The classical TAPP repair and modified TAPP surgical method: A comparative randomized parallel group study of Inguinal Hernia

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Abstract

Background: 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 non-closure of peritoneum. Objective: To compare equality of clinical outcome of simultaneous bilateral Trans abdominal preperitoneal (TAPP) repair of inguinal hernia by classical TAPP, with meticulous closure of peritoneal flap and modified TAPP, with peritoneal non closure 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?" Materials and Method: Between August 2011 and July 2012, 130 inguinal hernias of 65 patients who underwent TAPP repair were randomised 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 endpoints were bowel related complications and recurrence. Results: The two groups were comparable in age and types of hernia. TAPP 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 min vs. 76 min, 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 randomised 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: inguinal hernia, Laparoscopic repair, Trans Abdominal Preperitoneal; Professor and Head, Department of Surgery, ESIC Medical College & Post Graduate Institute, Joka, Kolkata (India)

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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) significantly less than laparoscopic cholecystectomy [LC]. Even today only 15-20% of hernia repairs are done laparoscopicaly 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 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's 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 required to peritoneum. cover prosthesis to avoid adhesion and internal herniation [5-7]. adhesion being precursor of unacceptable post-operative complications like intestinal obstruction and fistulisation. It scientifically compares the clinical outcome of the modified technique of absolute non-closure of peritoneal flap, which is only made larger and simply re-laid in position with controlled DE insufflations. Abdominal viscera gliding along posterior wall presses the flap sequentially from below upwards 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 classical 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 randomised 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).

Material & 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 yrs and fit to undergo general anaesthesia. 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 Post Graduate 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. hernias in 65 patients randomised 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 second for while the the left. Randomization codes for patients were kept in sealed envelopes in the custody of theatre nurse. Prospective data entry sheets were used for collection of data.

Modification of technique with rationale

The basic principle of Trans abdominal pre-peritoneal (TAPP)repair with wide dissection of pre-peritoneal space and securely anchoring a large (15cm*10cm) 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 2cm higher than normal. Good parietalization of the cord keeps the lower margin of the mesh firmly wedged. Only 2 point fixation of the mesh to

Cooper's ligament is done with 2-o 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 de 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 anaesthesia in supine and 10-15 degrees trendelenburg position with operating side tilted up and prophylactic antibiotic given on induction. Pneumoperitoneum was induced by supra umbilical veres needle insertion. One 10 mm port for optics was introduced here and two 5mm 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 2cm 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 crosses medial deferens umbilical ligament. A 10CM*15CM 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 2point 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 by instrument while up pneumoperitoneum is deflated in a controlled fashion, till it is re-laid back in position on anterior abdominal wall.

Observation and Results: 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 analysed 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.

Post operatively all patients received one 100 mg sustained released Diclofenac tablet each day for two 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 post operatively, expressed in gram.

A sample size analysis was performed using a 2 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

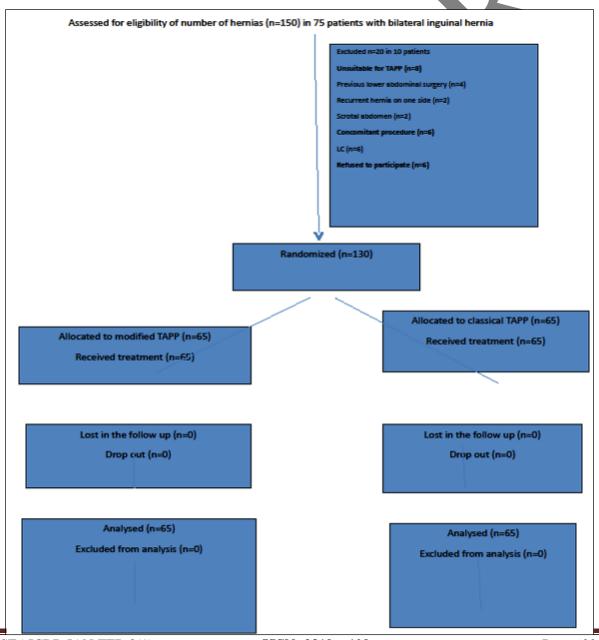
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and Group-2, receiving modified TAPP repair) had a sample size of 65 each.

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.

<u>Results:</u> 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. **Figure 1: Trial profile**



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[Table1].Figure 2 Shows incidences of type of hernia in bilateral setting as found in this study.

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

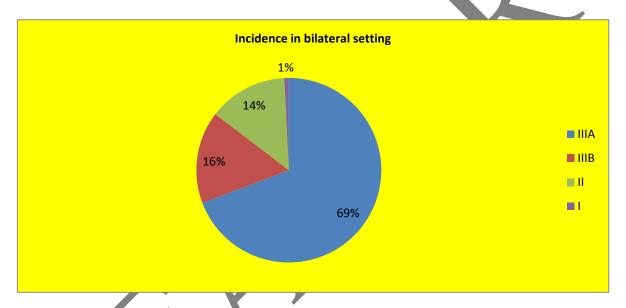
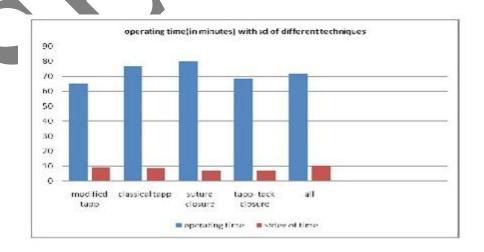


Figure 3: Operating time with standard deviation in minutes with different techniques of TAPP repair.



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Table 1: Patient 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 (%	5)]		
	0(0)	1(.76)	
	8(6.15)	10(7.69)	0.422^
IIIA	46(35.38)	44(33.84)	0.945^
шв	11(8.46)	10(7.69)	0.461^
Nyhus classification * Test statistics t			

All the TAPP repairs were successfully performed and there were no conversion to open surgery. No gastrointestinal 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 435-797 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 min(range 50 min -90 min) & 76.64 min(range 55min-95min) respectively. P value of <.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.

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Table 2: Post-operative complications

^ p-value from Z score

* Fisher's exact test

Complications	Modified TAPP N=65; No (%)	Classical TAPP N=65;No (%)	p-value
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*

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

Group	Patient &Technique	Analgesic Requireme (Gm) Mean[Rar		Hospital days Mean[R	,	Return to work (Day Mean[Ran	rs)
А	All TAPP Repair n=65	21.86[12-2	28]	2.10[1-3	1	17.87[11-	30]
В	Both sides by classical TAPP n=18	20.16[12-28]		2[1-3]		17.875[14-30]	
с	At least one side by Modified TAPP n=47	22.59[12-28]		2.14[1-3] p-value* when compared to		17.78[11-26]	
		A	В	A	В	A	В
		0.468	0.096	0.597	0.181	0.896	0.934

^{*}P-value from t-test

Table 4 demonstrates cost effectiveness of the modified technique comparing against major variants that determine effective cost of a procedure.

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

Variable determinants of cost	TAPP with Tack	TAPP with suture	Modified TAPP	
Type of Anaesthesia				
And related consumables	✓	·	✓	
peri operative medications	~	~	✓	
Hospital stay	~	~	*	
Readmission	nil	nil	nil	
	_	_		
Re exploration	nil	nil	nil	
Loss of work day	± 17 days	± 17 days	± 17days	
LUSS OF WORK day		± 17 days	± 1/days	
Cost of investigation in follow up	·	_	_	
cost of disposable surgical equipment	·	_	_	
	,			
Operating time	~	44	·	
Cost for treatment of complication				
1. Seroma	*	*	V	
Chronic pain Vaginal hydrocele	**	Ź	· ·	
4. Recurrence of hernia	*	*	*	
5. Bowel related complication	*	*	'	

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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. 14 out of total 15 incidences of post-operative seroma, developed following repair of direct hernia (IIIA) treated by either method.

Regarding post-operative 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 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 month follow up visit (10/11), and had a slightly protracted course and resolved in all but two patients by 1 year follow up. 2 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 analysesic requirement at home after discharge.

5 patients developed vaginal hydrocele, all detected at 3-month 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 was done on 40 separate instances in 34 patients in the follow up period for investigation of post operative seroma, chronic pain, vaginal hydrocele, abdominal pain and identifying recurrence of hernia. On 2 occasions when U/S could not conclusively eliminate recurrence in patients with chronic pain, 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. All patients attended the scheduled follow up till 1 year after operation without any drop out.

Discussion

LIHR has evolved over the years as an alternative to the best method

of open repair. However it is still not the gold standard. Stiff learning curve and increased cost being the major constrains. Average extra cost LIHR incurs over open repair has roughly been estimated to be 300-350 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 trials [12-14] have suggested increased visceral adhesion to exposed prolene mesh in intraperitoneal on lay placement, which forms the basis of preperitoneal or extra peritoneal placement of prolene mesh in TAAP and TEP respectively . However there are reports of animal study that suggests- prolene mesh placed preperitoneally by intra peritoneal route, the adhesion increases on suture closure of peritoneal incision in

comparison to leaving it open [15]. Apart preventing internal from 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 raised [14] and incidences cited [16] about bowel complications occurring post operatively if strict adherence to the practice of peritoneal closure is breached. minimize prosthesis induced To intraperitoneal adhesions relatively nonreactive PTFE mesh has been introduced which come with a price tag sufficient to compromise cost effectiveness further.

The study hypothesis proposed an alternative way of peritoneal reapproximation utilising the intraabdominal 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 2 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 2-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 peroperative 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 prosthesis, improper fixation, twisting or folding of mesh and lifting of mesh by haematoma. Contrasting views regarding anchorage of the mesh, while most advocates anchoring the mesh to prevent migration, many others suggest it [20,21]; moreover injudicious unnecessary of tack or staple below application 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 complications and operating time with increased experience. Post-operative gastrointestinal complications are port site hernia, internal herniation from improper peritoneal closure and adhesion leading to and intestinal obstruction occasional fistulisation when bowel is involved [4, 25-^{27]}. Bowel obstruction by herniation through trocar site or imperfect closure of

peritoneum ^[3] occur earlier (8days) 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 post-operative 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. ¹²⁸

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 month) and carried a rather protracted course, but resolved with counselling, analgesics and neuromodulating drugs like amitriptyline in vast majority of cases. As reported in an earlier study [18] post-operative 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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