

A Comparative Randomized Parallel Group Study between the Classical TAPP Repair and Modified TAPP Surgical Method for Inguinal Hernia Repair

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ABSTRACT

Objective: To compare equality of clinical outcome of simultaneous bilateral transabdominal preperitoneal (TAPP) repair of inguinal hernia by classical TAPP, with meticulous closure of peritoneal flap and modified TAPP, with peritoneal nonclosure and controlled release of pneumoperitoneum. Study to answer the research question—'is meticulous closure of peritoneal flap, the only way to provide adequate cover for the mesh in TAPP repair?'

Summary and background data: The objective of meticulous closure of peritoneum is to prevent internal herniation while covering the mesh adequately to avoid contact between mesh and abdominal viscera. The study proposes same objective can also be achieved with nonclosure of peritoneum.

Patients and methods: Between August 2011 and July 2012, 130 inguinal hernias of 65 patients who underwent TAPP repair were randomized in two groups. One group (n = 65) of hernias received classical repair with peritoneal closure (control), while the other (n = 65) without closure (study). The primary end points were bowel related complications and recurrence.

Results: The two groups were comparable in age and types of hernia. Transabdominal preperitoneal was successfully done in all cases. No bowel-related complication and recurrence occurred in either group. Mean operating time was significantly less with modified TAPP (65 mins vs 76 mins, $p < 0.05$). Lower incidence of chronic pain (3 vs 13.84%, $p = 0.007$) and seroma (7.69 vs 15.38%) was achieved during mean follow-up of 628 days.

Conclusion: The randomized prospective parallel group study demonstrated equality in clinical outcome on both primary end points by providing equivalent peritoneal cover for the mesh as meticulous peritoneal closure does in classical TAPP.

Keywords: Laparoscopic repair, Inguinal hernia, Preperitoneal, Transperitoneal, Complication, Intestinal.

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INTRODUCTION

Gall stone disease and inguinal hernia are two most common surgical problems amenable to laparoscopic surgery but the acceptance and spread of laparoscopic inguinal hernia repair (LIHR) is significantly less than laparoscopic cholecystectomy (LC). Even today, only 15 to 20% of hernia repairs are done laparoscopically in America. Two factors limiting its acceptability among patients and surgeons are: stiffer learning curve for surgeons and cost associated with LIHR.¹ Without aversion for use of modern technology, efforts to simplify the technique should be made by sparing the use of costly disposable equipment, when possible, without compromising safety and efficacy of the procedure. This should make it cost effective and acceptable. Increased cost in LIHR is due to use of disposable equipment like hernia staple or tack and longer operating time. Honing little extra skill and avoiding unnecessary use of gadgets make the procedure shorter and cost effective. It is the cost and technology dependence that has overshadowed the obvious benefits of LIHR, like shorter convalescence, equivalent efficacy, and early return to work.¹⁻⁴ This trial is intended to answer the research question: 'is meticulous closure of peritoneal flap, the only way to provide adequate cover for the mesh in TAPP repair?' The study focuses on an alternate concept of functional closure of peritoneum, required to cover the prosthesis to avoid adhesion and internal herniation,⁵⁻⁷ adhesion being the precursor of unacceptable postoperative complications like intestinal obstruction and fistulisation. It scientifically compares the clinical outcome of the modified technique of absolute nonclosure of peritoneal flap, which is only made larger and simply relaid in position with controlled DE insufflations abdominal viscera gliding along posterior wall presses the flap sequentially from below upward against the anterior abdominal wall where the repair is done and flap was initially harvested from, effectively covering the prosthesis and does exactly what meticulous closure do in

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classical transabdominal preperitoneal (TAPP) repair. This saves cost and operating time while achieving comparable clinical outcome regarding bowel related complications and hernia recurrences as shown in follow-up.

With low recurrence and complication rate achieved with LIHR, emphasis is now on finer issues, like operating time, incidence of seroma and chronic pain. The study also compares the techniques in a randomized prospective fashion to see whether any difference of statistical significance exists on those parameters.

Overall, it wants to test the validity of null hypothesis regarding clinical outcome between modified TAPP (non-closure of peritoneum) and classical TAPP (meticulous closure of peritoneum).

PATIENTS AND METHODS

Between August 2011 and July 2012, all patients with bilateral inguinal hernia presented to us were assessed for eligibility in the proposed study. Inclusion criteria were male patients with bilateral hernia and suited for TAPP repair, aged more than 18 years and fit to undergo general anesthesia. Patients with recurrent hernia or with indication for concomitant surgery for other pathology or with past lower abdominal surgery were excluded. The research protocol was approved by the Institutional Ethics Committee of ESIC Medical College and Postgraduate Institute of Medical Research, Joka, Kolkata (where the trial was conducted), before the commencement of the trial. Informed consent was obtained before patients were included in the trial. One hundred and thirty hernias in 65 patients were randomized using digit 1 and 2 with the option of repetitions to create a random sequence of 130 digits. Two consecutive digits formed a double digit randomization code which is allotted to one patient. Digit 1 stood for classical repair and digit 2 for modified TAPP. First digit of the code dictates treatment option for right side while the second for the left. Randomization codes for patients were kept in sealed envelopes in the custody of theater nurse. Prospective data entry sheets were used for collection of data.

Modification of Technique with Rationale

The basic principle of TAPP repair with wide dissection of preperitoneal space and securely anchoring a large (15 cm × 10 cm) prolene mesh to cover all myopectineal orifices in the region remains same. However in order to harvest a larger peritoneal flap, initial peritoneal incision is made 2 cm higher than normal. Good parietalization of the cord keeps the lower margin of the mesh firmly wedged. Only two-point fixation of the mesh to Cooper's ligament is done with 2-0 prolene suture. The peritoneal flap is relaid

back in position with controlled de insufflations of pneumoperitoneum. No attempt is made on peritoneal closure.

The repair and placement of mesh done in TAPP repair is on anterior abdominal wall, from where the peritoneal flap is harvested with its base at the line of reflection of peritoneum from posterior to anterior abdominal wall. On controlled release of insufflations and loss of Trendelenburg position viscera glides along posterior wall and puts sequential pressure on the flap from below and presses it back in position against the anterior wall. Weight of the viscera keeps it securely placed while rapid mesothelial healing takes place leaving no opportunity of direct contact between mesh and bowel.

Surgical Technique

Patients were operated under general anesthesia in supine and 10 to 15° Trendelenburg position with operating side tilted up and prophylactic antibiotic given on induction. Pneumoperitoneum was induced by supraumbilical Veress needle insertion. One 10 mm port for optics was introduced here and two 5 mm ports introduced at mid clavicular line at the level and on either side of umbilicus to accommodate operating instruments. In modified TAPP, initial curvilinear peritoneal incision starting at the level of anterior superior iliac spine laterally, is made 2 cm higher than in classical TAPP to make the flap larger. Dissection of preperitoneal space was carried out in similar fashion with parietalization of cord structure done adequately, the landmark for adequacy is to dissect up to the point where vas deferens crosses medial umbilical ligament. A 10 × 15 cm prolene mesh trimmed laterally to comfortably sit in the space of Retzius and Bogros, covering the myopectineal orifices is anchored to Cooper's ligament at two points by prolene sutures. Only in 27 cases when we used tack to close the peritoneum, this two-point fixation of mesh was done by tack. When in place, the lower margin of the mesh wedges at the line of dissected peritoneal reflection inferiorly, while its superior margin stays below the initial peritoneal incision. The peritoneal flap was held up by instrument while pneumoperitoneum is deflated in a controlled fashion, till it is relaid back in position on anterior abdominal wall.

Outcome Assessment

Primary end points were recurrence of hernia and any bowel related complications like intestinal obstruction and fistula. Presence or absence of recurrence was determined by clinical examination in follow-up, aided by radiological investigations like CT and US in selected cases. As regard to the gastrointestinal complications, combination of clinical history and examination backed up by radiology was used.

Three secondary parameters were compared and analyzed for any difference of statistical significance. Operating time,

incidences of seroma and chronic pain were compared between the groups. Seroma was defined as clinical presence of palpable fluid collection over the groin in the absence of bruising. Operating time was defined as the time taken from the skin incision to the last skin suture. Entry and closure time together were separately measured in each case and this common duration were added to either side repair time for equitable comparison. All time measurements were approximated to the nearest integer of 5. Total number of nights spent in the hospital after operation was defined as hospital stay.

Chronic pain was defined as discomfort /pain in the groin area at least 3 months after surgery and debilitating enough to interfere with daily activity requiring medical attention, in the absence of recurrence of hernia on the side of pain.

Postoperatively all patients received one 100 mg sustained released diclofenac tablet each day for 2 days, supplemented by 1 gm of oral paracetamol tablet (spaced 6 hourly) on demand basis. Paracetamol tablet was the prescribed analgesic for a maximum of 7 days on discharge. Analgesic requirement was calculated from the total amount of paracetamol consumed postoperatively, expressed in gram.

A sample size analysis was performed using a two-tailed t-test with a probability of type I error (alpha) of 0.05 and type II error (beta) of 0.2 (power 80%), and assuming a standard deviation of 10% (expected variance of 0.01) the required minimum sample size to prove equality of mean for the groups is calculated to be 63 in each group. In our study, both the groups (group 1 receiving classical TAPP repair and group 2 receiving modified TAPP repair) had a sample size of 65 each.

Statistical analysis was performed using computer software (MedCalc), and outcome measures were expressed with 95% confidence interval, p-value calculated from two-tailed t-test or chi-squared as appropriate.

RESULTS

Between August 2011 and July 2012, 75 patients presented with bilateral inguinal hernia were assessed for study eligibility. Figure 1 shows the profile of the trial according to the CONSORT statement. A total of 130 inguinal hernias with bilateral occurrence in 65 patients were randomized into study group (n = 65; Rx-modified TAPP) and control group (n = 65; Rx-classical TAPP). Out of 65 in the control group peritoneal closure was done with tack in 27 patients (n = 27) and by suturing in 38 patients (n = 38). The groups were comparable in age and Nyhus type of hernia as determined during surgery (Table 1). Figure 2 shows incidences of type of hernia in bilateral setting as found in this study.

All the TAPP repairs were successfully performed and there were no conversion to open surgery. No gastrointestinal

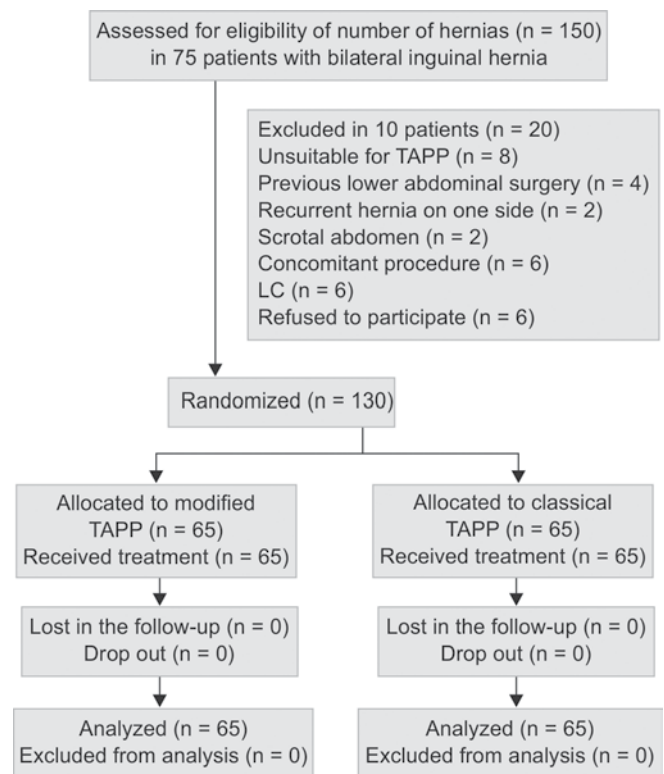


Fig. 1: Trial profile

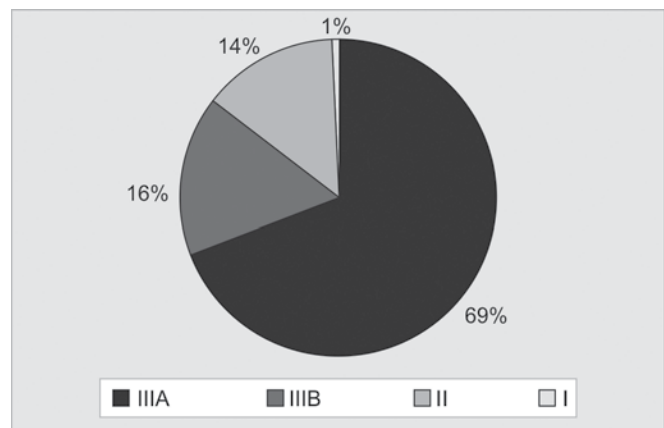


Fig. 2: Incidence of hernia type in bilateral setting as found in this clinical trial

Table 1: Patient's characteristics

Characteristics	Modified TAPP (n = 65)	Classical TAPP (n = 65)	p-value
Age in years [mean (range)]	50.93 (30-78)	47.66 (28-74)	0.116*
Types of hernia [number (%)]			
I	0 (0)	1 (0.76)	—
II	8 (6.15)	10 (7.69)	0.422**
IIIA	46 (35.38)	44 (33.84)	0.945**
IIIB	11 (8.46)	10 (7.69)	0.461**

Nyhus classification; *t-test statistics; **Chi-square test

complication and hernia recurrence happened in study (x = 0) and control (x = 0) group during follow-up, which is self-explanatory regarding equality of clinical outcome

in view of statistically calculated minimum sample size chosen at the beginning. Mean follow-up was 628 days with range between 435 and 797 days. Operating time and corresponding standard deviation of different techniques are shown in Figure 3. The mean operating time in the study and control groups were 65.15 (50-90 mins) and 76.64 minutes (55-95 mins) respectively. p-value of < 0.0001 calculated from t-score of 7.294. There were no intraoperative complication, need for readmission or re-exploration and hospital mortality in either group. Table 2 summarizes the postoperative complications, while Table 3 illustrates comparison of techniques on analgesic requirement, hospital stay and time for return to work. Table 4 demonstrates cost effectiveness of the modified technique comparing against major variants that determine effective cost of a procedure. No wound or mesh infection was reported in any patient. The study group had significantly lower incidence of seroma. Overall incidence of seroma was 11.53% (95% CI; 6-17%). In study group,

the incidence was 7.69% (95% CI; 1-14%), whereas, in the control group, the incidence was 15.38% (95% CI; 7-24%). However, with a p-value of 0.164, this observed difference lost statistical significance. Majority of seromas developed within couple of weeks and detected in follow-up visit 1 month after surgery and resolved spontaneously by 3rd month. Fourteen out of total 15 incidences of postoperative seroma, developed following repair of direct hernia (IIIA) treated by either method.

Regarding postoperative chronic pain, the overall incidence was 8.46% (95% CI; 3-13%) (n = 11). In the study group, it was 3% (95% CI; 0-7%) (n = 2) in contrast to higher incidence in the control group of 13.84% (95% CI; 5-22%) (n = 9). p-value of 0.0071 denotes significance of difference. One interesting finding was very high incidence of chronic pain when hernia tacker was used to fix the mesh with Cooper's ligament and for closure of peritoneum. Incidence was 29% (95% CI; 12-47%) (n = 8). Majority of chronic pain presented at 6 months follow-up visit (10/11), and had a slightly protracted course and resolved in all but two patients by 1 year follow-up. Two patients continued to have pain ever after a year, despite analgesics and neuromodulating medications and at present being cared for by pain clinic specialists. Chronic pain bore no relation with initial analgesic requirement at home after discharge.

Five patients developed vaginal hydrocele, all detected at 3 months follow-up visit and progressed to increased size and discomfort over time and had to be treated by surgery subsequently. On all occasions, TAPP was done for indirect hernia with high ligation of sac.

Ultrasound (US) was done on 40 separate instances in 34 patients in the follow-up period for investigation of postoperative seroma, chronic pain, vaginal hydrocele, abdominal pain and identifying recurrence of hernia. On two occasions when US could not conclusively eliminate recurrence in patients with chronic pain, computed tomography (CT) of involved groins was performed which successfully excluded recurrence on both occasion.

Average time taken for peritoneal closure by suturing was 12 minutes. Mean duration of follow-up has been 628 days.

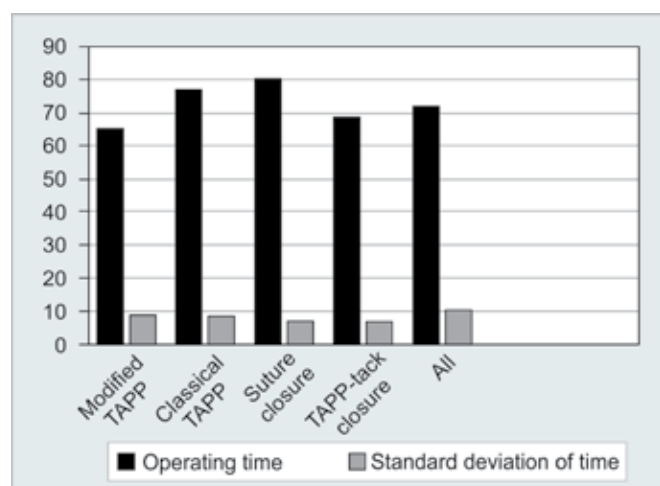


Fig. 3: Operating time with standard deviation in minutes with different techniques of TAPP repair

Table 2: Postoperative complications

Complication	Modified TAPP (n = 65)	Classical TAPP (n = 65)	p-value
	No. (%)	No. (%)	
Seroma	5 (7.69)	10 (15.38)	0.168*
Chronic pain	2 (3.07)	9 (13.84)	0.007*
Vaginal hydrocele	2 (3.07)	3 (4.61)	1**

*p-value from Z score; **Fisher's exact test

Table 3: Comparison of techniques on analgesic requirement, hospital stay and time for return to work

Group	Patient and technique	Analgesic requirement (gm) Mean (range)		Hospital stay in days Mean (range)		Return to normal work (days) Mean (range)	
A	All TAPP repair (n = 65)	21.86 (12-28)		2.10 (1-3)		17.87 (11-30)	
B	Both sides by classical TAPP (n = 18)	20.16 (12-28)		2 (1-3)		17.875 (14-30)	
C	At least one side by modified TAPP (n = 47)	22.59 (12-28)		2.14 (1-3)		17.78 (11-26)	
		p-value when compared to					
		A	B	A	B	A	B
		0.468	0.096	0.597	0.181	0.896	0.934

Table 4: Comparison of cost effectiveness on variable determinants of cost

<i>Variable determinants of cost</i>	<i>TAPP with tack</i>	<i>TAPP with suture</i>	<i>Modified TAPP</i>
Type of anesthesia and related consumables	✓	✓	✓
Perioperative medications	✓	✓	✓
Hospital stay	✓	✓	✓
Readmission	Nil	Nil	Nil
Re-exploration	Nil	Nil	Nil
Loss of work day	±17 days	±17 days	±17 days
Cost of investigation in follow-up	✓	✓	✓
Cost of disposable surgical equipment	✓	–	–
Operating time	✓	✓✓	✓
Cost for treatment of complication	✓	–	–
1. Seroma	✓	✓	✓
2. Chronic pain	✓✓	✓	✓
3. Vaginal hydrocele	✓	✓	✓
4. Recurrence of hernia	✓	✓	✓
5. Bowel-related complication	✓	✓	✓

DISCUSSION

Laparoscopic inguinal hernia repair has evolved over the years as an alternative to the best method of open repair. However, it is still not the gold standard. Steep learning curve and increased cost being the major constraints. Average extra cost LIHR incurs over open repair has roughly been estimated to be 300 to 350 UK pounds. Disposable equipment and longer operating time is the key cost driver.⁸ Efforts to curtail cost without compromising safety and efficacy have led to many modifications of TAPP procedure. To be considered, a viable alternative to most successful method of conventional surgery the recurrence rate should be <2%.⁹

Central to successful TAPP repair is the need for wide dissection of preperitoneal space and placement of a large and anchored mesh to adequately cover all the myopectineal orifices.⁹⁻¹¹ Case reports and animal trials¹²⁻¹⁴ have suggested increased visceral adhesion to exposed prolene mesh in intraperitoneal on lay placement, which forms the basis of preperitoneal or extraperitoneal placement of prolene mesh in TAAP and TEP respectively. However, there are reports of animal study that suggests—prolene mesh placed preperitoneally by intraperitoneal route, the adhesion increases on suture closure of peritoneal incision in comparison to leaving it open.¹⁵ Apart from preventing internal herniation through imperfect closure of peritoneal incision, it also provides a reassuring peritoneal cover for the mesh when the peritoneal incision is meticulously closed in classical TAPP repair. Apprehension has been raised¹⁴ and incidences cited¹⁶ about bowel complications occurring postoperatively if strict adherence to the practice of peritoneal closure is breached. To minimize prosthesis induced intraperitoneal adhesions relatively nonreactive PTFE mesh has been introduced¹⁷ which come with a price tag sufficient to compromise cost effectiveness further.

The study hypothesis proposed an alternative way of peritoneal reapproximation utilising the intra-abdominal biomechanics relevant to the area of repair that uses the pressure exerted on the flap by the viscera to keep it securely opposed to the anterior abdominal wall while healing takes place and thus provides equivalent peritoneal cover for the mesh. Absence of any adhesion with excellent peritoneal cover achieved (when modified TAPP was done earlier), as seen on two relook opportunities obtained during subsequent LC may not be entirely representative, but the finding strengthens the principle of hypothesis proposed. In order to satisfy the criteria set, one has to dissect the preperitoneal space widely with adequate parietalization, to the point of crossing of vas over medial umbilical ligament. Essentially it provides adequate space to accommodate a larger mesh comfortably with its inferior margin wedged firmly at peritoneal reflection without any tendency to be pushed up by the peritoneum during release of pneumoperitoneum, eliminating an important cause of immediate recurrence. This supplements medial anchorage to prosthesis provided by two-point fixation to Cooper's ligament, lateral anchorage being provided by the weight of viscera without any need for mechanical means.

Evolution of TAPP repair has been striking from late nineties to present day. Early reports show significant perioperative events, higher recurrences and longer operating time. Improved parameters in recent trials confirm the safety and efficacy of TAPP repair has improved with collective and individual experience over time.^{11,18,19} Several trials have identified the factors that lead to recurrence following TAPP-like surgeon's inexperience, inadequate dissection, and insufficient size of prosthesis, improper fixation, twisting or folding of mesh and lifting of mesh by hematoma. Contrasting views exist regarding anchorage of the mesh,

while most advocates anchoring the mesh to prevent migration, many others suggest it unnecessary,^{20,21} moreover, injudicious application of tack or staple below iliopubic tract carries an inherent risk of nerve damage.²² Very high proportional incidence of chronic pain in patients on whom helical tack was used for mesh fixation and peritoneal closure in this study needs due attention as a potential cause of such pain of somatic and neural origin. Intraoperative complications though rare, are serious in nature, mostly in the form of visceral injury.^{18,23,24} Trials have shown reduction of complications and operating time with increased experience. Postoperative gastrointestinal complications are port-site hernia, internal herniation from improper peritoneal closure and adhesion leading to intestinal obstruction and occasional fistulisation when bowel is involved.^{4, 25-27} Bowel obstruction by herniation through trocar site or imperfect closure of peritoneum³ occur earlier (8 days) than obstruction from adhesion which commonly happens after a month (mean onset 25 days),² just as majority of hernia recurrences following LIHR develops within a year.⁶ Both these statistics fall within purview of follow-up done in this study.

With preoperative and major postoperative complication like recurrence brought down to acceptable level in LIHR, the focus now have shifted to other parameters like chronic pain, analgesic requirement, return to work and most importantly the cost of surgery which is so important that advantages of LIHR with shorter convalescence and early return to work when weighed against cost, it leaves only bilateral and recurrent hernias following anterior approach the undisputed indications of LIHR.²⁸

Seroma developed early (within 1 month) though spontaneously resolved relatively quickly and occurred almost exclusively following repair of direct hernia in this study. This fact highlights the importance of inversion of fascia transversalis either by fixing it to pubic bone or by application of endoloop at the base of inverted fascia and amputating the redundant portion,^{29,30} neither of which was performed in this study. Chronic pain developed late (by 6 months) and carried a rather protracted course, but resolved with counseling, analgesics and neuromodulating drugs like amitriptyline in vast majority of cases. As reported in an earlier study¹⁸, postoperative hydrocele developed late, progressed with time and required surgery as they did not resolve spontaneously. They developed in larger indirect hernias where complete dissection of sac was not possible.

Regarding cost advantage, each procedure of modified TAP saved \$ 130 by avoiding use of hernia tack,²⁰ over and above the savings from shorter operating time.

The study concludes that, while offering equality of clinical outcome regarding gastrointestinal complications and hernia recurrence, when compared with standard

technique, it gave superior result regarding operating time and incidences of chronic pain. Cost of surgery was significantly less while giving compatible result regarding analgesic requirement, time for return to work and hospital stay. For ethical reason, direct evidence of effectiveness of this technique in providing peritoneal cover for the prosthesis was not collected during the trial, it provided enough indirect and limited direct evidence in support of the alternate hypothesis of peritoneal cover, as proposed in the study which did not assess and compared intra-abdominal adhesions in real time but it closely monitored the expected clinically significant effects of adhesion and found the end result extremely satisfactory and answered the research question comprehensively by providing a more physiological alternative way of proving a peritoneal cover for prosthesis and provokes the need for further studies to see if the study outcome can be reproduced.

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