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Single-port versus conventional laparoscopic total extra-peritoneal inguinal hernia repair: a prospective, randomized, controlled clinical trial

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Abstract
Background The advantage of single-port total extra-peritoneal (TEP) inguinal hernia repair over the conventional technique is still debatable. Our objective was to compare the outcomes of TEP inguinal hernia repair using either a single-port or conventional surgical technique, in two blind randomized groups of patients.
Methods In this prospective, randomized, double-blind, controlled clinical trial, 100 patients undergoing surgery for unilateral inguinal hernia were randomized into two groups: One group underwent conventional laparoscopic TEP inguinal hernia repair, while the other was selected for single-port TEP repair. Primary endpoint is postoperative pain (VAS), while secondary endpoints are recurrence, chronic pain and complications.
Results From 100 patients, 49 underwent single-port hernia TEP repair, 50 had conventional three-port TEP hernia repair, and one patient declined to participate after randomization. The two groups were comparable in terms of patient demographics and operative findings. Mean operative time was 49.1(±13.8) min in the conventional group and 54.1(±14.4) min in the single-port group ($p = 0.08$). Mean hospital stay was 19.7(±5.8) h in the conventional group and 20.5(±6.4) h in the single-port group ($p = 0.489$). No major complications and no recurrence reported at 11-month follow-up. No statistically significant difference noted in postoperative pain between the two groups at regular intervals.
Conclusions The outcomes after laparoscopic TEP inguinal hernia repair with a single-port device are similar but not superior to the conventional technique.

Keywords Single port · Total extra-peritoneal (TEP) · Inguinal hernia · Randomized trial

In the last two decades, surgery was aiming at reducing surgical trauma by reducing access and improving clinical outcome. This has been amplified by the minimal access surgery and followed advances such as natural orifice surgery, reduced port and trans-luminal approaches. Among them, single-incision, single-port and reduced port laparoscopic surgery has become increasingly popular in the last few years. Numerous procedures have been performed using these minimal access techniques, and most of them were found to be safe and feasible. Inguinal hernia repair has also followed the same evolution path and acquired minimal access techniques. The totally extra-peritoneal (TEP) approach for laparoscopic inguinal hernia repair was first described in 1992 [1]. First case of laparoscopic single-site surgery (LESS) for TEP inguinal hernia repair was reported in 2008 [2]. Safety and efficacy of LESS–TEP inguinal hernia repair has been assessed in a few prospective studies [3–6]. But only less than a handful of randomized controlled clinical trials comparing single-port versus conventional TEP (CTEP) inguinal hernia repair has been published up to now [7, 8]. Recently, we published our interim report on randomized controlled

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clinical trial comparing LESS–TEP with CTEP, and we found that there were no significant differences between the two techniques except for the obvious effect on cosmesis [7].

Our study is designed to determine whether laparoscopic TEP inguinal hernia mesh repair carried out with a single-port technique (LESS–TEP), compared to conventional three ports (CTEP), results in a reduction in postoperative pain, shorter hospital stay and less postoperative complications and recurrence, in two blind randomized groups of patients.

Methods

The study is a prospective, randomized, controlled clinical trial approved by National University of Singapore's Domain Specific Review Board (DSRB) (2011/00092). The trial was registered at ClinicalTrials.gov (registration number NCT02302937). We adhered to principles of reporting of results as suggested by the CONSORT protocol extended for non-pharmacological trials [9].

Patients

In our study, we included male patients with primary inguinal hernia, age between 21 and 80 years, ASA (American Society of Anesthesiologists) physical status classification I or II and a body mass index (BMI) <30 kg/m^2. Patients with bleeding disorders, incarcerated, obstructed, strangulated, recurrent or bilateral inguinal hernia were excluded. Patients who had previous lower abdominal surgery on the same side of the hernia or patients with previous cesarean section were also excluded from the study. Patients were prospectively recruited from our outpatient clinics. All patients agreed to participate after having received both verbal and written information regarding the trial as approved by Hospital DSRB. Each patient was randomly assigned to one of the two study arms using the closed envelope method: one arm receiving single-port LESS–TEP, while the other receiving conventional TEP inguinal hernia repair. All subjects and postoperative assessors were blinded to the procedure performed.

Surgical methodology (CTEP)

About 1.5-cm infra-umbilical transverse skin incision made and deepened down bluntly up to the anterior fascial layer. About 1.5-cm size vertical incision made in the anterior fascial layer, and muscle was retracted laterally to expose the pre-peritoneal space. Conventional 10-mm laparoscopic port was used to insufflate CO2. Olympus ENDOEYE (USA) 10-mm laparoscope was inserted through the 10-mm port, and dissection of the pre-peritoneal space was carried out up to the Retzius' space. Standard 5-mm port was inserted in the midline about three finger breadths from the pubis under vision. Another 5-mm port inserted in between the camera port and the 5-mm port. Lateral dissection carried out up to the Bogros' space laterally. Myopectineal orifices dissected to identify the hernia defects. Hernia sac dissected off from the cord structures, and contents reduced into the peritoneal cavity. In some patients where the sac is excessive, it was divided and ligated with pre-made non-absorbable surgical loop. Standard 10 × 15 cm polypropylene mesh was used to cover the myopectineal orifices in all cases. The mesh was secured with six absorbable tackers (AbsorbaTack^{TM} 5 mm, Covidien, USA): two at the Cooper's ligament, two at the rectus medial to the inferior epigastric vessels and two tackers lateral to the inferior epigastric vessels on the transversalis fascia. The rectus sheath was repaired with absorbable sutures, and subcutaneous absorbable sutures were used to close the skin.

Surgical methodology (LESS–TEP)

The surgical technique was similar as for CTEP method except a single-port device (TriPort+^{TM}, Olympus, USA) was used through the infra-umbilical incision. Olympus ENDOEYE (USA) 5-mm laparoscope was used.

Patients were asked to empty the bladder just before the procedure, and an indwelling urinary catheter was not used during any of the cases. At the end of the procedure, three standard skin plasters were placed over the abdomen at similar locations in both groups and advised not to remove for the first 24 h or until the patient leaves hospital. The nurse assessing the pain scores was only informed that the patient underwent a laparoscopic inguinal hernia repair without specifying that it is CTEP or LESS–TEP. The patients recognized whether they had CTEP or LESS–TEP only after removing plasters after their discharge. A standard analgesia regime was used for all patients postoperatively up to 5 days.

The surgeries were carried out by five surgeons which includes the supervising surgeon. Supervising surgeon remained the same for all cases. Cases were randomly and unequally distributed among the trainee surgeons.

Outcome and objectives

The demographic information, intra-operative findings, operative time and length of postoperative hospital stay of all patients were recorded in a data collection template. The European Hernia Society (EHS) groin hernia classification was used to record the intra-operative findings of type and

size of hernia defects [10]. Visual analogue scale (VAS) for pain during the postoperative period at 6 and 24 h or at discharge was recorded by a nurse. Patients were followed up at 1-week, 4-week, 3-month and then 6-month intervals and assessed for any postoperative complications, recurrence and VAS.

The primary endpoint of this non-inferiority study is the postoperative pain score (VAS) at 24 h, while secondary endpoints are postoperative VAS at regular intervals as mentioned above and recurrence, chronic pain and postoperative complications.

Statistical analysis

From our retrospective review of the laparoscopic inguinal hernia repair cases, it is found that the mean pain score of LESS–TEP inguinal hernia repair at 24 h post-surgery was 0.55 units less than that of CTEP hernia repair with standard deviation of 1.8 units. The non-inferiority can be declared only if the mean pain score of LESS–TEP hernia repair is not 0.4 units more than that of CTEP hernia repair. A trial size of 90 subjects in total will be sufficient to test the non-inferiority based on the assumptions which are described before, using one-sided two sample t test with 80 % power and 5 % significant level. The total accrual target would thus be 100, 50 per group, after considering the withdrawer, defaults and lost to follow-up.

Statistical analysis was done using IBM SPSS Statistics Desktop version 22.0.0. Fisher's exact test or χ^2 test was used where applicable for analysis of categorical variables. t test was used for analysis of continuous variables. p value <0.05 was considered as statistically significant.

The CONSORT diagram for randomization and follow-up is illustrated in Fig. 1.

Results

A total of 104 patients were assessed for eligibility and four of them declined to participate. The remaining 100 patients were randomized to CTEP and to LESS–TEP, 50 patients per each group. One patient in the LESS–TEP group declined to participate after randomization. A total of 49 patients from the LESS–TEP group and 50 patients from the CTEP group were studied, and the results were analyzed (Fig. 1). The patient demographic information studied showed no significant difference between the two groups (Table 1). Most common comorbidities were hypertension and hyperlipidaemia. Four patients in the CTEP group and two in the LESS–TEP group had previous open inguinal hernia repair on the opposite side. One patient from each group was on aspirin for ischemic heart disease.

The intra-operative findings, namely laterality of hernia, type and defect size of hernia, presence and grading of adhesions and type of sac contents, showed no significant differences between the two groups (Table 2). The peritoneal sac was divided and ligated in 6 (12 %) subjects in the CTEP group and 11 (22.4 %) subjects in the LESS–TEP group ($p = 0.192$). Peritoneal defects were found in 6 (12 %) and 4 (8.2 %) subjects consecutively in the CTEP and LESS–TEP groups ($p = 0.741$), and all defects were repaired with pre-made surgical loops. Conversion to open technique or use of additional ports was not required in both groups.

The mean operative time (MOT), length of hospital stay after surgery and postoperative complication rates between the two groups showed no statistically significant difference (Table 3). No major complications observed in both groups. The most common complication was postoperative seroma formation, and all of them were managed conservatively and resolved by the 3-month follow-up. In the LESS–TEP group, two subjects developed scrotal hematoma and they were symptomatic. Both were aspirated under local anesthesia in the clinic setting under aseptic conditions. The hematoma and symptoms were fully resolved by the 6-month follow-up. One subject in the CTEP group had port site superficial wound infection which was conservatively managed. Complications such as injury to cord structures and iliac vessels, acute urinary retention, mesh infection, recurrence of hernia, ischemic orchitis and chronic pain were not observed in any of the subjects. VAS for pain during the postoperative period and during the follow-up period showed no statistically significant difference between the two groups (Table 4). In the CTEP group, patients had no pain at 3 months, and in both groups, patients had no pain at 6 months.

Discussion

The transition of open to laparoscopic approach for inguinal hernia repair has taken a smooth and a steady journey despite early debates on recurrence and complication rates. Liem et al. [11] in 2003 observed lower recurrence rates and less chronic pain for laparoscopic approach in his randomized study comparing open and laparoscopic approaches for inguinal hernia repair. In the LEVEL Trial [12] in 2010, comparing Lichtenstein and TEP approaches, it was observed that TEP approach was associated with less postoperative pain, faster recovery of daily activities, quicker return to work and less impairment of sensibility after 1 year, and the recurrence rates and chronic pain were comparable. Wright et al. [13] in another randomized trial comparing open and TEP approach observed that recurrence rates and outcomes were similar for both groups. In a

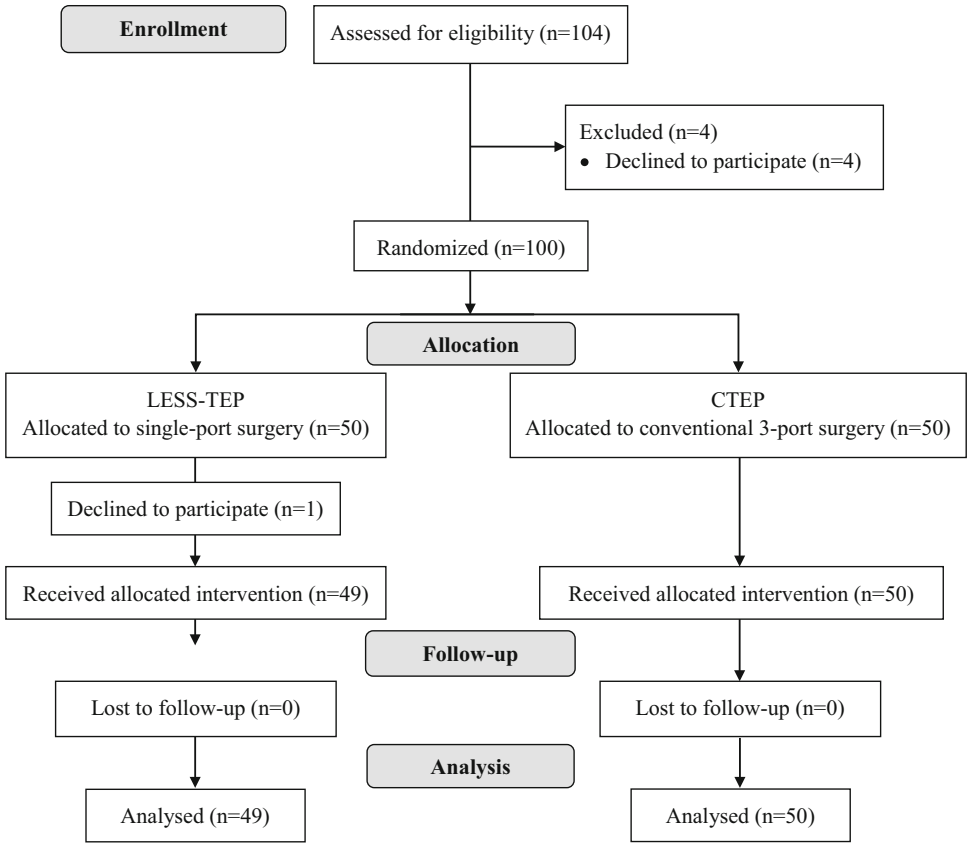

Fig. 1 CONSORT diagram of prospective, randomized, controlled trial to compare laparoendoscopic single-site surgery (LESS–TEP) with conventional totally extra-peritoneal (CTEP) approach for inguinal hernia repair

Table 1 Patient demographic information

Variable		CTEP group ($n = 50$)	LESS–TEP group ($n = 49$)	p value
Age	Mean (SD)	50.3 (±13.8)	47.2 (±14.9)	0.294[a]
Comorbidities	Hypertension	14 (28 %)	7 (14.3 %)	0.140
	Hyperlipidaemia	7 (14 %)	5 (10.2) %)	0.761
	Other[b]	9 (18 %)	8 (16.3 %)	>0.05
	Multiple	11 (22 %)	4 (8.2 %)	0.091
Allergies		3 (6 %)	4 (8.2 %)	0.715
BMI (kg/m^2)	Mean (SD)	24.2 (±2.9)	24.3 (±3.4)	0.898[a]
Previous open inguinal hernia repair on the opposite side		4 (8 %)	2 (4.1 %)	0.678

SD standard deviation

[a] p value based on t test

[b] (Other comorbidities): gout [2], diabetes mellitus [4], thalassemia [1], aortic regurgitation with heart block on pacemaker [1], history of subdural hemorrhage [1], hydrocele [1], Brugada syndrome [1], hypopituitarism [1], history of multi-nodular goiter [1], trauma [1], ischemic heart disease [2], anal fistula [1]

meta-analysis in 2012, O'Reilly et al. [14] studied TEP, trans-abdominal pre-peritoneal (TAPP) and open approaches for inguinal hernia repair and found that both TEP and TAPP approaches have reduced risk of chronic pain and numbness compared to open approach. Hence, laparoscopic approach for inguinal hernia repair has become the acceptable treatment for groin hernia repairs in the recent past due to its reduced postoperative pain and low recurrence rates [15, 16]. The safety and feasibility of the laparoscopic TEP approach has been repeatedly assessed over the years since 1993 when Ferzli et al. [17] published his series of 101 patients [15, 16, 18]. The concept of "reduced port surgery" has gained popularity in laparoscopic surgery in many sub-specialities. LESS approach is

Table 2 Comparison of intra-operative findings

Intra-operative finding		CTEP group ($n = 50$)	LESS–TEP group ($n = 49$)	p value
Laterality	Left side	25 (50 %)	23 (46.9 %)	0.841
	Right side	25 (50 %)	26 (53.1 %)	
Site of the defect (type of hernia)	Lateral	45 (90 %)	46 (93.9 %)	0.715
	Medial	26 (52 %)	24 (49 %)	0.842
	Femoral	3 (6 %)	–	0.242
	Multiple	23 (46 %)	21 (42.9 %)	0.841
Largest defect size[b]	Mean (SD)	2.1 (±0.6)	2.0 (±0.7)	0.433[a]
Adhesions present		7 (14 %)	8 (16.3 %)	0.786
Grade of adhesions[c]	Mean (SD)	1.1 (±0.4)	1.2 (±0.7)	0.727[a]
Bowel present in the sac		2 (4 %)	3 (6.1 %)	0.678
Omentum present in the sac		15 (30 %)	13 (26.5 %)	0.824

SD standard deviation

[a] p value based on t test

[b] Type and size of groin hernia defect are based on the EHS groin hernia classification. Type: lateral/medial/femoral; size: 1–3

[c] Grade of adhesions (0–3; 0: none, 1: mild, 2: moderate, 3: severe)

Table 3 Comparison of outcome variables: operative time, length of hospital stay and postoperative complications

Operative finding		CTEP group ($n = 50$)	LESS–TEP group ($n = 49$)	p value
Operative time (min)	Mean (SD)	49.1 (±13.8)	54.1 (±14.4)	0.080[a]
Hospital stay (h)	Mean (SD)	19.7 (±5.8)	20.5 (±6.4)	0.489[a]
Postoperative complications	Hematoma	–	2 (4.1 %)	0.242
	Seroma	7 (14 %)	3 (6.1 %)	0.318
	Other[b]	3 (6 %)	3 (6.1 %)	>0.05

SD standard deviation

[a] p value based on t test

[b] Other postoperative complications: skin ecchymosis [1], superficial wound infection [2], scrotal edema [3]

Table 4 Comparison of VAS (visual analogue scale) for pain in the postoperative period and during the follow-up

Outcome variable—VAS for pain[a]	CTEP group ($n = 50$)	LESS–TEP group ($n = 49$)	p value[b]
VAS 6 h post-surgery—mean (SD)[c]	2.6 (±1.3)	2.1 (±1.5)	0.146
VAS 24 h post-surgery[d]—mean (SD)[c]	2.1 (±1.5)	1.5 (±1.5)	0.067
VAS 1 week post-surgery—mean (SD)	0.6 (±1.0)	0.7 (±1.1)	0.588
VAS 4 weeks post-surgery—mean (SD)	0.1 (±0.3)	0.1 (±0.5)	0.801
VAS 3 months—mean (SD)	–	0.02 (±0.14)	0.325
VAS 6 months—mean (SD)	–	–	–

SD standard deviation

[a] *VAS* visual analogue score for pain (0–10)

[b] p value based on t test

[c] The assessor was blinded by using an identical type of wound dressing in both groups

[d] If the patient gets discharged before 24 h, then the VAS at the time of discharge was taken as the VAS at 24 h post-surgery

feasible and has been used safely for appendectomy [19, 20], cholecystectomy [21–23] and even for colectomy [24] with its obvious proven benefit of cosmetics and debatable effects on postoperative pain compared to the conventional laparoscopic approaches.

It has not taken much time for inguinal hernia repair to incorporate the concepts of "reduced port surgery" or "minimal access surgery." Lau et al. [25] in 2002 describes his needlescopic approach for groin hernia repair with its better postoperative pain compared to CTEP approach. In

2010, we described our institutional experience in LESS–TAPP approach for groin hernia repair with comparable outcomes to the conventional TAPP approach [26]. Kwon et al. [27] in 2011 performed TEP inguinal hernia repair in 24 patients without the supra-pubic port and demonstrated advantages in postoperative pain, urinary retention, operating time, postoperative hospital stay and cosmetic effect over the CTEP technique. Sato et al. [28] in 2010 compared LESS–TAPP, CTEP and Conventional TAPP approaches and found that LESS–TAPP is safe and feasible and the outcomes are comparable to the other two approaches.

In 2010, Agrawal et al. [29] described his experience in using the TriPort™ system in LESS–TEP technique to be safe and feasible and managed to perform the procedure with a median incision length of 30 mm. We used the same TriPort™ system in all our patients who underwent LESS–TEP with a standard 1.5-cm infra-umbilical transverse incision.

The LESS–TEP approach which was first described by Cugura et al. [2] in 2008 has been gaining popularity in the recent past, but the advantage of this technique over the CTEP is still debatable. Studies comparing LESS–TEP and CTEP started to appear in the literature a couple of years later. In 2010, Sherwinter [3] compared their first 52 patients who underwent LESS–TEP with CTEP approach and observed similar operative times and outcomes. In 2011, Do et al. [30] in their initial experience of LESS–TEP in ten consecutive patients observed that the technique is safe and feasible, and their mean operative time (MOT) was 53 min which was similar to our MOT of 54.1 min, but they had a slightly bigger skin incision and a longer postoperative hospital stay.

A number of retrospective studies comparing LESS–TEP and CTEP were published in the recent past. In most of these studies, the patient demographic data are similar and comparable to the data in our study. In a study by Buckley et al. [31], the MOT for unilateral LESS–TEP was 57.5 min. In a another retrospective study by Wakasugi et al. [32], the MOT for unilateral LESS–TEP was much longer (93 min) and they had 1 conversion to CTEP approach. The MOT for both unilateral and bilateral hernia repair was significantly longer in the LESS–TEP approach compared to CTEP approach in a study by de Araujo et al. [33], and they observed superior cosmetic results in the LESS–TEP group. In all these three studies, the postoperative complications and outcomes between the LESS–TEP and CTEP groups were similar and comparable.

Our study population characteristics are comparable to the study population in the randomized clinical trial conducted by Tsai et al. [8]. They reported a significantly longer ($p = 0.001$) MOT in the LESS–TEP group (63.5 min) compared to the CTEP group (50.5 min). They also reported a minor benefit of reduction in immediate postoperative pain in the LESS–TEP group. In our study, we did not observe any statistically significant difference in any of the above outcomes. Kim et al. [5] also reported no significant difference in the MOT time between the LESS–TEP and CTEP groups in his study. In a comparison study between CTEP and LESS–TEP, Cugura et al. [4] concluded that both techniques are comparable and LESS–TEP is a safe and a feasible technique with a short learning curve. Tai et al. [6] in their study concluded that inguinal hernia repair via the LESS–TEP technique is as safe as the CTEP technique. However, they believed that the LESS–TEP technique is not an efficacious surgical alternative to the CTEP technique for inguinal hernia likely due to the significantly shorter mean operative time (MOT) in the CTEP series. A recent meta-analysis of eight prospective studies by Lai et al. [34] concluded that LESS–TEP is feasible and safe in certain patients when compared to CTEP, and carries a similar outcome, with the exception of longer operative times for unilateral inguinal hernia repair. In our study, the mean operating time (MOT) for LESS–TEP is slightly longer than for CTEP, but this was not statistically significant.

In most of the above studies comparing CTEP and LESS–TEP, there were no significant differences observed in the postoperative hospital stay, complications, recurrences and postoperative pain scores and these studies and their results are comparable to our randomized controlled trial of 100 patients comparing LESS–TEP and CTEP. In our study, all patients underwent surgery, completed 11 months of follow-up, and 80 patients had at least completed 20-month follow-up, and there were no reported cases of postoperative chronic pain or recurrence.

The four trainee surgeons in our study had more than 6 months of training in TEP and performed over 50 cases under the supervising surgeon before they started performing both LESS–TEP and CTEP cases in our study. We observed that the learning curve for LESS–TEP for surgeons trained in CTEP seems to be short, especially considering that in our CTEP technique the sub-umbilical working ports are on the midline. Less than ten cases seems to be necessary to become proficient in LESS–TEP, and all the surgeons have already performed at least 15 cases each before enrolling in the trial. Patients may question in particularly regarding the cost and cosmesis, when we suggest a single-port hernia repair to them. Regarding the cost, the difference between CTEP using disposable trocars and LESS–TEP is minimal and does not influence the total cost of the procedure more than 1 %. Accordingly to our DSRB, all patients were informed and agreeable with the cost and its difference.

In conclusion, in our randomized double-blind controlled clinical trial of 100 patients, we observed that both primary and secondary outcomes of the single-port TEP

technique are comparable but not superior to the conventional TEP technique and these results are similar to our interim report results published previously [7].

Disclosures Doctors Sujith Wijerathne, Narendra Agarwal, Ahmad Ramzi, Dino H Liem, Wee B Tan and Professor Davide Lomanto have no conflict of interest and financial ties to disclose.

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