Prospective Study to Compare Laparoscopic Total Extra Peritoneal Repair (TEP) and Lichtenstein's Mesh Repair (LR) for Inguinal Hernias

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Abstract

Background: The present study is designed to compare laparoscopic total extra peritoneal repair and Lichtenstein's mesh repair For Inguinal Hernias, in terms of duration of operation, post operative pain, Intraoperative complications, postoperative complications and Post operative convalescence period. Methods: A prospective observational study of 50 patients with inguinal hernia was conducted at J.L.N. Medical College, Ajmer Rajasthan India; patients were assigned into two groups through randomization. Hernia repairs performed by either laparoscopic totally extra peritoneal route (TEP) or Lichtenstein repair (LR) according to group allocation. Data was recorded prospectively and each TEP repair was matched with a LR for analysis. Results: The mean duration of surgery was 84.60 minutes (SD=33.99) in the laparoscopic group, which was significantly more (P=0.0000) than the open group in which time duration was 51.56 minutes with SD of 5.53. The overall rate of complications in the 50 patients was 14/50 (28%). The complication rate was not significantly different in the two groups (P=0.0584). The minimum average time to return to normal activity was taken by the Laparoscopic TEP repair group (5.32 days, S.D. =1.35), which was statistically significant in overall comparison (8.28 days, P=0.000). Conclusion: Results for laparoscopic TEP hernia repair seem to be superior to results for open Lichtenstein's mesh (LR) repair in terms of

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length of hospital stay, wound infection, major complications, and overall return to normal activity.

Keywords: Laparoscopy; Inguinal Hernia; Laparoscopic Total Extra Peritoneal Repair; Lichtenstein's Mesh Repair.

Introduction

Laparoscopic inguinal hernia repair has emerged as a viable alternative to the open procedure. However unlike laparoscopic cholecystectomy, which was very quickly accepted by the surgical community, laparoscopic hernia repair has remained a contentious issue since its inception. The present study is designed to evaluate two tension free methods of Inguinal Hernioplasty using polypropylene (Prolene) mesh.

It is proposed to compare:

- A. Laparoscopic Total Extra Peritoneal repair
- B. Lichtenstein's mesh repair

For Inguinal Hernia, in terms of: Duration of operation, Post operative pain (Visual Analogue Score), Pattern of various Intraoperative and postoperative complications, Post operative convalescence period and Recurrence.

Material and Methods

This is a prospective, randomized study which has been carried out in the Department of Surgery, J.L.N. hospital Ajmer Rajasthan, to compare the two tension free methods of hernioplasty. The patients have been selected from those attending the Surgical Out Patient Department.

Selection Criteria

- 1. All adult patients over 20 years of age.
- 2. Patients having only inguinal hernias
- 3. Patients with bilateral hernias and also recurrent hernias.

Exclusion Criteria

- 1. Patient under age of 20 years.
- 2. All incarcerated/ strangulated or complicated hernias.
- 3. Patients who have had previous lower abdominal surgery.
- 4. Patients with concomitant intra-abdominal disease.
- Patients with contraindications of General Anesthesia.
- 6. Patients with coagulation disorders.

A total of 50 cases were included in the study. Of these, 25 patients were assigned to each of the surgical repair groups to be compared in the study, after randomization.

Randomization

The patients were taken up for the different surgical techniques to be compared and randomized by block design into two groups according to the type of surgery to be performed.

Informed Consent

All the patients included in the study, were informed about randomization of the procedure whereby any of the two procedures may be adopted in his/her case. Details of all the procedures including their advantages, disadvantages and possible complications were explained to the patient.

Preoperative Preparation

Routine preoperative preparations included part preparation, keeping the patient fasting overnight, injection of tetanus toxoid, sedation at night and preoperative does of Inj. Cefotaxime 1 gm I/V just before the operation, after test dose.

Type of Anaesthesia

 For open hernia repair, local/spinal/anesthesia was used, the choice being random • For laparoscopic repair, only general anesthesia was used.

Type of Surgery

Group A: Laparoscopic TEP repair Group B: Lichtenstein's mesh repair

Post Operative Assessment of Pain

Assessment of postoperative pain was made on a pain scale. This method is called "Visual Analogue Scale". The patient or the subject is presented with a line which is 10cm long and is told that one end represents no pain and the other represents the worst imaginable pain. He is then asked to make a mark on the line which represents the intensity of his pain. A ruler is used to get a numerical measure of pain intensity. Patients were asked to mark their pain score on post operative day one and day two. Persistent pain on subsequent follow up was also graded similarly. Injectable analgesics (Diclofenac sodium) were administered 8 hourly on the day of surgery followed by analgesics only on 'SOS' basis. Any analgesic requirement over and above the routine doses was noted.

All patients were followed up one week, two months, six months and nine months.

Statistical Analysis

Findings were tabulated and Analysis was conducted with SPSS for Windows version 9.05. The results were expressed as Mean± Standard Deviation (S.D.).

The student – T test and ANOVA-F test was used for comparison between two groups

A 'p' value < 0.05 was considered significant

Results

A total number of Fifty patients with inguinal hernia were included in the study, 25 (50%) had a Lichtenstein repair (LR) and 25 (50%) had Laparoscopic Total extra peritoneal (TEP) repair. There were total 6 Left indirect inguinal hernia (3 in LR and 3 in TEP), 5 Left direct inguinal hernia (2 in LR and 3 in TEP), 17 Right indirect inguinal hernia (10 in LR and 7 in TEP), 9 Right direct inguinal hernia (5 in LR and 4 in TEP), 13 Bilateral inguinal hernia (5 in LR and 8 in TEP).

The mean age of the 50 patients was 47.54 years ranged from 30 years to 68 years with standard deviation (SD) of 9.03, out of them mean age for Lichtenstein repair was 47.68 years with SD of 9.52 and mean age for Lap. TEP was 47.40 years with SD of 8.72 [Table 1].

Majority of the patients were males i.e., 49/50 (98.0%) and was not statistically significant (P=0.312). Mean weight of all the cases was 61.34 kilogram ranged from 45 kg to 75 kg (SD=6.26) and there was no significantly difference in weight between the two groups (P=0.438) [Table1].

All patient undergoing laparoscopic repairs (25 patients) received general anaesthesia. Local anaesthesia was randomly given to 7 of the 25 patients in the open group (28 %) while spinal anaesthesia was administered to the other 18 (72%) [Table 1].

The mean duration of surgery was 84.60 minutes (SD=33.99) in the laparoscopic group, which was significantly more (P=0.0000) than the open group in which time duration was 51.56 minutes with SD of 5.53 [Table 1].

Conversion Rate; Out of 25 Lap. TEP cases 2 (8%) were converted to open, reason being peritoneal tear in 1 (4%) and hemorrhage in 1 (4%).

The overall rate of complications in the 50 patients was 14/50 (28%). The complication rate was not significantly different in the two groups (P=0.0584). Haemorrhage was seen in 6/50 cases (12%). In the laparoscopic group 3 patients bleed from branches of inferior epigastric artery while as in the Lichtenstein's repair, bleeding occurred from some minor vessels. Peritoneal tear was observed in 3/25 (12%) of laparoscopic cases, one of which needed conversion to open surgery due to decrease in working space caused by pneumoperitoneum, which could not be managed even by introduction of Veress needle into the peritoneal cavity. In the other two cases, pneumoperitoneum was successfully dealt with by introducing a Veress needle into the peritoneal cavity. Transaction of the ilioinguinal nerve was seen in 2 patient of the open mesh hernioplasties (Lichtenstein's repair group) - 2/50 (4%). Subcutaneous emphysema extending onto the lower chest wall was seen in 3 patients of the laparoscopic TEP repair group which resolved spontaneously uneventfully. No patient had bladder/bowel/vas deferens injury [Table 2].

The overall rate of post operative complication was 15/50 (30%). The complication rate did not vary significantly between the two groups (P=0.622). The Lichtenstein's repair group experienced the maximum number of complications (10/25) 40% but this was

not statistically significant. Urinary retention more than 6 hours was the most common complication noted 6/50 (12%). One patient in the laparoscopic group had sub umbilical port site infection and two patient of Lichtenstein's repair group had stitch abscess which had to be drained. Scrotal oedema was noted in 4 patients (8.0%) who resolved spontaneously. No hematoma was noted. Fever >39p C was noted in one of the patients of the laparoscopic group which was due to urinary tract infection. Prolonged ileus (>24 hours) was seen in one patient (2.0%) in the Lichtenstein's repair group [Table 3].

A total of 38 patients (76.0%) required analgesic over the routine doses. Of these, 18 patients (36.0%) required more than one oral dose which was maximum in case of Lichtenstein's repair group (15/25, 60%) as compared to Lap TEP repair group (3/25, 12%).

Pain Scores (Visual Analogue Scale)

Postoperative Day 1: The mean pain scores by the Visual Analogue Scale (1-10) were highest for the Lichtenstein's repair group (6.00, S.D.=0.58) as compared the minimum pain score for the laparoscopic TEP group (5.72, S.D.=0.74).

Postoperative Day 2: The mean pain scores on post operative day 2 were highest for the Lichtenstein's repair group (4.76, S.D. =0.78) as compared to the minimum pain score for the Lap. TEP group (2.28, S.D. =1.31) which was significant in comparison to the groups.

The average time to oral feed was the highest in the Laparoscopic TEP repair group (20.96 hours, S.D. =5.10), which was statistically significant (P=0.000) as compared to Lichtenstein's repair group. The time ranged from 8-24 hours. The average time to feed in the Lichtenstein's repair group was (13.20 hours, S.D. =5.03).

Mean duration of hospital stay for all the cases was 2.44 days (S.D. =0.73) Hospital stay ranged from 2-5 days. The longest mean duration of hospital stay was of the Lichtenstein's repair group (2.60 days, S.D. =0.82) but this was not statistically significant in comparison to other group (2.28 days, P=0.062).

The average time taken for return to normal daily activities by all the 50 patients was 6.80 days (S.D.=2.28). The minimum average time to return to normal activity was taken by the Laparoscopic TEP repair group (5.32 days, S.D.=1.35), which was statistically significant in overall comparison (8.28 days, P=0.000).

The follow-up rate was 100%. 38/50 patients (76%)

had a healthy scar and no other complaints. Wound infection was seen in 3 patients (6.0%), seroma in 2 (4.0%) and persistent pain in 7 patients (14%), none > 2 on VAS. There was no statistically difference in the distribution of these complaints amongst the groups (P=0.564) [Figure 1].

The follow-up rate was 82% i.e., 9 patients were lost to follow-up. No recurrence was seen in any of

the patients. 2 patients (4%) had a poor cosmetic scar, both in Lichtenstein's repair group. 3 patients (6.0%) had persistent pain (none>2 on VAS) in the inguinal region while there was no case of pain in the Laparoscopic TEP repair group. This was not statistically significant (P=0.135) [Figure 2].

At nine months the follow-up rate was 74.0%. No complication or recurrence was seen in any of the patients reviewed.

Table 1: Characteristics of patients at baseline

Characteristics	Lichtenstein Repair	Lap. TEP	P value	
Mean age in years (SD)	47.68(9.52)	47.40(8.72)	0.457	
Male	24	25	0.312	
Female	1	-		
Mean weight in Kilograms (SD)	61.48 (4.98)	61.20(7.43)	0.438	
Type of Anaesthesia				
Local	7	-		
Spinal	18	-		
General	-	25		
Mean duration of surgery in minutes (SD)	51.56(5.53)	84.60(33.99)	0.000	

Table 2: Distributions of Intraoperative complications

Intraoperative Complications							
Complications	Lichtenstein repair	Lap. TEP	Total	P value			
None	20	16	36				
Haemorrhage	3	3	6				
Peritoneal tear	-	3	3	0.0584			
Injury to ilioinguinal nerve	2	-	2				
Subcutaneous emphysema	0	3	3				
Total	25	25	50				

Table 3: Distributions of Postoperative complications

Postoperative Complications				
	Lichtenstein Repair	Lap TEP		P value
None	15	20	35	
Urinary retention >6 hours	4	2	6	
Fever	0	1	1	0.622
Ileus >24 hours	1	0	1	
Scrotal edema	3	1	4	
Wound infection	2	1	3	
Total	25	25	50	

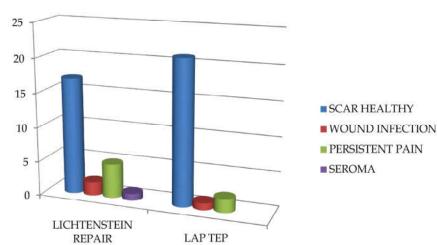


Fig. 1: Shows graph follow up at week one

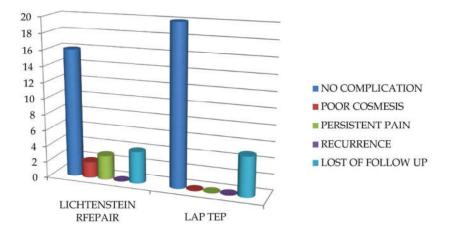


Fig. 2: Shows graph follow up at two months

Discussion

The ideal method of hernia repair would cause minimal discomfort to the patient, both during the surgical procedure and in the postoperative course. In the present study, both the open techniques and the laparoscopic technique had a prolene mesh incorporated in repair, in a tension free manner. This design makes it possible to evaluate the role of the minimal access trauma itself in the outcome of the hernia repair. The parameters used for comparison were–duration of operation, postoperative pain, complications (Intraoperative and postoperative), post-operative convalescence period and recurrence.

Epidemiology

Age

In this study, patients with inguinal hernia presented to the hospital at a mean age of 47.54 years (S.D. =9.03) with a range of 30 to 68 years. There was no statistically significant difference in the distribution of the ages of the cases in the three groups (P=0.457). 21/50 patients were of the age 50 years and above. These observations are supported by standard literature.[1] Which mention that inguinal hernia can present at any age with arise in incidence with age (45% of males over & 5 years of age have hernia) [2].

Sex

In the present study, 49/50 cases were males (98.0%). There was no significant difference with respect to distribution of males and females between the groups (P=0.312). In various reports, the male: female ratio varies from 17:1 to 20:1. [2].

Duration of Surgery

In this study, the mean duration of surgery in the two groups was 68.08 minutes (S.D. =29.32). The average taken by the laparoscopic repair group was 84.60 minutes (S.D=33.99), which was significantly more (P=0.000) than the other open group.

Phillips et al. reported an average operating time for the laparoscopic TEP repair as 81 minutes (unilateral) and 84 minutes (bilateral) [3].

Liem et al. stated that median duration of surgery for laparoscopic repair was only five minutes more than the conventional group [4].

Thus although mean time taken for open repairs in this study does not show much variation from that given in literature, the time taken for laparoscopic repair was significantly longer. This could be attributed to the 'learning curve' phenomenon which had a marked effect in the initial cases. Importantly, the duration of surgery in the laparoscopic group in our study decreased considerably in the last half of the cases, for the last 10 cases in the laparoscopic TEP group was an average 54.2 minutes which was not significantly different from the open hernia repair (average 51.56 minutes).

Conversion Rate

In our study the conversion rate to open surgery in the laparoscopic repair group was 2/25 (8%). The reasons for conversion being peritoneal tear in 1 case (4%) leading to pneumoperitoneum and thereby decreased working space. Hemorrhage occurred from the inferior epigastric artery in 1 (4%) case which decreased the visibility of the operating field in the laparoscopic vision.

Phillips et al., the pioneers in laparoscopic TEP repair, reported a conversion rate of 3/253 (1.12%) in their initial series. They converted one case to open surgery due to hypercarbia and two cases to TAPP due to peritoneal leak [3].

The apparently high conversion rate in this study was largely due to the initial learning curve and the relative inexperience on the part of the operating surgeons, as all the two conversions occurred during the earlier part of the study. Due to the small sample size of the group in this study, even these small number of cases converted increased the overall percentage of conversions disproportionately.

Complications (Operative and Postoperative

The rate of operative complication was 14/50 (28%) while the rate of postoperative complications was 15/ 50 (30%). There was no significance difference between operative complications (P=0.0584) or the postoperative complications (P=0.622) in the two groups. In the operative complications haemorrhage occurred in six patients (12%), peritoneal leak occurred in 3 patients (12%) of the laparoscopic repair group. Nerve injury occurred in 2 patients (4%), none of the cases of the laparoscopic repair group had any nerve injury. A complication exclusive to laparoscopic repair group was subcutaneous emphysema which occurred in 3 patients (12%) operated in the initial phase of the study. In the post operative complications urinary retention >6 hours was the commonest complications occurring in 6/50 (12%) cases. Fever >39p C occurred in 1/50 (2%) cases in the laparoscopic repair group. 1/25 (4%) of the laparoscopic repair group had a sub umbilical port site infection and 2/25 of the Lichtenstein's repair group had an incision wound infection which required drainage. Scrotal oedema occurred in 4/50 (8.0%) cases, prolonged ileus >24 hours occurred in one case (2.0%). Though not significant statistically, the Lichtenstein's repair group had the higher rate of complications in comparison to the laparoscopic group, 10/25 (40%) in the postoperative period.

The complication rates for laparoscopic inguinal hernia repairs have been reported in various studies:

- 1. Phillips et al. (1990) 19% mostly seromas and in 1995-10% (major 7%, minor 8%) [3].
- 2. MRC Laparoscopic Groin Hernia Trail Group (1999)-43.5% in the open group [5].
- 3. Kumar et al. (1999)- 16% in Laparoscopic versus 48% in the open group [6].
- 4. Vanclooster and colleagues (2001) 8.4% (both per and post operative complication) for

laparoscopic repair [7].

5. Johan Westerdahl et at. (2003) reported no difference in overall complications between the laparoscopic TEP repair and Lichtenstein's repair though there was a higher frequency of postoperative hematomas observed in Lichtenstein's group [8].

Pain Scores

Pain is an important criterion in the assessment of an inguinal hernia repair due to the large number of nerves interfered with in this area while dissection, also differing with the technique involved due to variable extent of dissections done in each. Subjective pain was analyzed using the Visual Analogue Pain Score System (1-10), on post operative day 1 and day 2.

On postoperative day 1, the Lichtenstein's repair group had the highest pain score (6.00, S.D. =0.58) while the Laparoscopic TEP repair group had the minimum pain score of (5.72, S.D. =0.74) but this was not significant statistically (P=0.071).

On post operative day 2, the Lichtenstein's repair group again showed the highest mean pain score (4.76, S.D. = 0.78) and Laparoscopic repair group the minimum mean pain score of (2.28, S.D. =1.31) which was statistically significantly (P=0.000).

Tahsin Colak et al, in their study of 132 patients comparing laparoscopic TEP repair with tension free open mesh repair in inguinal hernia assessed the postoperative pain by Visual Analogue Scale (VAS) and concluded that the mean VAS score was significantly lower in the TEP group when compared with the open mesh repair (2.73±1.69 vs. 4.61± 1.77; P=0.001) [9].

Analgesic Requirment

A total of 38 patients (76%) required analgesics over the routine dose. 18 patients (36%) required more than one oral dose; which was maximum in case of Lichtenstein's repair group (15/25, 60%) as compared to Laparoscopic TEP repair group (3/25, 12%). Only 13 patients (52%) of the Laparoscopic TEP repair group required extra analgesia and the rest 48% did not require any extra analgesia as compared to the other open tension free mesh hernia repair in which extra analgesia was required by all. This was statistically significant (P=0.000).

Kumar et al (1999), in a prospective trial, recorded analgesic use for an average 6.4 days after Lichtenstein's repair compared with 3.4 days after laparoscopic repair (P<0.05) [6].

Thus the use of analgesic over and above the routine doses were in consistence with the pain scores recorded in our study, i.e., more analgesic were used by the open repair group as compared to the Laparoscopic TEP repair group in which 48% did not required any extra analgesia.

Time to Oral Feed

The average time to oral feed was 17.08 hours (S.D. =6.37) for all the patients. The laparoscopic group cases took the longest average time to oral feeding (20.96 hours, S.D. =5.10). This was statistically significant (P=0.000). Most patients of the open group 21/25 (84%) were allowed orally within 12 hours of operation as compared to only 5/25 (20%) of the laparoscopic repair group. Many studies have not commented separately on the time to oral feeding, as open herniorraphies in large series were done under local anaesthesia and patients were allowed orally shortly thereafter [10].

Duration of Hospital Stay

The mean duration of hospital stay for all the cases was 2.44 days (S.D. =0.73). The longest mean duration of hospital stay was of the Lichtenstein's repair group (2.60 days, S.D. =0.82), but this was not of statistical significance (P=0.062) in comparison to the open group.

Lau et al. noted, the mean hospital stay for patients undergoing Laparoscopic TEP repair as two days (S.D. =1)91. Apparently most reports suggest an early discharge from hospital (less of hospital stay) in patients undergoing the laparoscopic repair [9].

There was not much of a difference noted in the 2 groups studied in terms of hospital stay probably because in the Indian scenario many social modifiers influence the timing of discharge. Also, due to apprehension, the initial few cases were discharged late to allow for complete recovery and see for the early results or complications by us.

Return to Normal Activity

The average time taken to normal daily activities for all the 50 patients was 6.80 days (S.D. =2.28). The minimum average time taken to normal activity was shown by the Laparoscopic TEP repair group (5.32 days, S.D.=1.35) which was significantly less in comparison with the open hernia repair group (P=0.000).

Lau et al found that 47/97 (57%) patients returned to normal activities within one week of laparoscopic repair [9].

Wellwood and colleagues, on the basis of diary card data of patients, found the median time at which patients returned to every activity, was shorter for the laparoscopic group, and most of these differences were significant. They analyzed different types of leisurely and heavy activities separately [11].

The results of our study go in concordance with the results achieved in studies worldwide i.e., laparoscopic repair has a significantly shorter convalescence period, in terms of time taken to return to normal activities and work than the open repair, though the average time taken is on the higher side which can be due to the social factors governing these two parameters, in the Indian scenario.

Follow UP

In our study; follow up rate till 2 months was satisfactory, despite the economic and administrative constraints of our set up. Follow up rates at 6 and 9 months did fall appreciably. Follow up beyond this time, though essential for evaluating hernia surgery outcome was not possible due to constraints of completing the study.

Conclusion

It is of great importance that the laparoscopic technique in hernia surgery be thoroughly evaluated before considering it as one of the standard procedures for hernia surgery. In our study, we found substantial advantage for the laparoscopic approach over the open repair, in terms of the decreased post operative pain, time to return to work and to full recovery. However, longer operating time and need for General Anesthesia remain the predominant drawbacks. No difference was seen in overall complications among the two groups. Future randomized studies should therefore focus on subgroups of patients who could potentially benefit from a laparoscopic approach.

Conflict of Interest: The authors declare that they have no competing interests.

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References

1. Eubanks S. Hernias. In Sabiston DC, Lyerly HK, (ed.). Sabiston Text book of surgery. 15th ed. Singapore.

- WB Saunders Co. 1999;2:1215-33.
- 2. Abrahamson J. Hernias. In Zinner MJ, Shartz SI, Ellis H, et al. (ed.). Maingot's Abdominal Operations. 10th ed. Singapore. Mc Graw Hill, 2001;1:479-581.
- 3. Phillips EH, Carroll BJ, Fallas MJ. Laparoscopic preperitoneal inguinal hernia repair without peritoneal incision. Surg Endosc 1993;7:159-162.
- Cheek CM, Black NA, Derlin HB et al. Groin Hernia Surgery: A systematic review. Am R Coll Surg 1998; 80:51-80.
- 5. The MRC Laparoscopic Groin Hernia Trial Group. Laparoscopic versus open repair of groin hernia: a randomized comparison. Lancet 1999;354:185-90.
- Kumar S, Nixon SJ, Mac Intyre IMC. Laparoscopic or Lichtenstein repair for recurrent inguinal hernia: one units's experience. JR Coll Surg Edinb 1999;44: 301-2.

- 7. Vanclooster P, Smet B, de Gheldere C, et al. Laparoscopic inguinal hernia repair: review of 6 years experience. Acta Chir Belg 2001;101:135-138.
- 8. John Westerdahl, Bodil Anderson, Perleveau. Laparoscopic extraperitoneal inguinal hernia repair versus open mesh repair. Surgery 2003;133:464-72.
- 9. Tahsin Colak, Tamer Akca, Arzu Kanik. Randomized clinical trail comparing Laparoscopic Totally Extraperitoneal Approach with open mesh repair in Inguinal Hernia. Surgical Laparoscopy. Endoscopy and Percutaneous tecniques 2003;13(3):191-195.
- 10. Lichtenstein I L, Shore J M: simplified repair of femoral and recurrent inguinal hernias by a "plug" technique. Am J Surg 1974;128:439.
- 11. Well wood J, Stokes D, Sculpher MJ, et al. Randomized controlled trial of Laparoscopic versus open mesh repair for inguinal hernia: Outcome & Cost. BMJ 1998; 317:103-110.