP) in 1992 [6]. Laparoscopy is a comfortable option for all kinds of abdominal wall hernias [7-9]. This technique is superior compared to other methods since it provides better outcomes for the patients, such as shorter hospital stays, reduced post-operative pain, and improved cosmetic results [10,11]. However, the technique suffers from a long and challenging learning curve due to the complex anatomy and narrow operation spaces involved in laparoscopic repair [2]. There are two main ways of repair described in the literature; Transabdominal Preperitoneal (TAPP) and Totally Extraperitoneal (TEP) [12].

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The current work aims to evaluate the learning curve for TEP hernia repair. As a secondary objective, this work aims to define the phases of the learning curve and its effects on the complications and intraoperative incidents in TEP hernia repair, in order to be a guide to the new learners of the TEP technique.

Materials and methods

The surgical data of patients who underwent laparoscopic inguinal hernia surgery from September 2017 to June 2019 were used to evaluate the learning curve for TEP hernia repair. The patient pool included 125 patients with a inguinal hernia diagnosis and were treated by the first author (KE) in a tertiary center. KE had adequate laparoscopic surgery experience to perform laparoscopy but did not have prior experience with laparoscopic inguinal hernia repair beforehand. All data used in the study was collected retrospectively, through written charts filled inpatient and outpatient visits prospectively. Patients with scrotal hernia, complicated hernia, irreducible hernia, and patients who were not suitable for general anesthesia were not treated laparoscopically. In addition, the data from patients with bilateral hernia and recurrent hernia, and any surgeries converted to open surgery were initially excluded from the learning curve analysis but included in the chronological secondary analysis.

The demographic data (age, sex, body mass index (BMI)), American Society of Anesthesiologists (ASA) score, operative time, intraoperative incidents, and post-operative complications were recorded on a pre-prepared form. The operation time was recorded as the time from the first incision until skin closure. Patients were seen at an outpatient visit at the 10th, 20th, and 90th days of surgery for follow up, and evaluation of post-operative complications like hematoma, seroma, surgical site infection, and urinary retention. These complications were also recorded in the patient sheet. After the 90th day outpatient visit, patients' written data was entered into a database that has been created through Excel Version 16.16 (Microsoft Corp, Redmond, WA). The study was approved by the University of Health Sciences, Antalya Education and Research Hospital ethics committee, patients were informed in detail and informed consents were signed by patients before the surgery.

Statistical analysis

All statistical analysis was carried out with JMP version 15.1 (SAS Institute Inc., Cary, NC, 1989-2019). Descriptive statistical results (mean, standard deviation (SD), standard error of the mean (SEM), frequency, percent, minimum, and maximum) were used to evaluate the study data. Independent samples t-test, the Wilcoxon test and Fisher exact test were employed to compare the quantitative variables of groups. For all statistical tests, a confidence interval of 95% ($p<0.05$) was employed. Time series was analyzed for stationary of the data where the stationarity of the time series was analyzed by "Box-Jenkins method". If the trend was found not to be stationary, then the calculation was repeated after exclud-

Table I - *Summary of demographic data*

Parameter	All cases performed (n=125)	Patients evaluated for time analysis (n=92)
Age, y (range)	46.4 ± 1.2 (18-78)	45 ± 1.4 (18-78)
Gender, n (male - female)	115 (92%) - 10 (8%)	84 (91%) - 8 (9%)
Comorbid disease, n	23 (18%)	15 (16%)
BMI, kg/m2 (range)	26.14 ± 0.3 (18.4- 35.2)	26.08 ± 0.3 (18.4-35.2)
Operative time, min (range)	49.4 ± 1.5 (30-110)	45.5 ± 1.2 (30-100)
Side, n		
Right	55 (44%)	52 (57%)
Left	44 (35%)	40 (44%)
Bilateral cases	26 (21%)	0 (0%)
Hernia type, n		
direct	90 (72%)	67 (73%)
indirect	34 (27%)	25 (27%)
Recurrence of hernia, n	6	0
ASA, n		
1	80	62
2	39	26
3	6	4
Intra-operative incident occurred cases, n	11 (8.8%)	3 (3.3%)
Post-operative complication occurred cases, n	9 (7.2%)	4 (4.3%)
Intra & Post-operative complication occurred cases, n	11 (8.8%)	4 (4.3%)
Inpatient time, d (range)	1.04 ± 0.018 (1-2)	1.04 ± 0.021 (1-2)

Continuous data are expressed as mean ± SEM, bilateral, recurrence and converted to conventional cases excluded in time analysis group

Table II - *Summary of intra-operative incidents and post-operative complications*

	All cases performed (n=125)	Patients evaluated for time analysis (n=92)
Intra-operative incidents, n		
Peritoneal tear	10	3
Bleeding	4	2
Conversion to open surgery	2	0
Post-operative complications, n		
Hematoma	3	1
Seroma	3	1
Glob vesicale	3	2

Table III - *Demographic and clinical details of groups*

	Group 1 (n=28)	Group 2 (n=70)	Group 3 (n=27)	P value
Age, y (range)	46.5 ± 2.5 (22-77)	47.8 ± 1.6 (19-78)	42.5 ± 2.5 (18-65)	0.21
Gender, n (male - female)	25 (89%) - 3 (11%)	66 (94%) - 4 (6%)	24 (89%) - 3 (11%)	0.56
Comorbid disease, n	6 (21%)	14 (20%)	3 (11%)	0.54
BMI, kg/m2 (range)	25.5 ± 0.6 (18.4-31.3)	26.4 ± 0.4 (21-35.2)	26.2 ± 0.6 (21.5-32.9)	0.57
Operative time, min (range)	67 ± 4.1 (40-110)	46.6 ± 1.3 (30-90)	38.51 ± (30-45)	<0.001
Side, n				0.03
Right	7	32	16	
Left	10	27	7	
Bilateral cases	11	11	4	
Hernia type, n				0.08
direct	16 (57%)	55 (79%)	20 (74%)	
indirect	12 (43%)	15 (21%)	7 (26%)	
Recurrence hernia, n	0 (0%)	6 (8.6%)	0 (0%)	0.08
ASA, n				0.40
1	18	41	21	
2	8	25	6	
3	2	4	0	
Intra-operative incident occurred cases, n*	6 (21%)	5 (7%)	0 (0%)	0.014
Post-operative complication occurred cases, n *	4 (14%)	5 (7%)	0 (0%)	0.12
Intra & Post-operative Complication occurred cases, n *	7 (25%)	4 (6%)	0 (0%)	0.002
Inpatient time, d (range)	1.11 ± 0.06 (1-2)	1.03 ± 0.02 (1-2)	1 ± 0 (1-1)	0.1

Continuous data are expressed as mean ± SEM, (*) some cases have more than one incident & complications

ing chronologically previous patient, and the procedure repeated until the variation is no longer statistically significant. This point describes the stationary of the model or the series evolve around a mean with a constant. SD of the operative times of cases calculated by moving average method used to indicate the difference of operative time between the cases to determine groups. All continuous data are expressed as mean ± SEM.

Operative technique

All operations were performed under general anesthesia, where patients were given a single prophylactic dose of a 1st generation cephalosporin 30 minutes before the incision. All patients were operated in the supine position. A mini-incision was made under the umbilicus, and anterior fascia of the rectus muscle was cut. Then, a 10 mm trocar for a camera was inserted above the posterior layer of the rectus abdominis muscle. Two additional 5 mm working trocars were also positioned under direct vision. After the insertion of trocars, the patients were positioned to 10-degree Trendelenburg. A polypropylene light mesh, 10x14 cm in size, was fixed with an absorbable tacker following the hernia sac reduction. All patients were given a non-steroid anti-inflammatory analgesic after the surgery.

Results

There were 125 patients (115 male - 10 female) enrolled in the study. The mean age was 46.4 ± 1.2 years (18 - 78) and mean BMI score was 26.1 ± 0.3 kg/m^2 (18.4 - 35.2). The mean operation time of all cases was 49.4 ± 1.5 minutes (30 – 110). All other demographic variables are summarized in Table I.

Ninety-two of the patients were diagnosed as primary

and unilateral and were evaluated for time series analysis. The remaining 33 patients were initially excluded and then re-added for the analysis of groups, determination of learning phases and evaluation of complications. Twenty-six of these patients had bilateral inguinal hernia, 6 patients had recurrent hernia, and two were converted to open surgery (one bilateral hernia was converted to open surgery).

Table II summarizes the intraoperative incidents and post-operative complications. In 125 patients, there were 10 peritoneal tears, and 2 patients were converted to open surgery. There was minor bleeding controlled with cautery in 4 patients. No organ injury, such as bladder and bowel, was observed.

Postoperatively, seroma was observed in 3 patients, 3 patients had urinary retention, and 3 patients had hematoma. There were no other complications such as pulmonary and wound infections.

Our analysis included two steps: (1) Time series analysis, and (2) Formation of groups based on the SD of moving average. First, Box-Jenkins method was performed for time series analysis to determine the learning curve of a surgeon to reach a stationarity operative time. This stationarity in the operative time describes the number of cases in which the surgeon stops or pauses improvement on their operative time. To determine the surgeon's progress and perform the time series analysis, bilateral and recurrent hernias, and cases converted to open surgery were excluded from analysis. Hence, only unilateral hernias and primary cases were included in the Box-Jenkins analysis where a total of 92 patients were analyzed. Fig. 1 shows the time distribution of the time series group (mean: 45.5 ± 1.2 (30 - 100)).

For the second analysis, three groups were created based on the results of SD decline points of time series patients. Then, the time-series patients (n=92) and discarded cases (n=33) were merged (total=125), and chronologically sorted to determine the impact of the learning curve on the clinical outcomes. Groups were analyzed for the impact of time series on post-operative complications, intraoperative incidents, and conversion to open surgery. From the results of the Box-Jenkins time series analysis, it was determined that the 43rd case was the point where stationary trends started. Among all cases, this was the 63rd case of the surgeon.

Fig. 2 shows the relation between SD decline points in time to intra-operative incidents and post-operative complications. The result of SDs calculated by moving average is shown in Figure 2a where two SD decline points were identified. These points represent significant decreases in overall surgery time. The first decline in the SD value was 9.1 to 6.4 at the 16th patient, which represents the surgeon's 28th case. The second decline in the SD value was 5.8 to 3.8 in the 69th case, which represents the surgeon's 98th case.

Fig. 2b shows the cumulative numbers of intraoperative incidents and post-operative complications in all cases. Each decrease indicates an intraoperative incident and post-operative complication occurrence separately. There were no post-operative complications after the 72nd patient, and there were no intraoperative incidents after the 81st patient.

Statistical analyses of the groups were as follows. Operative time was statistically different between each group separately. There is no difference between groups for demographic values, except all recurrent hernias were

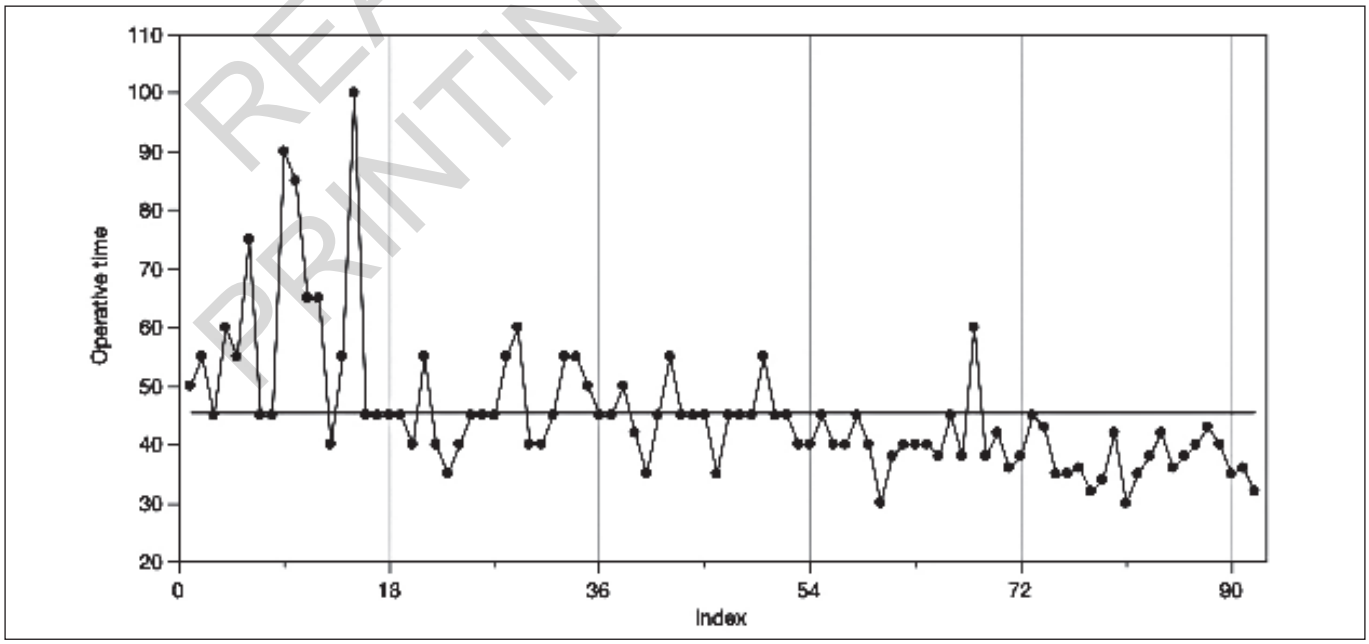

Fig. 1

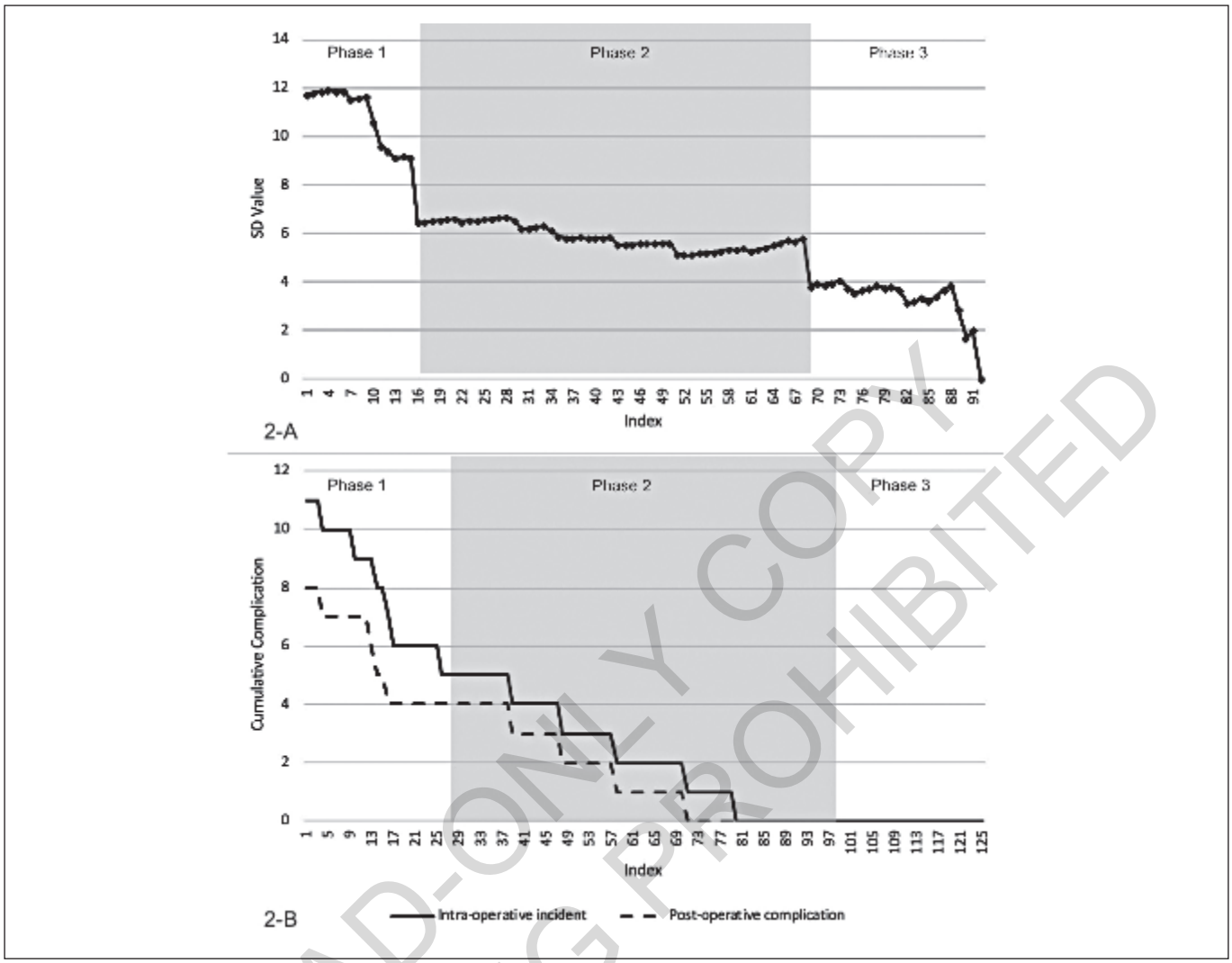

Fig. 2

in the second group. This did not affect the conclusion because none of the incidents or complications had occurred in the recurrent cases. Group-1 had 21% 6, Group-2 had 7% 5 and Group-3 had 0% (0) intraoperative incidents. This was statistically different between group-1 and other groups while being unfavorable for group-1. There was no statistical difference between group-2 and 3, and this was also the same between the groups in terms of post-operative complications. Groups' demographics and clinical details are summarized in Table III.

In total, Group-1, Group 2, and Group-3 had 25% 7, 6% (4), 0% (0) intraoperative incidents and post-operative complications, respectively.

This was also statistically significant between group-1, and other groups, unfavorable for group-1. There was no statistical difference between group-2 and group-3. Percentage of intra-operative incidents, post-operative complications, and the sum of the incidents in the groups are shown in Fig. 3.

Discussion

There are plenty of reports and guidelines which state that laparoscopic hernia repair is superior to open repair in means of quick recovery to work, better cosmetic outcomes, and less post-operative pain [10,13,14]. Nevertheless, most of the surgeons are still hesitant perform laparoscopy because of the difficulties in the learning period, complex pelvic anatomical structure, possible intra-, and post-operative complications in laparoscopic surgery. The term "learning curve" is defined as the rate of someone's progress in learning a new skill [15]. Since this is a skill, it can be adapted to most of the surgical operations. The term "progress" is the time needed to achieve an optimum and acceptable quality of operation in terms of duration and complication rate. So, we can define the term "learning curve" as the number of cases needed to perform a surgical procedure to achieve acceptable operative time, favorable clinical outcome, and for the surgeon to reach a "comfort zone."

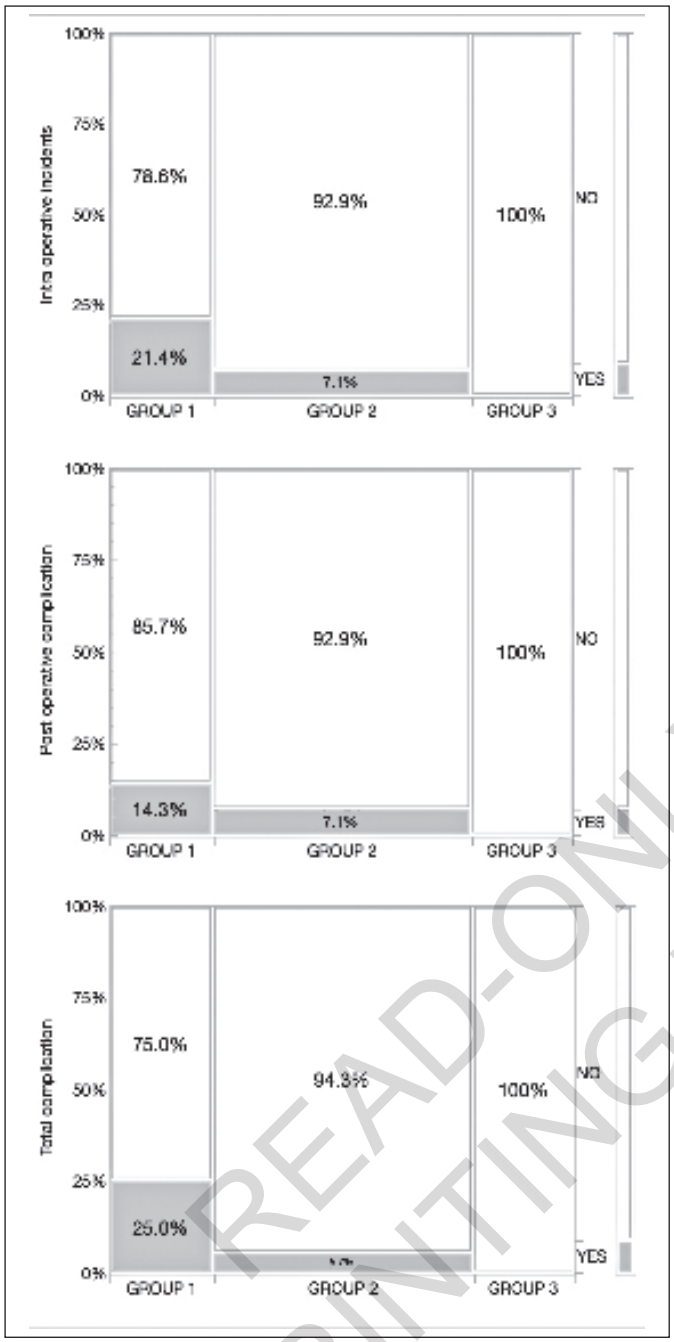

Fig. 3

We analyzed the learning curve throughout a systematic approach by discarding complex and bilateral cases from the main data to perform the time analysis as homogeneously as possible. After getting the results of the analysis, discarded cases were added to the main data again by chronological order to get the exact number of cases needed to be performed to reach the comfort zone for the surgeon. We think the discarding, analyzing, and re-adding process was mandatory because, in similar studies, we observed that discarding complex cases and not re-adding them after analysis was affecting the detection of the exact number of surgeries needed to reach the comfort zone and other learning curve analysis.

A statistically significant decrease in overall operative time was reported in some studies varying between 13th to 100th cases [16-19]. In our study, we found the 63rd case as the start of the comfort zone. In a study carried out by Lim et al. including 90 laparoscopic repairs, it was mentioned that 30 patients could be enough for the learning curve, and after the 40th case, the operating time stabilizes. This number was 65 in the study of Yuji et al. [17]. For the secondary analysis, we also discarded complex cases and applied moving average method for the SD of mean time of cases. We have identified two decline points in the SD graph of operative time, which was representing a significant improvement of skill and consistency of time for the surgeon. We merged discarded cases chronologically with the same systematic and created the groups among these points.

Among the analysis, in our opinion, these 3 groups represent surgeon's 3 phases of learning; the first phase is the beginner phase of the surgeon. In this phase surgeon's operation time is far from being consistent due to a lack of experience. Even when all cases are selected wisely, some cases can be smoothly done, while some causes trouble to the surgeon because of unnecessary struggling and lack of ability to perform tricky maneuvers necessary for a smooth surgery. This is the phase where most of the intraoperative incidents occur, and these incidents increase the time of operation. This phase is surgeon's "getting to know" phase for the technique and where they get familiar with the complex anatomy of the inguinal region.

In the second phase, the surgeon gains experience, and cases are smoother, and the surgeon has created their own maneuvers to speed up the surgery. Throughout this phase, the surgeon is gaining speed and consistency. It must be noted that the comfort zone is reached in this phase. This phase is the most prolonged and the main learning phase.

At phase three, the surgeon reached their maximum speed and safety; after this phase, the surgeon can be called an expert in this type of surgery. According to our study phase one was between the 1st and 28th cases, phase two was the most prolonged and was between 28th and 98th cases, and phase three was started after the 99th patient.

The groups were statistically similar in terms of complications. We think this was due to the laparoscopic patient selection criteria of the surgeon. Our analysis for the groups shows that phase 1 of learning was the phase in which most intraoperative incidents occurred. Surgeons should take extra care in this phase and try to avoid intraoperative incidents aimed to reduce operative time. In our opinion, complex cases should be operated during phase two, but not before reaching the comfort zone, which we calculated as the 63rd case.

The long learning curve, some severe complications such

as vascular, nerve, or organ injury, are the dilemmas of laparoscopic technique [20]. In a study performed by Schouten et al. in 2013, the 3432 patients' overall complications were at a rate of about 7% [21]. Our complication rate was %7.2 in our overall data and this was similar with the literature. We did not observe any major organ or nerve injury. There was no significant surgical site infection.

To our knowledge, this is the first study that describes phases of learning of the TEP hernia repair and compares these phases in terms of complications and operative time. The difference and value of our study is that it divided the three groups with the guidance of the SD analysis; hence made the three phases of the learning curve of the TEP technique easily observable.

Conclusion

A stabilization of mean operating time has been observed in the 63rd case of TEP in our study, which was the optimal ending of the learning curve for the surgeon regarding operative time. Also, two decline points in the SD of mean time showed 3 phases in learning of the TEP technique. Intra-operative incidents in cases ended after the 81st patient, and there were no post-operative complications after the 72nd patient.

Based on these analyses, we recommend taking extra care in the selection of patients in the first 28 patients (first phase) to avoid intraoperative incidents, to achieve smooth surgery and reduce the complication rate. After their 63rd TEP operation, the surgeon can broaden their patient spectrum.

The learning curve of the TEP technique has three phases; selecting optimal patients is vital for surgeons to pass the above described milestones as smoothly as possible and learn the technique with as few incidents as possible.

Riassunto

Obiettivo: la tecnica di riparazione totalmente extraperitoneale (TEP) è una delle tecniche laparoscopiche più utilizzate per la riparazione dell'ernia inguinale. Questo studio mirava a indagare la curva di apprendimento della tecnica e le fasi coinvolte per aiutare a guidare gli studenti inesperti.

Materiali e metodi: Metodo Box-Jenkinson per l'analisi delle serie temporali e metodo della media mobile per l'analisi della deviazione standard (SD) e sono stati utilizzati per la determinazione del gruppo e la valutazione della curva di apprendimento. Sono stati creati tre gruppi individuali sulla base dei risultati dell'analisi statistica e ogni gruppo è stato valutato per determinare l'accuratezza delle fasi di apprendimento.

Risultati: Le fasi di apprendimento della tecnica sono state classificate come: (1) Fase 1 (1 ° -28 ° caso), (2) Fase 2 (29 ° -98 ° caso) e Fase 3 (dopo il 99 ° caso). Il tempo di funzionamento era statisticamente diverso tra ciascuna fase. Inoltre, anche il numero di incidenti intraoperatori è risultato statisticamente diverso tra la fase 1 e le altre fasi, con la fase 1 sfavorevole.

Conclusione: A nostra conoscenza, questo è il primo studio che descrive le fasi di apprendimento della riparazione dell'ernia TEP e confronta queste fasi in termini di complicanze e tempo operatorio.

Raccomandiamo ai chirurghi alle prime armi di prestare particolare attenzione in termini di selezione dei loro pazienti durante i primi 28 casi e di ampliare il loro spettro di pazienti dopo il 63° caso. La curva di apprendimento della tecnica TEP ha tre fasi e ogni passaggio deve essere attentamente considerato per la selezione del paziente in modo che le pietre miliari possano essere raggiunte nel modo più fluido possibile senza complicazioni.

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