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Effectiveness of Enhanced-View Totally Extra Perotoneal Approach (E-TEP) For Inguinal Hernia Repair

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Abstract

Introduction: Inguinal hernia is one of the most prevalent surgical diseases in clinical practice. This study aims to assess the effectiveness of the Enhanced - view Totally Extra Peritoneal (E-TEP) approach in repair of inguinal hernias.

Materials and Methods: A prospective case-control study was performed in the Department of General Surgery, Medical College, Baroda. In a period of one year, a total of 25 patients were enrolled and laparoscopic E-TEP repair has been done.

Results: The mean age of patient in the study was 46.52 ± 6.33 years. The mean time taken for laparoscopic E-TEP repair was 52.6 ±2.64 minutes. (Mean ± 2SD). In our study, a total of (8%) cases with intra-operative complications were noted. (8%) had post operative complications. The result of this study shows that E-TEP approach, can be considered as an acceptable alternative to the traditional TEP approach.

Conclusion: In conclusion, the Enhanced-view Totally Extra-Peritoneal Approach (E-TEP) can be considered as an effective method, which provides a wider view of the operative field than the traditional TEP approach.

Keywords: Inguinal hernia, Enhanced-view Totally Extra peritoneal approach, laparoscopy.

Introduction

Inguinal hernia is one of the most prevalent surgical disease in clinical practice. Various open and

laparoscopic methods have been used for the surgical management of inguinal hernias. Laparoscopic total extra-peritoneal (TEP) has gained popularity over the past many years as an acceptable alternative to the open Lichtenstein repair for the treatment of unilateral inguinal hernias given the similar recurrence risk and decreased post-operative pain, early ambulation and return to work. The major advantage of this approach is that it does not involve entry in the abdominal cavity, thus lessening the risk of intestinal and vascular injuries as well as herniation at the trocar sites. However, one of the major limitations of the TEP approach is that it is a technically difficult procedure, with a greater learning curve. The drawbacks of the classical TEP technique include a limited space for dissection and mesh placement, restricted port placement, intolerance to pneumo-peritoneum, and difficulty in teaching and learning the technique. This has led to development of several innovations in technique and instruments to make it technically easier and effective.

The enhanced/extended view totally extra-peritoneal procedure (ETEP) is one such modification made to the traditional TEP technique. The E-TEP technique is based on the anatomical principle that the extra-peritoneal space can be reached from almost anywhere in the anterior abdominal wall. It combines the advantages of tension-free mesh reinforcement of the groin with those of laparoscopic surgery and aims to overcome the limitations of the traditional TEP approach.

Aims and objectives

To assess the effectiveness of the Enhanced - view Totally Extra Peritoneal (E-TEP) approach in repair of inguinal hernias, in terms of outcome parameters such as operative time, intra and post-operative complications, need for conversion to open surgery and recurrence.

Inclusion criteria

Patient with uncomplicated unilateral inguinal hernia having age more than 18 years.

Exclusion criteria

1. Bilateral Inguinal Hernia
2. Patients not giving consent for laparoscopic repair of hernia.
3. Recurrent inguinal hernia after laparoscopic repair

Materials and methods

This prospective study consisted of 25 patients with diagnosis of unilateral inguinal hernia who were admitted to the general surgical ward, Government Medical College and Sir Sayajirao General Hospital, Vadodara, and underwent laparoscopic E-TEP repair. Study was started from the time of approval of the study by institute ethics committee till June 2020 Duration of study –April 2019-June 2020.

Sample size

Due to restrictions in non- emergency admissions and less number of patients coming to outpatient department due to COVID-19 pandemic, final sample size of patients was taken as 25.

Study setting

Department of General Surgery, Government Medical College and Sir Sayajirao General Hospital, Vadodara. Patients of unilateral inguinal hernia underwent laparoscopic E-TEP repair after written consent for the same.

Statistical analysis

Statistical analysis was done using unpaired t test, student t test Chi-square. Test using Medcalc software and conclusion was drawn based on the results of statistical analysis.

Methodology

Patients visiting outpatient department or admitted in ward from completion of Institutional Ethics Committee review in April 2019 to June 2020 matching the above inclusion and exclusion criteria were explained about the study and on willingness were enrolled after written informed consent was obtained.

- We recorded all the observation in operative procedure during all steps for uniformity of study.
- A written informed consent was obtained.
- History data and clinical examination findings collected on printed proforma attached here with.
- Preoperative Investigations:
  - Routine blood investigations including complete blood count, Renal function tests, Liver function tests, serum electrolytes and random blood sugar.
  - USG prostate with PRV
  - USG bilateral inguinoscrotal region.

Nil per oral according to anesthetist advice. The procedure was done under general anesthesia. Per urethral catheter was inserted and prophylactic antibiotic was given at the time of induction of anesthesia. In all, 25 cases of laparoscopic E-TEP repair were done. All intraoperative events were noted.

The primary port of entry was from the same side as that of hernia in all cases. Space creation was done using the balloon dissector method in all cases, and the remaining ports inserted as done for the E-TEP approach. Adequate dissection done and placement of mesh done. A polypropylene mesh of size 15*15cm was placed and fixation done using tackers. The sheath in primary port was closed using Portt Vicryl (polyglactin) (1-0). The skin was closed using Ethilon 2-0 (Polyamide black) in vertical mattress manner/Vicryl rapide(polyglyclactin) in subcuticular manner/surgical skin stapler based on availability.

Complications during operation were noted if any. The total duration of operation – from incision over the first port of entry to closure of all ports - was also noted. Post operatively the patients were kept nil by mouth for 6hours and advised complete bed rest till the effect of anesthesia completely worn out, till then they are given supportive maintenance intravenous fluids. Foley's catheter was removed approximately one hour after surgery, once the patient had been shifted out of the operating theatre. Patients were advised and encouraged to ambulate and start their activities of daily life as early as possible.

Prophylactic oral antibiotics given for duration of 5 to 7 days, of which parenteral antibiotics given for the first 24 hours.

Analgesics were given at 12-hour interval for a period of 3 to 5 days - intravenous analgesics on the first post-operative day and then shifted on to oral tablets. Patients were observed for any complications like subcutaneous emphysema in the immediate post-operative period and hematoma, seroma, wound sepsis during their stay in hospital and also assessed for postoperative pain and its severity.

Patients were discharged once free of complications and once they resumed their activities of daily normal life. Patients were discharged within the next day or within 48 hours. At discharge they were advised to come for follow up on 5th and 10th post op day and stitch removal done accordingly after assessment. Then they were asked to follow up on 1st and 6th month post-surgery to check for recurrence. Telephonic follow up was taken if patient was unable to attend the follow up due to some unavoidable circumstances.

Operative time: Time taken from placing the incision over the site of first port of entry to closure of all the port sites to be calculated in minutes.

Conversion to open: The number and percentage of cases out of the total studied which required conversion from laparoscopic to open surgery.

Pain Assessment: The pain assessment was done using the Visual Analogue Scale, to assess the severity of pain at 6 hours and 12 hours after surgery (which was under injectable analgesic cover) and on the first and third postoperative day.

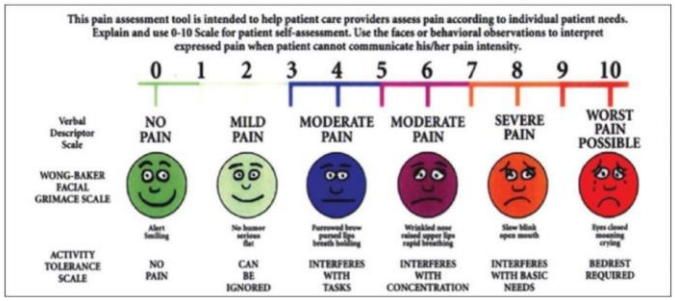

Figure 1: Visual analogue scale

The local sites were also examined for seroma/Surgical Site Infections prior to discharge and on follow-up. Seroma formation: A seroma is a pocket of clear serous fluid that develops at the site of surgical intervention. Patient was to be examined on 1st and 5th post-op day and development of a new, abnormal swelling at site of incision will be followed with Ultrasound of local site to look for seroma formation.

Surgical site infection: Of three types of Surgical Site Infections, (superficial incisional, deep incisional, and organ/space infection) the superficial incisional SSI will be studied – characterized by – local signs of inflammation such as redness, pain, heat, swelling or drainage of pus on 5th and 10th post-operative day.

Recurrence: Recurrence of the hernia will be studied on 1st and 6th month of follow up.

Results and Analysis

A prospective interventional study with 25 patients undergoing Laparoscopic E-TEP repair for unilateral inguinal hernia who were admitted to the general surgical ward, Government Medical College and Sir Sayajirao General Hospital, Vadodara, after fitting the inclusion criteria and after having taken consent for the same, was undertaken to study the efficacy of E-TEP approach based on intraoperative complications, total duration of operation, conversion to open surgery, post-operative pain, post-operative complications and recurrence.

The findings were tabulated and the following observations were made.

Table 1: Age Distribution of Patients Studied

Age in years	No. of patients	%
18-20	1	4
21-30	5	20
31-40	2	8
41-50	6	24
51-60	5	20
61-70	5	20
71-80	1	4
81-90	0	0
Total	25	
Mean ±2 SD	46.42±6.33	

Table 2: Associated Disease of Patients Studied

Associated Diseases	No. of Patients	%
Absent	17	68
Hypertension	4	16
Diabetes Mellitus	4	16
BPH	2	8
COPD	0	0
Others	0	0

Table 3: Types of Inguinal Hernia

Types of Hernia	No. of Patients
Direct	9
Indirect	16

Table 4: Sides of Hernia

Side of Hernia	No. of Patients
Right	16
Left	9

Table 5: Intraoperative complications

Intraoperative Complications	No. of Patients
Vascular Injury	0
Urinary Bladder Injury	0
Bowel Injury	0
Cord Structure Injury	0
Cord Structure Injury 0 Nerve Injury	0
Abdominal Distention Due to Intraperitoneal Co2 Leak (Space Inadequacy)	2
Visible Peritoneal Tear	0
Bleeding From Port Sites	0

2 cases (8%) had intra-operative complications noted. Both the cases had intra-operative abdominal distension due to intraperitoneal CO2 leak, which led to space inadequacy.

Both cases were managed by intra-operative Veress needle insertion at palmer's point to facilitate a passage for gas removal. There was no need for conversion to open surgery.

No other complications in terms of injury to vital structures such as urinary bladder, cord structures, major vessels or nerves, or bleeding from port sites was noted. **There were no cases converted to open surgery.**

Table 6. Operative Time

Operative Time (in minutes)	No. of patients
30-40	0
41-50	14
51-60	8
61-70	3
71-80	0
MEAN ± 2SD	52.6 ±2.64

The mean time taken for laparoscopic E-TEP repair was 52.6 ±2.64 minutes. (Mean ± 2SD)

The time taken was considered as from incision over the first port of entry to closure of all ports.

Table 7: VAS score for Post-operative pain assessment on first post-operative day (24 hours after surgery)

Post Op Pain (Vas Score) On Day 1	No. of Patients
0	0
1	0
2	16
3	7
4	2
5	0
>6	0

The VAS score for post operative pain assessment was noted.

On the first post-op day, 24 hours after surgery, 16 patients had a score of 2, 7 patients had a score of 3 and 2 patients had a score of 4.

No patient had scores of 5 or more than 5. The mean score on day 1 was 2.44 ± 0.25 (Mean ± 2SD)

Table 8: Post operative complication.

Post Operative Complications	No. of Patients
Urinary Retention	0
Subcutaneous Emphysema	1
Seroma	0
Surgical Site Infection	1
Other	0

2 cases had post operative complications. There was one case of immediate post operative subcutaneous emphysema, which was managed by pressure-rolling of air out through the port sites. It was relieved completely by the first operative day. There was one case of surgical site infection noted on the 5th postoperative day. The primary port of entry (camera port) (10mm) had been infected. The skin closure had been done using Vicryl Rapide (polyglactin 910) (2-0) in subcuticular manner. The patient presented with pus discharge from the site during his follow up on the fifth postoperative day.

The remaining two port sites were normal. The stitch line was opened, wound swab sent for culture and sensitivity. Appropriate antibiotics were given and regular dressing done until healing was achieved. No other complications in terms of urinary retention/seroma were noted.

There was no recurrence after 6 months of follow up in any patient.

Discussion

Laparoscopic surgery was primarily introduced to reduce the surgical stress and complications associated with large incisions. It has been shown to improve outcomes, shorten the duration of hospital stay, without adversely affecting long-term results as compared to open surgeries. Laparoscopic surgery is thus gaining popularity in various kinds of surgical procedures. In 1992 Ferzli et al. reported the first Laparoscopic TEP (totally extraperitoneal) inguinal hernia repair. It proved to be safe and effective and laparoscopic TEP repair has since been accepted as a standard alternative to the conventional open procedure for inguinal hernia repair. Though it has been associated with well-known advantages of laparoscopic surgery such as less pain, faster recovery, and the reduced risk of potential intra-peritoneal complications, the widespread dissemination of laparoscopic TEP repair has been hampered by various limitations, mainly technical.

The major drawbacks of the classical TEP technique include a limited space for dissection and mesh placement, restricted port placement, intolerance to pneumoperitoneum, and difficulty in teaching and learning the technique.

The working space obtained in the conventional TEP can act be a hindrance to surgeons especially in their early years of experience. That is why perhaps, the technique is still not very liberally used by non-experienced hands and newer surgeons.

This led to development of concept of creation of a workable extraperitoneal space from almost any point on the anterior abdominal wall, with the intention of overcoming some of the above-mentioned challenges associated with the traditional TEP approach. This was introduced as the E-TEP (Enhanced view TEP) approach by Jorge Daes.

The key technical aspects of E-TEP are – high camera port placement, flexible port distribution, division of posterior fascia (Arcuate/Douglas line), and ultimately, an ease in hernia repair due to broad view obtained. The following study was undertaken in an effort to identify the effectiveness of the E-TEP approach,

broadly in terms of intra-operative & post-operative complications, operative time and other parameters. This was a prospective interventional study consisting of 25 patients – more than 18 years of age, with unilateral inguinal hernia - conducted in Government Medical College, Baroda & Sir Sayajirao General Hospital, Vadodara from April 2019 to June 2020.

A study with regard to following parameters were made:

1. Operative time
2. Intraoperative complications:

• Vascular injury • Urinary bladder injury • Bowel injury • Cord structure injury • Nerve injury

• Abdominal distention due to intraperitoneal co2 leak (space inadequacy) • Visible peritoneal tear •Bleeding from port sites

3. Conversion to open surgery
4. Post operative complications: • Pain • Subcutaneous emphysema(duration)

• Urinary retention • Seroma formation • Surgical site infection

5. Recurrence

Age and gender distribution

In our study mean age of patients in was 46.52 years with a standard deviation of ± 6.33 years (at 95% confidence intervals). All the patients in our study were males.

Reza et al in their study of 25 patients of inguinal hernia repair using E-TEP approach, in 7(28%) cases age group was 25 to <35 years, 15(60%) patients were in 35 to <45 years and 3(12%) patients were in 45-55 years age group. All of the patients were male.

Deshpande et al in their study of E-TEP approach had 18 cases of inguinal hernia. The mean age was 52.94. All patients were males.

Andrade CJA et al in their study duration of 23-month period, had 44 patients who underwent E-TEP inguinalplasty of these, 37 made up the group of male patients (84%) and seven females (16%), with an average age of 56.5 years with a range of 29 to 80 years old.

Gallo KJG in the study of inguinal hernia repair using E-TEP approach, a total of 20 patients were operated on. There were 18 (90%) males and two (10%) females. The average age was 43 years (range 26 to 64 years). Thus, the predominantly adult male patients presenting with inguinal hernia correlates with the fact that the prevalence of inguinal hernia is more in males than females.

Type and side of Inguinal Hernia

In our study, 9 (36%) patients had direct inguinal hernia, whereas the remaining 16 patients (64%) had indirect inguinal hernia 16 patients (64%) had right sided inguinal hernia, and the other 9 patients (36%) had left sided inguinal hernia.

Deshpande et al [25] in their study had 6 cases of right inguinal hernia, 6 cases of left inguinal hernia and 5 cases were of bilateral inguinal hernia.

Andrade CJA et al, in their study of 44 patients, 41 (93%) were primary hernias and three (7%) were recurrences of previous repairs. Twenty patients (45%) presented unilateral hernias, four (20%) being left and 16 (80%) right and 24 of them bilateral (55%). Thus, a total of 75 hernias were repaired in the 44 patients, 46 cases (61.33%) with indirect defects, while direct defects comprised 24 cases (32%). Femoral defects were noted in three cases (4%), and one obturator (1.33%) and one (1.33%) Spiegelian hernia was found.

Gallo KJG in the study of the 20 operated patients, 10 were hernias on the right side, 5 on the left side and 5

bilateral patients. In all cases, they were reducible hernias, not incarcerated or strangulated. 2 patients (10%) had recurrent hernias, with a history of open Lichtenstein-type hernioplasty, and the remaining 18 (90%) had primary hernias. Fifteen patients (75%) had direct hernias and five (25%) indirect. Hence, a varied combination of direct and indirect inguinal hernias on either side were noted in the various studies related to ETEP approach for inguinal hernia. Bilateral and recurrent inguinal hernias were excluded from our study.

Total Operative Time

The total operative time was considered as from incision over the first port of entry to closure of all ports. The mean time taken for laparoscopic E-TEP repair was 52.6 minutes with a standard deviation (2SD) of ±2.64 minutes. 14 out of the 25 patients (56%) had operative time between 41 to 50 minutes.

The operative time ranged from 44 minutes to 70 minutes**.**

Jorge Daes in his study of 36 participants of E-TEP for inguinal hernia from October 2010 to June 2011, had an average operative time of 38 minutes.

Reza et al [24] had operating time ranging from 1 hour and 15 minutes, to 2 hours and 10 minutes, with an average operating time of 1 hour and 35 minutes (95 minutes). Most of the operations were completed between 1 hour 30 minutes and < 2 hours (14 operations, 56%), with 3 cases taking more than 2 hours of time, and the remaining 8 cases having an operative time range of 1 hour to 1.5 hours.

Deshpande et al had an average operating time of 1.2hrs (70 minutes) in their study of E-TEP for inguinal hernia. Andrade CJA et al [26] in their study had an average operative time of 127.41 minutes with a range of 75 to 250 minutes. However, the longest times were due to the performance of another surgical procedure performed at the same time for some concomitant pathology, for which joint management was planned, such as two cases of GERD (Nissen fundoplication), four umbilical hernia repairs and one case of laparoscopic cholecystectomy.

Gallo KJG had an average surgical time of 45 min with a range of 30 to 55 min. For bilateral hernia repair, the average was 80 min with a range of 60 to 95 min.

	Average operative time
Jorge Daes	38 minutes
Reza et al	95 minutes
Deshpande et al	70 minutes
Andrade CJA et al*	127.41minutes
Gallo KJG	45 minutes
Mean operative time of our study	52.6 minutes

*higher operative time attributed to performing another surgical procedure at the same time.

The difference in average operating time between our study and that of Jorge Daes was statistically significant (t=-19.615, p<0.001).

However, the operative time for any surgery depends on various factors such as intraoperative complications, experience of the surgeon, etc.

Moreover, the method of space creation and the use/non usage of tackers also affects the final time taken. In most studies, all these variable attributable factors have not been distinctly defined. In our study, all cases were operated by the same, experienced laparoscopic surgeon.

Intraoperative Complications

In our study, a total of 2 cases (8%) with intra-operative complications were noted. Both the cases had intra-operative abdominal distension due to intraperitoneal

CO_2 leak, which led to space inadequacy (loss of space). However, no need for conversion to open procedure arose. Both cases were managed by intra-operative Veress needle insertion to facilitate a passage for intra-peritoneal gas removal.

There were no cases of conversion to open surgery.

No other complications in terms of injury to vital structures such as urinary bladder, cord structures, major vessels or nerves, or bleeding from port sites was noted. In the study of 36 E-TEP procedures for inguinal hernia performed by Jorge Daes, 'The peritoneum was often accidentally opened and air leaked into the peritoneal cavity without interfering with the completion of the surgery".

Reza et al had 2 cases of peritoneal tear and 1 case of blood vessel injury (12%). No nerve injuries were noted. One operation was converted to open procedure. Andrade CJA et al [26] in their study had 5 cases (11.36%) where there were tears of the peritoneal membrane resulting in secondary pneumoperitoneum. However, in none of the cases was there any intraabdominal injury and it was only necessary to evacuate the pneumoperitoneum by puncture under direct vision after repairing the peritoneal tear. There were no cases converted to open surgery. In Gallo KJG study of 20 cases of ETEP approach for inguinal hernia, there were no incidents or intraoperative complications, nor was there a need for conversion to open surgery in any of the cases.

On comparing the proportion of intra-operative complications with Reza et al, and Andrade et al, there was no significant difference statistically in both cases ($p=0.647$, and $p=0.615$ respectively).

Thus, very few intra-operative complications have been noted across various studies, thereby enhancing the case for application of E-TEP approach for inguinal hernia repair.

Post Operative Complications

2 cases (8%) had post operative complications. There was one case of immediate post operative subcutaneous emphysema, which was managed by squeezing the air (pressure-rolling) out through the port sites. The surgical subcutaneous emphysema was completely resolved within 24 hours of the surgery. There was one case of superficial surgical site infection noted on the 5th post-operative day. The primary camera port (10mm) had been infected. The stitch line was opened, wound swab sent for culture and sensitivity. Appropriate antibiotics and regular dressing was done until healing was achieved.

No other complications in terms of urinary retention/vomiting/seroma formation were noted.

Post-operative pain

It was assessed using the Visual Analogue scale at regular intervals in the post-operative period. On the first Post-Op day, 16 patients had a score of 2, 7 patients had a score of 3 and 2 patients had a score of 4. The mean score was 2.44.

In the study by Reza et al [24], by the end of 1st week, only one patient had surgical site infection in the port site, 1 patient developed seroma and one patient developed scrotal swelling (12%). All the complications were managed conservatively. No hematoma/mesh infection was seen in any of the patients. Reza et al also measured post-operative pain using visual analogue scale. During the first follow up at the end of first week, 15 patients had no pain, 8 patients had mild pain (score <4), and rest of the 2 patients had moderate pain. (score 4 – 7).

In the study conducted by Deshpande et al, the average pain score using the Visual Analogue Scale was 1.38 at 24hrs, and 1.11 at 48hrs.

The variation in the post-operative pain score could be attributed the analgesics, their strength, quality and dosage given, and ultimately patient's tolerance levels. In Jorge Daes' study of 36 patients, 2 cases of small seromas were noted, and 1 instance of umbilical wound sloughing. (8.33%) Andrade CJA et al in his study, in the immediate postoperative period, no complications were noted. There were 2 uncomplicated seromas noted on follow up that required puncture drainage and 1 patient who presented ecchymosis on the penis and scrotum without any other symptoms and which eventually remitted without requiring any treatment (4%). All patients were discharged in an average of 1.2 days with a range of one to two days.

Postoperative complications in Gallo KJG were the following: One patient had postoperative vomiting, which resolved with an antiemetic. No patient had inguinodynia or chronic inguinal pain. Two patients (10%) presented a seroma a week after the follow-up visit, being clinically diagnosed, in which there was no need to drain them, resolving spontaneously one month after the procedure. Hospitalization time was 24 hours in all patients, discharging the day after surgery.

There was no statistically significant difference on comparing the proportion of post-operative complications with the study of Jorge Daes (p=0.963), Reza et al (p=0.641) and Andrade et al (p=0.429).

Recurrence

No recurrence of hernia was noted in our study after 6 months of physical follow up and 1 year 6 months of telephonic follow up.

Jorge Daes' study of 36 cases also showed zero recurrences.

Andrade CJA et al had an average follow-up of six months with a range of 1 to 16 months. No recurrences were detected.

Gallo KJG had one case of recurrence. It was recorded a week after surgery, in which self-adhesive mesh had been placed without fixation in a defect of more than 5 cm. It was resolved with an open surgery with the Lichtenstein technique six weeks after the initial surgery. However, the short duration of follow up could act as a limitation, impacting the outcome and the actual rate of recurrence over a longer period of time.

Conclusion

In conclusion, the Enhanced-view Totally Extra-Peritoneal Approach (E-TEP) can be considered as an effective method, which provides a wider view of the operative field than the traditional TEP approach, with very few intra-operative complications which could be managed without the need for conversion to open surgery. No other major complications of the likes of injuries to surrounding vital structures also signify the safety of the procedure.

The post-operative complications of surgical site infection and subcutaneous emphysema were seen in a single case each, and could be managed without need for prolonged or re-admission, thus aiding in the reduced post-operative stay in patients, as is the case in most of the laparoscopic surgeries.

The average operative time of less than an hour, albeit partly due to the experience of the laparoscopic surgeon, acts as another point favoring this approach. Thus, the E-TEP approach, can be considered as an acceptable alternative to the traditional TEP approach.

Limitations

The limitations of this study are:

➢ Small sample size.

➢ The COVID-19 pandemic further hampered the study as non-urgent, planned surgeries were suspended for a period of about 2 months due to the pandemic and its effects on reduced anesthetist staff, and concerns with General anesthesia during the pandemic.

➢ Another limitation is that this was a single center study, so multicenter study should be conducted and large scale results should be published so that a standard procedure is adopted as protocol for laparoscopic E-TEP inguinal hernia repair is established.

➢ There was no long term physical follow up of patients so complications like recurrence of hernia after more than 6 months and other complications were not recorded.

➢ As we provide free services at Sir Sayajirao General Hospital, Vadodara, cost could not be evaluated in this study.

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