A Comparative study between Open meshplasty technique versus Total extra peritoneal (TEP) positioned mesh for inguinal hernia in General Surgery Dept. of an Industrial Hospital (HAL HOSPITAL).

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Date of Submission: 01-11-2022 Date of Acceptance: 12-11-2022

Abstract

I. Introduction and Background:-

An Inguinal hernia occurs when soft tissue - usually part of the intestine - protrudes through a weak point or tear in the lower abdominal wall. The resulting bulge can be painful – especially when coughing, bending over or lifting a heavy object. Not necessarily dangerous by itself, an inguinal hernia does not get better or go away on its own. An inguinal hernia can lead to life threatening complications. For this reason, it is likely to recommend surgical repair of an inguinal hernia.

" Inguinal hernia repair is a common surgical procedure" it is repaired conventionally using open surgery with a suture or a mesh prosthesis and the defect will be closed. mesh prosthesis is a synthetic material that reinforces the tissue or bridges the defect it can be done on the other hand with laparoscopic hernia repair by using TAP and TEP technique in this case small incisions used and mesh is placed in the abdominal cavity. The search for "the best" inguinal hernia repair technique is an ongoing evolution globally, aiming to keep the low recurrence rates of the Lichtenstein and to prevent the main complication of postoperative chronic pain in patients. This study is to compare the two techniques open and laparoscopic TEP with self retaining mesh repair.

II. Review of literature and Lacunae:

Earliest records of inguinal hernia dates back to 1500 B.C (1).

The Lichtenstein technique open meshplasty (or tension-free mesh repair) is the present reference technique for inguinal hernia treatment(2).

Introduction of laparoscopic approach for repair of inguinal hernia in early 1900s led Ger to attempt for the 1st time, a minimal access groin hernia repair by closing the opening of an indirect inguinal hernial sac by Michel clips in 1982(3).

The preperitoneal approach laid dormant until it was ressurected by Henry in 1936(4).

The preperitoneal approach has been described Nyhus(5) and is a preferred technique through the concept of preperitoneal approachModified and adapted for treatment of recurrent hernia using prosthetic mesh, with superior results (6).

A large multicentric trial of 841 patients evaluated the complications associated with laparoscopic hernioplasty(7).

Refinement of laparoscopic technique to the now widely accepted TAPP approach and TEP technique has established a sound base for laparoscopic approach to repair of groin hernias(8).

Laparoscopy identifies unexpected groin hernias during repair of inguinal hernia(9).

Diagnosing the occult contralateral inguinal hernia is accomplished during repair of inguinal hernia laparoscopically(10).

Meta-analysis of randomized clinical trials comparing open and laproscopic inguinal hernia repair has shown distinct advantages of laparoscopic repair over open methods of repair of inguinal hernia(11).

Laparoscopic preperitoneal mesh repair for recurrent inguinal hernia is associated with reduced rate of recurrence of hernia(12).

Laparoscopic mesh versus open preperitoneal mesh verses conventional technique for inguinal hernia repair has revealed certain advantages of laparoscopic repair over open methods of repair of inguinal hernia(13).

A prospective trial sponsored by the Veterans Administration randomized 1983 patients to undergo an open Lichtenstein repair or laparoscopic repair, of which 90% were TEP repairs. Most surgeons in this study may have had a suboptimal experience with the laparoscopic approach; only 25 prior repairs were necessary to be eligible to enroll patients, which is consistent with the seemingly high conversion rate of 5%.(14).

In another study, surgeon inexperience with laparoscopy and surgeon age older than 45 years were both predictors of recurrence after laparoscopic repair(15).

LACUNAE

Although laparoscopy is a newer technique there are still debate of recurences and the out comes compared with open method .

A National wide 8 years follow-up study on the role of type of repair by Bisgard et al in 2008stated that there are important differences in the primary hernia repair. Hernia recurrence is the primary outcomes assessed by most studies. Large series, including multiple types of repairs have suggested that recurrence ranges from 1.7% to 10%(16).

However, due to recent advances in minimally invasive surgery, which is a combination of modern technology and surgical innovation, new techniques of laparoscopic hernioplasty have been developed, which have been shown to give results comparable to that of the conventional open procedure with fewer complications. Also, some authors even claim that laparoscopic procedure is theoretically superior to open technique.

The use of **Self gripping mesh**during laparoscopic TEP repair may eliminate the need for fixation and thus reduce the post operative pain without added concern for mesh migration.(17),(18).

This trial investigates that the laparoscopic repair of inguinal hernias with self retaining mesh may have a definite learning curve to achieve an acceptably low recurrence rate and compare complications, operative time, postoperative pain, length of hospital stay, and return to work.

Back ground and Aim

Repair of inguinal hernia is one of the commonest surgical procedures worldwide. Since the era of tension free repair using synthetic mesh, the basic tenets of hernia repair has changed little. Currently there are two methods of mesh placement: open method and laparoscopic method.

Although a number of clinical studies have explored the potential benefits and drawbacks of open and laparoscopic repair for inguinal hernia, no one procedure has emerged as having a clear benefit over the other. The aim of our study is to compare the outcomes of laparoscopic (Self retaining mesh) (TEP) with open mesh repair of inguinal hernia.

III. Material And Methods

After getting Ethical Committee clearance a prospective observational study was conducted in HAL hospital, Bangalore from may 2016 to 2018.

SELECTION CRITERIA: After obtaining written informed consent 70 patients diagnosed with inguinal hernia were included in the study as per preset inclusion and exclusion criteria and were followed up for 1 year duration.

INCLUSION CRITERIA-

Patients who will be operated in HAL Hospital. Patients willing to participate in the study and follow up. Patients diagnosed as having inguinal hernia aged 18 years and above giving valid written informed consent. Patients with unilateral or bilateral inguinal hernia. Patients with recurrent inguinal hernia.

EXCLUSION CRITERIA

Patients with complicated inguinal hernia Patients with ASA -IV,V, E categories Patients not consenting for surgery Patients lost to follow up

These 70 patients were divided into laparoscopic arm or open arm according to patient's choice. The outcomes were assessed post operatively at 10 days, 6weeks, 3 months, 6months and 1year intervals.

Primary outcome

The primary outcome of the study was to know whether there is recurrence of hernia within one year after the repair. The patients were followed for a minimum of one year.

Secondary outcomes

- \Box 1.Duration of operation (min)
- □ 2.Vascular injury
- □ 3.Visceral injury
- □ 4.Wound complications
- \Box 5.Length of hospital stay (Days)
- 6.Time to return to work(Days)
- □ 7.Seroma formation
- □ 8.Post-operative pain
- □ 9.Chronic Persisting inguinal pain (defined as inguinal pain of any
- severity as near 12 months after the operation as possible provided this was at least after 3 months) (19)

Collected data was analysed by using Pearson $\chi 2$ test or Fisher exact test where appropriate for categorical data and Student t test for parametric data. Qualitative parameters were calculated using Student-t test.

Quantitative parameters were calculated using Chi square test. A p-value 0f < 0.05 is taken as significant difference in outcome measure.

Statistical software: The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Sample size with justification –Sample size is calculated based on the following previous similar studies. In a prospective randomized study by Heikkinen etal in which the sample size was 38 including laparoscopic (no=20) and Lichtenstein (n = 19)(20).

The total sample size for the study is as follows

$$N = \frac{(r+1)(Z_{\alpha/2} + Z_{1-\beta})^2 \sigma^2}{r d^2}$$

IV. Observation & Results:

The patients were predominantly males (69 males, 1 female) and their age ranged from 19 to 73 years with 45 years being median age at presentation for LAP group and 43 years being median age at presentation for Open group. Maximum number of patients belonged to age group 35-55 years. In our Results recurrence rate of hernia after LAP repair was 2.8% as one case had recurrence at 6 months ,and that of open repair was 0% The comparison of recurrent rate was statistically not significant (P value=0.342).

In our study postoperative pain was measured by visual analogue scale (VAS). And the mean VAS score after LAP repair (2.00) was less when compared to open repair (2.40) which is statistically significant (P=0.005).

In our study the average time taken for LAP repair (62mins) is 15 min more than open repair (47mins) which was statistically significant(P value<0.001).

In our study no major vascular injuries were noted in both LAP and open groups which is statistically not significant there were no conversions from LAP to open repair.

In our study postoperative pain was measured by visual analogue scale (VAS). And the mean VAS score after LAP repair (2.03) was less when compared to open repair (2.48) which is statistically significant (P=0.001).

In our study the average number of days of hospital stay after LAP(2.11days) repair was less when compared to open repair (4.20days) which was statistically significant(P value< 0.001)

In our study average time required to resume to work in LAP(6.94 days) is 3 days less when compared to open repair(11.20days) which is statistically significant(P value<0.01). 11In our study no wound infections were noted following LAP repair and open methods and wound infection rate following open repair was nil case which was statistically not significant (P value=1).

In our Results 5.7% (n=2) developed seroma after open surgery and no patient from Lap group developed seroma, which was statistically less significant (P Value=0.493).











V. Conclusions

From the results of this study we find the outcomes of laparoscopic inguinal hernia are comparable with open repair. Laparoscopic repair has an advantage of less post-operative pain, decreased hospital stay, faster recovery. It may soon become the procedure of choice not only for bilateral and recurrent hernias but also for primary, unilateral hernias.

The open repair has a definite advantage over laparoscopic repair; however the decreased hospital stay and faster recovery may reduce the economic burden of laparoscopic surgery to some extent.

The open repair remains a good option especially for older, high risk patients and for the underprivileged as it is easy to perform, inexpensive and can be done under local anaesthesia. However, with advancement in the evolution of mesh design and the trend in surgery today in favour of minimally invasive surgery which produces less pain, less scarring, and give equivalent results with open repair makes this study relevant. The use of self retaining mesh avoiding use of tacks was evaluated in this study making this study unique.

LIMITATIONS

The study should be replicated on large number of hernia patients It is non-randomized, non-blinded study

This study has not evaluated TAPP approach of hernia repair

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Dr K Y GOPI KRISHNA, et. al. "A Comparative study between Open meshplasty technique versus Total extra peritoneal (TEP) positioned mesh for inguinal hernia in General Surgery Dept. of an Industrial Hospital (HAL HOSPITAL)." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 21(11), 2022, pp. 24-30.