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To Analyse and Compare the Operative Complications of total Extra Peritoneal Inguinal Hernia Repair with Drain and total Extra Peritoneal Inguinal Hernia Repair without Drain

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ABSTRACT

The prospective comparative study compared the operative complications of laparoscopic total extraperitoneal hernioplasty with drain and total extraperitoneal hernioplasty without drain for inguinal hernia which was carried out in our rural tertiary health care centre of central India in department of surgery. Both groups were evaluated and compared for complications seroma, hematoma, urinary retention, scrotal oedema, mesh infection, drain site infection, post-operative pain at 24 hours, 7 days and 1 month after surgery and recurrence.

A total of 106 cases of inguinal hernia repair were studied between the period of January 2020 to June 2021 of which 57 were operated for laparoscopic total extraperitoneal hernia repair without drain placement and 49 were operated for laparoscopic total extraperitoneal hernia repair with drain placement.

Our finding were seroma formation was more in laparoscopic total extraperitoneal inguinal hernia repair without drain placement than laparoscopic total extraperitoneal inguinal hernia repair with drain placement and the difference was statistically significant. Mean VAS score for postoperative groin pain at 24 hours, 7 days and 1 month were more in laparoscopic total extraperitoneal inguinal hernia repair with drain placement than in laparoscopic total extraperitoneal inguinal hernia repair without drain placement hence, we can say that laparoscopic total extraperitoneal inguinal hernia repair without drain placement was less painful in terms of postoperative pain.

The P-value for other parameters like urinary retention, hematoma, scrotal oedema, mesh infection, drain site infection was >0.005 which was statistically not significant (P>0.005).

Thus, from present study we concluded that, the laparoscopic total extraperitoneal inguinal hernia repair with drain placement was safer but slightly more painful and having lesser complications than the laparoscopic total extraperitoneal inguinal hernia repair if a trained surgeon with optimum experience in laparoscopic surgery was available.

Key Words: *Inguinal hernia repair, Drainage, Laparoscopy, Complications*

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INTRODUCTION

Groin hernias are one of the most common conditions referred to surgeons all over the world and over five lakh hernia repairs are performed annually [1]. The lifetime risk for men is greater than that of women.Hernia is the "protrusion of the viscous or part of the viscous through an abnormal opening in the walls of its containing cavity". If hernias are not operated, often they go for complications and increase the morbidity and mortality.The collagen metabolism in patients with a hernia is altered at three levels: the type I: III collagen ratio is decreased, the collagen quality is poorer, and collagen breakdown is increased [2]. A systematic review strongly suggested that patients with inguinal hernias have a lower collagen 1:3 ratio in the abdominal wall tissue compared with controls [2][3]. These changes lead to weakening of the fibro connective tissue of the groin and development of inguinal hernias. Thus the need for prosthetic reinforcement of weakened abdominal wall tissue was recognized.

Inguinal hernia repair is probably the most common procedure in general surgery. It is also one of the earliest operations in a junior surgical resident's postgraduate training period [4]. The standard method for hernia repair had changed little over a hundred years. Introduction of synthetic mesh had changed the scenario. It can be placed either by open or laparoscopic techniques. Laparoscopic hernia repair was first reported by L Ger and colleagues in [5] [6]. Since bassini published his landmark paper on the technique of tissue repair [7], numerous modifications have been proposed. There has been a revolution in surgical procedures for groin hernia repairs after introduction of prosthetic material by

Usher [8]. Open preperitoneal mesh repair by Stoppa [9] was found to significantly reduce recurrence rate for multi centric groin hernias. However it was associated with significant postoperative pain and morbidity. The concept of tension free open mesh repair was first described by Lichtenstein in 1984.

The first reported laparoscopic hernia repair done in 1982 by approximating the internal ring with stainless steel clips [10]. The laparoscopic trans-abdominal pre-peritoneal (TAPP) repair was a revolutionary concept in the hernia surgery and was introduced by Arregui [11] and Dion [12] in early 1990s. Laparoscopic groin hernia repair can be done by TAPP approach and TOTAL EXTRA PERITONEAL approach (TEP). Better understanding of laparoscopic anatomy and technological advances including that of optics did not drastically reduce the complication rate and recurrence rate, hence leading to dissatisfaction not only among patients, but also among the laparoscopic surgeons. The leaning curve of laparoscopic repair of inguinal hernia has been made all the more steep because of lack of documentation of results with regard to patient satisfaction, postoperative pain, duration of stay in hospital, complication and recurrence of hernia, hence making stratification of patients for either TEP with drain or TEP without drain.

Our purpose in this study is to compare the results of TEP hernia repair with drain in situ and TEP hernia repair without drain and determine if relative advantages achieved could be put in practice in large scale and also identify criteria which may help stratify the patient to a particular type of repair to obtain encouraging results for that particular patient.

METHODOLOGY

This prospective comparative double-blind study was conducted to compare complications of laparoscopic total extraperitoneal inguinal hernia repair without drain and laparoscopic total extraperitoneal inguinal hernia repair with drain. This study was carried out in rural tertiary healthcare centre in central India from January 2020 to June 2021. The study was approved by the ethical committee of our institute and signed informed consents were obtained from the patients.

In this study, a total of 106 adult male patients of primary uncomplicated inguinal hernia were evaluated.Patients were categorized into two groups:Group Aand Group B consistedof 57 and 49 patientswho were preoperatively examined by anaesthetist and after getting fitness for surgery, as per institutional protocol, laparoscopic totally extraperitoneal hernia repair without drain placementand with drain placement done under general anaesthesia respectively.Intra operative complications like vascular injury, visceral injury, injury to vas deferens, injury to urinary bladder were not noticed during the study. Surgeries were done by professional and trained surgeons with proper visualization of structures.The patients were compared on the basis of seroma, hematoma, scrotal edema, urinary retention, surgical site infection, post-operative pain and recurrence.

SELECTION OF CASES

Inclusion Criteria: Males aged between 18 to 65 years of age having 18-35 kg / m2 BMI were diagnosed of having Primary inguinal hernia, unilateral or Bilateral with an indication for elective correction and recurrent cases (with open repair) were included in the study.

Exclusion Criteria: Patients were excluded from the study if they were diagnosed ofprior midline laparotomy, contraindications for general anaesthesia, Cirrhosis or ascitis, Incarcerated hernia, recurrent hernia, obstructed hernia and strangulated hernia, any contraindications for laparoscopic surgery, history of prostatectomy and abdominal bladder surgery, patients refusing to voluntarily participate in the study, performance of any additional procedure, patients undergoing emergency hernia repair, patient unfit for anaesthesia and patient having comorbidities like hypertension and diabetes mellitus.

Antibiotic prophylaxis: We used IV ceftriaxone 1 gm, 30 minutes before surgery in all our patients.

Equipment: Anaesthetic equipment embedded with a cardiac monitor and a pulse oximeter for high-risk patients with comorbidities and usage of surgical laparoscopic instruments.

Technique of General Anesthesia was appliedby mouth for 6 hours, Xylocaine sensitivity test & its interpretation, tab pantop 40mg & tab alprax 0.5 mg HS before the day of surgery as per department protocol. Followed an appropriate surgical technique by establishing a plane of dissection outside of the peritoneal cavity between the posterior surface of the rectus muscle and the posterior rectus sheath and peritoneum.

Post-operative Care

Group A patients operated under general anaesthesia were discharged by 3 days after surgery and Group B patients operated under general anaesthesia were discharged by 4days after surgery with drain removal before a day of discharge. In case of pain in the postoperative period suitable analgesics were prescribed. The dressing was removed on the third

postoperative day, and stitches were removed on seventh postoperative day. Patients were advised to resume light work after a week and heavier jobs after 6 weeks.

Post-operative Observation

Patient data were recorded at following points:During the hospital stay, at a time of suture removal (usually on 7th day), at 1 month post-operative period, post-operative seroma, post-operative hematoma, post-operative scrotal edema, post-operative urinary retention, post-operative Mesh infection and Drain site infection, post-operative groin pain at 24 hours, 7 days, 1 month and recurrence at 6 months post operatively.

Post-operative pain

Pain was recorded using a visual analog scale (VAS) (0–10) in the hospital at next day morning and 7 days and 1 month after the operation. Inpatients had the VAS score recorded in the hospital. Mean VAS score for patients in both group A and B was calculated on day 1, day 7 and 1 month postoperatively. All patients received the same post-operative instructions and were encouraged to return to work and normal activities as soon as possible.

Each parameter was compared for both groups in terms of percentages and P-value by 'independent samples T-test'. On the basis of P-value, it was observed weather the above mentioned parameters were statistically significant or not. An 'independent group t-test' was carried out for thecomparison of means between two independent groups. P value <0.05 was considered as statistically significant.

RESULTS

Present study is a hospital based prospective comparative study of perioperative complications of total extraperitoneal hernia repair without drain placement under general anaesthesia and total extraperitoneal hernia repair with drain placement was conducted with 106 patients from January 2020 and June 2021 to analyse the complications in rural tertiary care centre in central India. The total numbers of subjects were 57 in GROUP A and 49 in GROUP B.

Postoperative seroma was noted in approximately 10.52% patients (6 patients) who underwent totally extraperitoneal repair without drain placement (Group A) and approximately 2% patients (1 patient) in extraperitoneal repair with drain group B. P-value for patients having postoperative seroma through 'independent samples T-test' was found to be 0.033 which is statistically significant.

No Postoperative hematoma and urinary retention was noted in either group.4% of Patients from group A experienced scrotal edema who underwent laparoscopic total extra peritoneal hernia repair without drain placement. On the other hand, 2% patients from group A developed scrotal edema.P-value through 'independent samples T-test' was found to be 0.68 which is statistically not significant.

Postoperative drain site infection was noted in 2% patients (1 patient) in group B. No mesh infections were reported in either group.

There was no postoperative recurrence noted in group A and group B.

Table 1: Comparative analysis of complications between total extra peritoneal hernia repair without and with drain under general anaesthesia (%) (A) and group (B) respectively

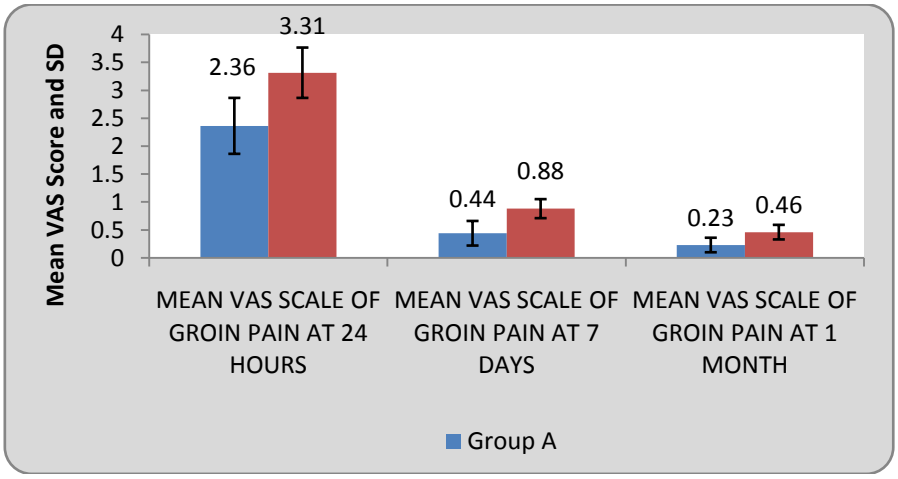
Complications	Total Extra Peritoneal Hernia Repair without Drain Under General Anaesthesia (%) (A) (N=57)	Total Extra Peritoneal Hernia Repair with Drain Under General Anaesthesia (%) (B) (N=49)	P-Value
Seroma	10.52 %	2 %	0.033(S)
Hematoma	0	0	-
Retention of Urine	0	0	-
Scrotal Oedema	3.5%	2%	0.68(Ns)
Drain Site Infection	0	2%	0.49(Ns)
Mesh Infection	0	0	-
Recurrence	0	0	-

Table 2: Comparative study of mean VAS scale of groin pain after 24 hours, 7 days and 1 month in group A and B

Group	Mean Vas Scale of Groin Pain at 24 Hours	Mean Vas Scale of Groin Pain at 7 Days	Mean Vas Scale of Groin Pain at 1 Month
A	2.36±0.50	0.44±0.22	0.23±0.13

B	3.31±0.45	0.88±0.17	0.46±0.13
t-value	10.13	11.30	8.58
p-value	0.0001(S)	0.0001(S)	0.0001(S)

VAS scale of groin pain (1-10) after 24 hours postoperatively was found to be 2.36 and 3.31 in groups A and B respectively. P-value through 'independent samples T-test' was found to be 0.0001 which was statistically significant. The mean VAS scale of groin pain (1-10) after 7 days postoperatively was found to be 0.44 and 0.88 in groups A and B respectively. P-value through 'independent samples T-test' was found to be 0.0001 which was statistically significant. Similarly, the mean VAS scale of groin pain (1-10) after 1 month postoperatively was found to be 0.23 and 0.46 in groups A and B respectively. P-value through 'independent samples T-test' was found to be 0.0001 which was statistically significant.



Graph 1: Comparative study of mean VAS scale of groin pain after 24 hours, 7 days and 1 month in group A and B

DISCUSSION

This prospective comparative study compared short term results of two different groups i.e. laparoscopic total extraperitoneal inguinal hernia repair without drain placementand with drain placement was carried out in a rural hospital in central India between January 2020 to June 2021. Total 106 patients were included in which 57 patients were in Group A (laparoscopic totally extraperitoneal inguinal hernia repair without drain placement under general anesthesia) and 49 patients were in Group B (laparoscopic totally extraperitoneal inguinal hernia repair with drain placement under general anesthesia).

As per our research very few studies on laparoscopic total extraperitoneal hernia repair with drain placement, were found. In our study, postoperative seroma was noted in 6(10.52%) patients who underwent totally extraperitoneal repair without drain placement in group A and 1(2%) patient in extraperitoneal repair with drain in group B. P-value for patients having postoperative seroma through 'independent samples T-test' was found to be 0.033 which was statistically significant.Most of the patients in which seroma was noted were of bilateral inguinal hernia. Ultrasonography of inguinoscrotal region was used to diagnose seroma.

Due to extensive dissection on either side, it might have resulted into seroma in case of bilateral inguinal hernia. Very few studies have reported to measure incidence of seroma formation after laparoscopic total extraperitoneal hernia repair. Daes et al [13] pinned the giant distal hernia sac to the posterior inguinal wall during total extraperitoneal inguinal hernia repair.One out of six patients (16.7%) developed seroma that was then cleared. However, this technique transferred the potentially collected liquid in the distal sac into the preperitoneal space instead of draining. The increased collected fluid in the preperitoneal space was slowly absorbed, which significantly increased the risk of infection. It has also been reported that formation of a preperitoneal seroma with a secondary abscess occurred six years after total extra peritoneal hernia repair.

Ismail et al [14] reported that 929 patients with inguinal hernias who underwent TEP hernia repair were divided into two groups: the drainage group (849 patients) and no-drainage group (80 patients). The drain was removed within 24 h after the operation. The results showed that the drainage group had a remarkably lower incidence of seroma formation than the no-drainage group (0.75% VS 15.1%, $p < 0.0001$).

Gao et al [15] studied a retrospective review on preperitoneal drainage for TEP hernia repair, involving 321 patients with drainage and 157 patients with no-drainage. The drain was removed 48 h after the operation. The drainage group had a lower incidence of seroma formation than the no-drainage group (2.87% vs. 9.85%, $p < 0.05$).

Fan et al [16] conducted a randomized controlled trial (RCT) with preperitoneal drainage for TEP hernia repair, compared 41 patients with drainage and 37 patients with no-drainage. The drain was removed at 23 h after the operation. The drainage group had lower incidences of seroma formation and smaller seroma on POD 1 and POD 6 than the no-drainage group. In line with previous studies, our study showed an extremely low incidence of seroma formation (1.5%) even in patients with large inguinoscrotal hernias, indicating the efficacy of drainage. However, there were some differences between the previous studies mentioned above and the present study.

First, most types of inguinal hernias were included in these studies. It was not necessary to place a drain for small inguinal hernias due to the low risk of seroma formation. For direct hernias, many measures have been proven to be effective, including fixation of the pseudo-sac to Cooper's ligament or rectus abdominis and closure of the defect with a barbed suture15 or an Endoloop technique.

Second, drains were removed soon after the operation in these studies, in less than two days. In Fan's study [16], 21the incidence of seroma formation on POD 6 was higher than that on Post- operative day 1 (41.6% VS 14.6%). This finding reflected the persistent secretion in the distal hernia sac and preperitoneal space after post-operative day 1, which contributed to the increased incidence of seroma formation. With significant similarities, the incidence of seroma formation in the subgroup of giant scrotal and irreducible hernias in Gao's [15] study was compared with that in the present study. Interestingly, the incidence of seroma formation in our study was significantly lower than that in the former study. Moreover, the previous studies showed that the peak of drainage volume occurred within 48 h, which was in accordance with our study. Our study also showed that the drainage volume rapidly decreased on post-operative day 2, whereas the reduction became slowly thereafter. In another aspect, short-term drainage only drains the fluid in the preperitoneal space that collected early on. As a result, the fluid collected after 48 h significantly increased the risk of seroma formation, especially for large inguinoscrotal hernias. Therefore, appropriate prolonged drainage (5 days, as indicated in this study) was necessary to reduce the incidence of seroma formation to an extremely low level. Third, in the present study, the tube was inserted into the distal hernia sac in the scrotum via the preperitoneal space above the iliopubic tract to prevent nerve injury. It could then simultaneously drain out the fluid in the distal hernia sac and the preperitoneal space with persistent and sufficient effects and significantly decrease the incidence of seroma formation. Furthermore, the carbon dioxide in the distal hernia sac and preperitoneal space was drained by suction after the closure of the peritoneal flap to allow visualization of the mesh and fixate the mesh between the abdominal wall and peritoneum. Therefore, drainage not only decreased the incidence of seroma formation but also decreased the incidence of chronic pain by facilitating the rapid fixation of the mesh instead of suture or staple fixation. Drainage theoretically increases the risk of infection. However, no mesh infection or Drain site infection was reported in these three studies or in the present study, indicating the safety of drainage.

No incidences of hematoma formation were noticed in Group A or Group B in our present study. In our study all surgeries were performed by trained surgeons with careful dissection with proper visualization of structures.In our study we found that 3.5% of patients i.e. 2 patients out of 57 patients in Group A have developed scrotal edema and 2% i.e. 1 patient out of 49 patients in Group B has developed scrotal edema with P value which was statistically insignificant.No studies were found to support role of drain to reduce or to aggravate scrotal edema.

In our study 2% of patient i.e. 1 patient was found to develop drain site infection in Group B. Drain was placed and fixed through one of the 5 mm port. While, placement of drain, port site were cleaned thoroughly with betadine and normal saline to minimize the chances of infection. Drain site infection was noticed on post-operative day 3. Appropriate measures were taken to halt the further progression of infection. Debridement of infected or necrotic tissue and thorough wash given with betadine and normal saline followed by daily dressing for 3 to 4 days. Patient was given discharge with healthy wound on post-operative day 7.

No mesh infection was noticed in our present study.No recurrence in either group was noticed.Patients of Group A and Group B were assessed post-operatively regarding pain with help of VAS scale and compared accordingly. Patients were assessed at different time intervals i.e at 24 hours post-operatively then at 7 days post operatively and at last 1 month after surgery.

Mean VAS scale of groin pain (1-10) after 24 hours post-operatively was found to be in group A and in group B. P-value through 'independent samples T-test' was found to be 0.0001 which was statistically significant. Mean VAS scale of groin pain (1-10) after 7 days post-operatively was found to be in group A and group B. P-value through 'independent samples T-test' was found to be 0.0001 which was statistically significant.Mean VAS scale of groin pain (1-10) after 1 month postoperatively was found to be in group A and B. P-value through 'independent samples T-test' was found to be 0.0001 which is statistically significant.

CONCLUSION

From present study we concluded that, the laparoscopic total extraperitoneal inguinal hernia repair with drain placement was safer but slightly more painful and having lesser complications than the laparoscopic total extraperitoneal inguinal hernia repair if a trained surgeon with optimum experience in laparoscopic surgery was available.

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