



A COMPARATIVE AND RANDOMIZED STUDY BETWEEN TRANS ABDOMINAL PRE-PERITONEAL VERSUS TOTALLY EXTRA-PERITONEAL LAPAROSCOPIC TECHNIQUES OF INGUINAL HERNIA REPAIR

General Surgery

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ABSTRACT

A hernia, an abnormal protrusion of an organ or tissue through a defect in its surrounding wall is a very common surgical problem. Approximately 75% of all hernias are usually groin hernias, among which 95% are inguinal region hernias. Various methods of repair have been employed which have progressed from open repair to various laparoscopic approaches. There is insufficient data to draw conclusions about the relative effectiveness of the two laparoscopic methods. Overall superiority of the two laparoscopic methods has not been demonstrated in available literature.

Aim: The purpose of this study is to compare the clinical effectiveness and relative efficiency of laparoscopic TAPP and laparoscopic TEP for inguinal hernia repair.

Materials And Methods: Hospital based comparative randomised study on 100 patients admitted in General Surgical wards with Inguinal hernia at a tertiary care centre of Eastern India. Randomization in two groups was done by lottery system. A well designed proforma containing various parameters under study was used for data collection. Baseline information were collected via structured interview using predesigned questionnaire. For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS version 24 and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test (χ^2 test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

Results: TAPP was associated with significantly higher incidence of haematoma, length of hospital stay, early postoperative pain and longer operative time as compared to TEP. Visceral injury and vascular injury were found more in TAPP as compared to TEP but this was not statistically significant. Seroma, port site hernia, persisting numbness and mesh/deep infection was higher in group-A (TAPP) as compared to group-B (TEP) but this was not statistically significant. Conversion to open procedure and persistent pain were comparable among the two methods. Hernia recurrence rates were higher in the TEP group in this study although it was statistically insignificant.

Conclusion: TAPP was associated with significantly higher incidence of haematoma, length of hospital stay, early postoperative pain and longer operative time as compared to TEP.

KEYWORDS

Trans abdominal pre-peritoneal repair, Totally extra-peritoneal repair, laparoscopic inguinal hernia repair, Inguinal hernia

INTRODUCTION:

A hernia, an abnormal protrusion of an organ or tissue through a defect in its surrounding wall is a very common surgical problem¹. Various sites of the body are vulnerable to the occurrence of hernia, but the abdominal wall particularly the inguinal region is most commonly involved region². Approximately seventy five percent (75%) of all hernias are usually groin hernias, among which 95% are inguinal region hernias and the remainder being femoral canal defects. Inguinal hernias being very common in men than in women can be either indirect or direct^{3,4}. The aims of successful hernia repair include, achieving an effective repair with lowest possible recurrence rate, minimal perioperative and post operative complications, rapid return to normal work, and performing a cost-effective procedure. To achieve these goals, various methods of repair have been employed which have progressed from open repair to various laparoscopic approaches⁵.

Lacunae In Literature

1. There is insufficient data to draw conclusions about the relative effectiveness of the two laparoscopic methods.
2. Overall superiority of the two laparoscopic methods has not been demonstrated in available literature.

AIMS AND OBJECTIVES

The purpose of this study is to compare the clinical effectiveness and relative efficiency of laparoscopic TAPP and laparoscopic TEP for inguinal hernia repair.

The aim of present study is to compare the laparoscopic TAPP and laparoscopic TEP for inguinal hernia repair in terms of Persisting pain, Hernia recurrence, Duration of operation (min), Opposite method initiated, Conversion, Haematoma, Seroma, Mesh/Deep Infection, Port site hernia, Length of hospital stay (Days), Time to return to usual activities (Days), Persisting numbness and Post-operative pain (VAS).

MATERIALS AND METHODS

Study Site:

Department of General Surgery, Ramakrishna Mission Seva Pratishthan, Kolkata, West Bengal.

Study Population:

All patients presenting with inguinal hernia in OPD of our Department.

Study Period:

July 2017 - May 2019

Study Design:

A Prospective, randomized and comparative study.

Sample Size Calculation:

Rao G et al^{14, 6} found in their study that in India, lingual hernias had the highest prevalence 21.8%. So for this study $p=0.218$.

Thus the number of patients required for this study was $100.27 \sim 100$ with power 86%.

The formula used for sample size calculation was as follows:-

$$n = 4pq / (L^2)$$

Where

n = required sample size

$p=0.218$ (as per the study by Rao G et al)

$q=1-p$

L = Loss % (Loss of information)

Calculation:

Here $p=0.218$

$q=1-p=1-0.218=0.782$

$4pq=4 \times 0.218 \times 0.782=0.6819$

$L^2=0.0068$

$$n = 4pq / (L^2) = 0.6819 / 0.0068 = 100.27 = 100 \text{ Patients}$$

Study Group:

Group-A (TAPP Method) - 50 patients

Group-B (TEP Method) - 50 patients

Randomization And Data Collection Forms:

Randomization in two groups was done by lottery system. A well designed proforma containing various parameters under study was used for data collection. The data was maintained in computer. After obtaining the approval and permission from IEC the study tools were developed. All patients were admitted in our hospital. Data collection was started after explaining the purpose of the study and obtaining informed consent of the legal guardian. Baseline information were collected via structured interview using predesigned questionnaire.

Statistical Methods:

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 24.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test (χ^2 test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

Explicit expressions that can be used to carry out various *t*-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a *t*-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test.

Once a *t* value is determined, a *p*-value can be found using a table of values from Student's *t*-distribution. If the calculated *p*-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis.

p-value ≤ 0.05 was considered for statistically significant.

Parameters Measured:

Age

Sex

Serious adverse events (including visceral injuries and vascular injuries)

Visceral injury urinary bladder and intestine

Nerve injury- To avoid interference in "triangle of pain" to avoid post-

operative tingling numbness, pain along groin or lateral aspect of thigh.

Deep seated vessels, e.g- external iliac vessels- to avoid interferences in "triangle of doom"

Persisting pain

Hernia recurrence

Secondary outcomes:

Duration of operation (min)

Opposite method initiated

Conversion

Haematoma

Seroma

Mesh/Deep Infection

Port site hernia

Length of hospital stay (Days)

Time to return to usual activities (Days)

Persisting numbness

Post-operative pain (VAS)

Inclusion Criteria:

All Patients with Inguinal hernia undergoing elective mesh repair of age 18 years or more.

Exclusion Criteria:

1. All patients presenting with complicated Inguinal hernia like with obstruction or strangulation.
2. All patients with comorbid conditions making them unfit for general anaesthesia.
3. Sliding Hernia.

METHODOLOGY:

Selection of patients in this study was based on strict inclusion and exclusion criteria. Only patients with clinical diagnosis of inguinal hernia were included.

Patients were advised to undergo surgery and after they gave consent, they were taken up for surgery.

Patients were explained in detail about participating in this study and its purpose, in a language he/she understands. Patient information sheet was provided and written informed consent was taken from all the patients included in the study.

For all patients agreeing to participate in the study detailed history and proper physical examination was done. Patients were admitted a day before surgery after relevant investigation, pre anaesthetic check up and fitness for surgery.

Randomization of patients into two groups of TEP and TAPP in laparoscopic inguinal hernia repair was on the basis of simple randomization technique by computer generated random number. Patients were randomly allocated using sequentially labelled sealed opaque envelopes which were handed to the operating surgeon on the morning of surgery. There was no blinding.

RESULTS AND ANALYSIS

Table 1: Comparison of various intraoperative and post operative factors in between Transabdominal Preperitoneal (TAPP) Repair and Totally Extraperitoneal Repair (TEP) of Inguinal Hernia

PARAMETER	GROUP A (TAPP)	GROUP B (TEP)	P-VALUE	STATISTICAL SIGNIFICANCE
MEAN DURATION OF OPERATION(mean±s.d.) IN MIN	87.1800 ± 6.9508	74.5400 ± 5.9632	<0.0001	SIGNIFICANT
MEAN LENGTH OF HOSPITAL STAY(mean±s.d.) IN DAYS	3.8400 ± 1.8446	3.0600 ± 2.0445	0.0479	SIGNIFICANT
MEAN TIME TO RETURN TO NORMAL ACTIVITIES(mean±s.d.) IN DAYS	17.3800 ± 6.3756	15.7400 ± 9.8267	0.3246	NOT SIGNIFICANT
MEAN POST OPERATIVE PAIN (VISUAL ANALOGUE SCALE) (mean±s.d.)	5.9000 ± 1.1294	4.6800 ± 0.9988	<0.0001	SIGNIFICANT
MEAN AGE(mean±s.d.) IN YR	45.5800 ± 8.4227	46.9800 ± 8.2052	0.4019	NOT SIGNIFICANT

Table 2: Comparison of post operative adverse events in between Transabdominal Preperitoneal (TAPP) Repair and Totally Extraperitoneal Repair (TEP) of Inguinal Hernia

ADVERSE EVENTS	GROUP A (TAPP) in %	GROUP B (TEP) in %	CHI SQUARE VALUE	P-VALUE	STATISTICAL SIGNIFICANCE
VASCULAR INJURY	2	2	0.3439	0.8420	NOT SIGNIFICANT
NERVE INJURY	2	0	2.0408	0.1531	NOT SIGNIFICANT
PERSISTING PAIN	8	10	0.1221	0.7267	NOT SIGNIFICANT

HERNIA RECURRENCE	2	6	1.0417	0.3074	NOT SIGNIFICANT
OPPOSITE METHOD INITIATED	0	3	3.0928	0.0786	NOT SIGNIFICANT
CONVERSION TO OPEN PROCEDURE	4	6	0.2105	0.6463	NOT SIGNIFICANT
VISCERAL INJURY	4	2	0.3439	0.8420	NOT SIGNIFICANT
SEROMA FORMATION	8	4	0.7092	0.3997	NOT SIGNIFICANT
HAEMATOMA FORMATION	12	2	3.8402	0.0500	SIGNIFICANT
MESH/ DEEP SPACE INFECTION	12	4	2.1739	0.14036	NOT SIGNIFICANT
PORT SITE HERNIA	4	0	2.0408	0.1531	NOT SIGNIFICANT
PERSISTING NUMBNESS	10	8	0.1221	0.7267	NOT SIGNIFICANT

TAPP was associated with significantly higher incidence of haematoma, length of hospital stay, early postoperative pain and longer operative time as compared to TEP. Visceral injury and vascular injury were found more in TAPP cases as compared to TEP but this was not statistically significant. Seroma, port site hernia, persisting numbness and mesh/deep infection had higher incidence in group-A (TAPP) as compared to group-B (TEP) but this was not statistically significant. Conversion to open procedure and persistent pain were comparable among the two methods. Hernia recurrence rates were higher in the TEP group in this study although it was statistically insignificant.

DISCUSSION

Laparoscopic Repair

There are two main methods of laparoscopic repair: transabdominal preperitoneal (TAPP) and totally extra-peritoneal (TEP) repair. When performed by a surgeon experienced in hernia repair, laparoscopic repair causes fewer complications than Lichtenstein, particularly less chronic pain. However, if the surgeon is experienced in general laparoscopic surgery but not in the specific subject of laparoscopic hernia surgery, laparoscopic repair is not advised as it causes more recurrence risk than Lichtenstein while also presenting risks of serious complications, as organ injury. Indeed, the TAPP approach needs to go through the abdomen. All that said, many surgeons are moving to laparoscopic methodologies as they cause smaller incisions, resulting in less bleeding, less infection, faster recovery, reduced hospitalization, and reduced chronic pain.⁷

Recurrence rates are identical when laparoscopy is performed by an experienced surgeon. When performed by a surgeon less experienced in inguinal hernia lap repair, recurrence is larger than after Lichtenstein.^{8,9}

Complications And Prognosis

Inguinal hernia repair complications are unusual, and the procedure as a whole proves to be relatively safe for the majority of patients. Risks inherent in almost all surgical procedures include:

- Bleeding
- Infection
- fluid collections
- damage to surrounding structures such as blood vessels, nerves, or the bladder
- urinary retention requiring a catheter
- Risks that are specific to inguinal hernia repairs include such things as:
- recurrence of the hernia
- impairment of sexual activity, such as genital or ejaculatory pain¹⁰
- in males, injury to the tube that conveys sperm from the testicle to the penis
- in males, bruising and swelling of the scrotum
- chronic regional pain (also known as post-herniorrhaphy inguinodynia, or chronic postoperative inguinal pain)

The development of laparoscopic techniques has revolutionized hernia repairs, which is the most common procedure in general surgery worldwide. Among endoscopic hernioplasties, totally extraperitoneal (TEP) and transabdominal preperitoneal (TAPP) approach are widely accepted alternatives to open surgery, both providing less postoperative pain, hospital length of stay and early return to work.^{11,12,13,14}

Positioning was in the Trendelenburg position with the upper limb

along the body on the opposite side of the hernia. As the surgeon must be on the opposite side of the hernia in order to increase and facilitate the work space.

Operative Period

Extraperitoneal Access

For this technique, two regular trocars on the midline are placed. The 10 mm trocar is inserted into the subcutaneous plane in horizontal direction after a transverse infra-umbilical incision and then elevated at 60° angle. The 5 mm trocar is inserted at the same level of the pubis with direct vision.

Preperitoneal space dissection

A 0° optical laparoscope is introduced through the infra-umbilical incision for visualization and preperitoneal dissection. Insufflation pressure must stay below 12 mmHg. In this meantime, the free hand of the surgeon must be at the abdominal wall to ensure balance.

Surgeon must be aware not to grasp the peritoneal fold itself, to prevent tearing, and not to dissect with diathermy too closely onto the psoas muscle laterally, as this may cause nerve damage.

Medial Dissection

When looking through the laparoscope, it is important to pay attention to some anatomical landmarks such as: 1) pubic bone, 2) arcuate line and 3) inferior epigastric vessels

Lateral Dissection

Lateral dissection extends to the level of the psoas muscle inferolaterally. The aim is to expose the nerves of the "triangle of pain". Blunt dissection is carefully performed to divide the loose areolar tissue of the lateral space.

An important anatomical landmark is the angle between the inferior epigastric vessels and the arcuate line. Besides, it's necessary to make a safe and adequate dissection when making a small incision in the arcuate line, if it is at a lower level.

Hernia Dissection

The hernia dissection and reduction on spermatic cord structures are performed, besides the reduction of the hernia sac and its reflections. Must pay attention to the "triangle of doom" bounded by the vas deferens (medially), spermatic vessels (laterally), internal inguinal ring (apex) and peritoneum (base)

When dissecting out an indirect hernia sac, we must ensure an adequate hemostasis while retracting to avoid small bleeders. This might also prevent seromas and hematomas.

During peritoneal retraction, grasping the ductus deferens may cause fertility problems; overzealous dissection of the cord structures and genital branch of the genitofemoral nerve probably contributes to postoperative neuralgia; dissecting medially the "triangle of doom" is not recommended due to potential injury to the great vessels.

Mesh Placement

The length of polypropylene mesh is calculated and cut anatomically (at least 10x15 cm). Then, it is inserted through the 10 mm trocar to cover the hernia sites: inguinal, femoral and obturator.

In bilateral hernia cases, it is easier to put two meshes instead of only large one. Commonly, the mesh is not fixed in order to avoid nerve injury.

Deflation Period

The hernia sac and the lipoma are placed behind the mesh. Then, inspection for hemostasis in the extraperitoneal space, deflation and closure of skin incisions is performed.

In deflation, the peritoneal sac and the dorsal edge of the mesh are repositioned in order to avoid bending or mesh displacement. It is also important to remember that drainage is not necessary.

Postoperative Period

The operation described can be made as out-patient surgery, since average discharge is less than 12 hours.

Wake BL et al¹⁵ found that Vascular injuries were rare and there was no obvious difference between the groups. This corroborated with our findings.

Similar to or results, Bansal VK et al¹⁶ found that the chronic groin pain was comparable in both TEP and TAPP

Wei FX et al¹⁷ found there was no significant difference in terms of hernia recurrence between the 2 groups. Our study found no statistically significant difference among the two groups.

Jeelani S et al¹⁸ found that both TEP and TAPP mesh repair techniques were comparable in conversion to open, similar to our results.

McCormack K et al¹⁹ reported no statistically significant difference between TAPP and TEP in haematoma. **Elhendawy AO et al**²⁰ found postoperative Hematoma was higher in TAPP technique. In our study, incidence of haematoma formation was significantly higher in TAPP cases although seroma formation rates were similar.

Elhendawy AO et al²⁰ found that there was no difference regarding wound infection, mesh infection and recurrence which correlated with our findings.

Wake BL et al¹⁵ found that the TAPP is associated with higher rates of port site hernias. No increased incidence was reported in our study.

Jeelani S et al¹⁸ found that both TEP and TAPP mesh repair techniques were comparable in terms of operative time, intraoperative complications, conversion to open, and recurrence.

McCormack K et al¹⁹ found no statistically significant difference between TAPP and TEP when considering duration of operation, haematoma, length of stay, time to return to usual activities, and recurrence.

Elhendawy AO et al²⁰ found that Operative time was 151.7 ± 24.8 in TAPP approach in comparison to 88.42 ± 30.6 minutes in TEP approach.

In group-A (TAPP), the mean duration of operation (mean \pm s.d.) of patients was 87.1800 ± 6.9508 min. In group-B (TEP), the mean duration of operation (mean \pm s.d.) of patients was 74.5400 ± 5.9632 min.

McCormack K et al¹⁹ found no statistically significant difference between TAPP and TEP when considering duration of operation, haematoma, length of stay, time to return to usual activities, and recurrence.

Elhendawy AO et al²⁰ and **Jeelani S et al**¹⁸ found that duration of hospital stay was significantly more in TAPP group than TEP group, similar to our results.

Bansal VK et al¹⁶ and **Jeelani S et al**¹⁸ found that time to return to normal activity also was similar between the two groups. This corroborated with our findings.

Wei FX et al¹⁷ found there was no significant difference in terms of operation time, time to return to usual activities, hospital stay and total complications between the 2 groups.

In group-A (TAPP), the mean time to return to normal activities (mean \pm s.d.) of patients was 17.3800 ± 6.3756 days. In group-B (TEP), the mean time to return to normal activities (mean \pm s.d.) of patients was 15.7400 ± 9.8267 days. Distribution of mean time to return to normal

activities vs. group was not statistically significant ($p=0.3246$).

Rambhia SU et al²¹ found that there was statistically significant difference in pain at 24 hours, which was more in TAPP group than TEP group. **Jeelani S et al**¹⁸ and **Wei FX et al**¹⁷ found there was no significant difference in terms of pain scores between the two groups which differed in comparison to our study in which mean post operative pain was higher in the TAPP group.

CONCLUSION

TAPP was associated with significantly higher incidence of haematoma, length of hospital stay, early postoperative pain and longer operative time as compared to TEP. Visceral injury and vascular injury were found more in TAPP as compared to TEP but this was not statistically significant. Seroma, port site hernia, persisting numbness and mesh/deep infection had higher incidence in group-A (TAPP) as compared to group-B (TEP) but this was not statistically significant. The notable short comings of this study are:

1. The sample size was very small. Only 100 cases are not sufficient for this kind of study.
2. The study has been done in a single centre.
3. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

CONFLICT OF INTEREST:

The authors declare that there is no conflict of interest.

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