

Contoured 3D mesh in laparoscopic inguinal hernia repair: does it reduce inguinodynia?

Abstract

Background: Inguinal hernia repair is currently performed by a large variety of surgical prosthesis. Post- surgical pain and recurrence can occur due to the mesh inflammation, shrinkage and various method of fixation of mesh. Chronic pain may be incapacitating and can affect the quality of life. Laparoscopic transabdominal preperitoneal meshhernioplasty using self-fixating and anatomically contoured mesh is a new and innovative technique.

Aim: The aim of our study is to identify the incidence of pain, recurrence and morbidity after repair of inguinal hernia with anatomically contoured 3D mesh.

Method: Our study is a prospective observational study including 48patients of inguinal hernia from Sep 2013-Sep 2015 with laparoscopic transabdominal preperitoneal mesh hernioplasty using anatomically contoured mesh, proprietary name BARD 3D Max LIGHT Mesh was done in 111 hernias. All 48patients were analyzed with Visual Analog Scale (VAS) at 7th postoperative day, 1stmonth and 3rd month.

Result: A total of 48patients were included in the study, and all repaired with 3D mesh. On comparing the grades of VAS score on follow- up of three month , 47patients (97.9%) were reported no pain and one patient (2.1%) was reported having mild pain (p=0.011) (Figure 1). All the patients were discharged on 1stpostoperative day and 46patients (95.8%) were returned to normal activity without pain in 1 month. In our study at the end of 3months mean VAS score (n=48) was .0417±.20194. No patient reported swelling and recurrence on 3month follow-up.

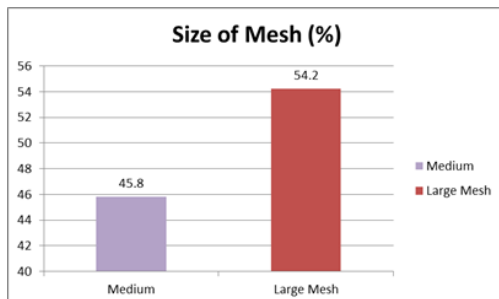


Figure 1 Distribution of Size of 3 D Mesh.

Conclusion: Laparoscopic transabdominal preperitoneal mesh hernioplasty using 3 D mesh is an effective method of repair as it obtains satisfactory results in terms of pain, recurrence and morbidity.

Keywords: hernia, inguinal, 3Dmesh, laparoscopy, pain, surgeons, chronic postherniorraphy, postoperative

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Key Message: Laparoscopic TAPP inguinal hernia repair with 3D contoured mesh has a technical advantage as this mesh is easy to place in correct position. Laparoscopic inguinal hernia repair using this mesh is an effective method of repair as it decreases the pain and recurrence.

Introduction

Inguinal hernia repair is the most common surgical procedure performed worldwide, with approximately 20million inguinal hernia performed annually.¹ Inguinal hernioplasty has undergone a gradual evolution over the past 100years. In the 1800's surgeons such as

Bassini, Halsted and Macvay studied the anatomy of hernias and approached inguinal floor dissection with primary tissue repair. In 1970's, prosthetic repair of the inguinal floor was started and later Nyhus, Stoppa and Wantz did inguinal hernioplasty by applying a prosthesis to the posterior wall of groin. Over the past two decades laparoscopic inguinal hernia repair has gaining significant popularity and widespread use.² Laparoscopic hernia repair was first reported by Ger. And colleagues in 1990. Since then laparoscopic hernia repair has undergone revolutionary advances in technique of repair, types of meshes used and various methods of fixation of mesh.³

The true measure of success for any type of hernia repair is based

on its outcome. When we compare the results of open mesh repair and laparoscopic inguinal hernia repair the incidence of complications decreased in laparoscopic inguinal repair.⁴ Although, complications after laparoscopic inguinal hernia repair decreased but; recurrence of hernia, postoperative groin pain, seroma, and other mesh related complications such as mesh shrinkage and migration remains a concern.³

Chronic postherniorrhaphy groin pain (inguinodynia) is defined as pain that persist more than 3months after surgery. The cause for groin pain after inguinal hernia repair are perioperative nerve damage, mesh related fibrosis and shrinkage, mesh fixation with sutures or tackers. Chronic pain is less after laparoscopic inguinal hernia repair than open repair.^{3,4} Various studied showed that inguinal hernia repair with mesh cause less chronic pain compared to nonmesh inguinal herniorrhaphy.^{5,6} A comparative study of laparoscopic inguinal hernia repair, results showed that fixation of a mesh with tacker is comparable to non-fixation in terms of chronic groin pain ($p=0.67$).⁷ To overcome these disadvantages currently various self-fixation meshes are in use and of late Progridmeshes are being incorporated in open hernia surgeries. Similarly, in laparoscopic inguinal hernioplasty Bard 3D mesh are in use. This mesh developed by Dr. Philippe Pajotin, is structured according to the inguinal anatomy. The advantage of this mesh is its ease of placement and less incidence of chronic pain. In various studies laparoscopic inguinal mesh hernioplasty using 3Dmesh the incidence of chronic pain syndrome varies from 3.4 percent to 1 percent in mean follow-up of 1-2year^{8,9} and in 6.66% patients in mean follow up of 1month.¹⁰

Hernia recurrence is also one of the complications of laparoscopic inguinal hernioplasty. The causes of recurrence is incomplete dissection often associated with inadequate reduction of hernia sac, missed hernia, missed lipoma that causes improper placement of mesh or rolling of mesh edges and inadequate overlap of hernia defect. The 3D mesh of medium or large size overcome these disadvantages and its anatomically contoured surface and stiffness make it easy to manipulate in preperitoneal space and adequately cover the hernia defect with minimal or no helical tacker. The risk of recurrence using 3D mesh range from 0.0%–0.45 % in mean follow-up of 23-26month.^{9,11}

Material and methods

Study design and setting

This was an prospective observational study to assess the incidence of post-operative pain, groin swelling and post-operative morbidity up to 3months after undergoing inguinal hernia surgery using a 3D MAX Light mesh in the period between September 2013–September 2015. 48patients diagnosed with inguinal hernia requiring surgical correction were operated in Apollo Main Hospital Chennai. All the surgeries were performed by a single experienced senior surgeon and pain score was evaluated by assistant doctor.

Inclusion criteria

- All the patients who were having clinically detected direct and indirect hernias.
- Any age of patients undergoing elective laparoscopic TAPP surgical repair with 3D Contoured mesh between September 2013–September 2015.

Exclusion criteria

- Strangulated and Inguinoscrotal hernia.
- Hernias in which previous lower abdominal surgery was done eg, Retropubic prostatectomy, Open appendectomy.
- Patients having multiple comorbidity.

Operative procedures

In all the 48patients Laparoscopic Transabdominal Preperitoneal inguinal hernioplasty was performed under general anesthesia and prophylactic antibiotic (2gm Magnex) was administered. Pneumo peritoneum was created with veress needle. One 10mm supra umbilical port was inserted as optic port. Two 5mm ports inserted lateral to the rectus muscle in lower abdomen. Inferior epigastric artery was secured and indirect/direct hernia was confirmed. Peritoneum was incised 2cm lateral to anterior superior iliac spine to the median umbilical ligament. Peritoneum reflected and preperitoneal space entered and dissected. Herniasac dissected and reduced. Spermatic cord and gonadal vessels were identified. Lateral cutaneous nerve of thigh and femoral branch of genitor femoral were exposed and secured. In few cases lipoma of cord and pseudo sac was also identified and dissected. After creating adequate preperitoneal dissection one 3D mesh (Large/Medium size) deployed through 10mm port and placed in preperitoneal space in anatomically correct position to completely cover the defect as previously marked orientation marks present over the mesh. Mesh secured in place with one or two protack medially near the pubic tubercle. Peritoneal flap was closed with Protack/3-0 Prolenesuture. Trocar site closed with 3-0Monocryl Figure 2.

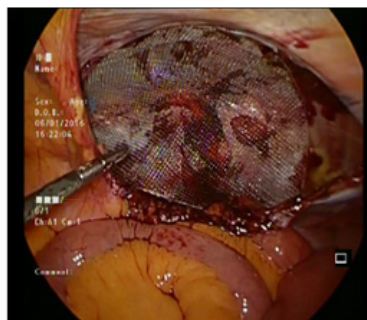


Figure 2 Showing placement of 3D mesh in preperitoneal mesh.

Study outcomes and data collection

All the 48cases were reviewed as outpatients at 7th day, 1stmonth and 3rd month after the surgery. Data collection was completed via questionnaires and a focused physical examination.

- Postoperative pain was recorded on VAS scale. Post-operative pain was classified as, No pain Vas– score (0), Mild pain VAS–score (1-3), Moderate pain VAS–score (4-6), Severe pain VAS–score (>6).
- Post-operative groin swelling was evaluated via a physical examination.
- Secondary outcome as defined by duration of postoperative hospital stay and return to normal activity were also assessed.

Statistical analysis

All the continuous variables were assessed for the normality using

Shapiro- Wilk’s test .If the variables follow a Gaussian distribution, they were expressed as mean+SD. If the variables were not following Gaussian distribution, they were expressed as median (Interquartile range). Comparison of normally distributed continuous paired variables were done by paired t–test .Comparison of non-normally distributed continuous variable were done by Mann-Whitney U Test. Comparison of categorical variables were done by either Chi-square test or Fisher ’s exact test . All frequencies were represented in percentages. Data entry was done in MS-EXCEL spread sheet. Data analysis was carried out by SPSS Ver16.0. All ‘p’ values <0.05 was considered as statistically significant.

Results

Patient characteristics

Gender distribution: In our study in 48patients, 40(83.3%) patients were male and 8(16.7%) patients were female Figure 3.

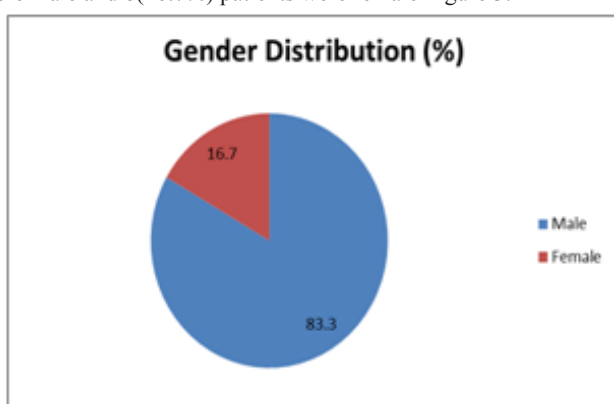


Figure 3 Showing the gender distribution.

Age distribution: In our study, 27.1%patients were above the age of 65years and 14.6%patients less than 35years. Mean age was 53.4+14.3years Figure 4.

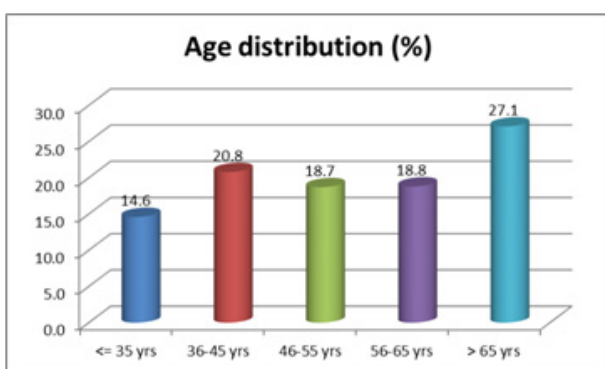


Figure 4 Showing age distribution.

Type of hernia: In our study 31.3%patients were operated for direct hernia and 68.7%patients were operated for indirect hernia Figure 5.

Size of 3D mesh: In our study, in 22(45.8%) patients a medium size 3D mesh was placed and in 28(54.2%) patients large size 3D mesh was placed Figure 1 & Table 1.

Table 1 Patient demographics

Total patients	N=48
Gender (Male/Female)	40 (83.3%)/8(16.7%)
Mean Age (years)	53.4+14.3
Unilateral	35 (72.9%)
Bilateral	13(17.1%)
Indirect	33(68.7%)
Direct	15(31.3%)
Mean Size of defect (cm)	3.5+0.96cm
Mesh Size (large/medium)	26(54.2%)/22(45.8%)
Fixation	1-2protack
Mean Operative time(Min)	83.58+19.94
Mean Hospital stay (Days)	2days

Surgical outcome

Postoperative pain: On comparing the mean VAS score on 7th postoperative day(2.18±2.12) and 1month (0.72±1.10) significant difference in mean vas score was present and p value was (p=0.0001), and gradually when we followed our patients in 3rdmonth mean VAS score has decrease to 0.04±0.20 . On comparing the mean VAS score on 7th and 3rd post operative month p value was (p=0.008), thus gradually statistically significant difference in mean VAS score was present in 3month follow up (Table 2).

Table 2 Showing comparison of mean VAS- score at 7th, 1month and 3rdmonth

Postoperative day	Mean Vas score	P value
1--7 th day	2.18+2.12	0.0001
1month	0.72+1.10	
1-- 7 th day	2.18+2.12	0.008
3month	0.04+0.20	
1month	0.72+1.10	0.0001
3month	0.04+0.20	

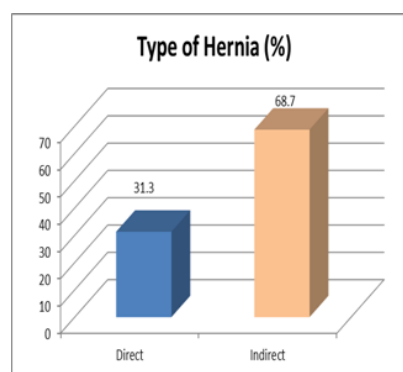


Figure 5 Showing percentage of the patient with direct and indirect hernia.

Similarly on comparing the mean VAS score at the end of 1st month (0.72±1.10) and 3rd month (0.04±0.20) statistically significant difference was present. (p=0.0001) (Table 2 & Figures 6-9). Postoperatively when we compare the grades of pain at 7th day, 1 month, and 3rd month, the proportion of patients with pain was found to decrease (Figure 6). 4(8.3%) patients were having severe pain in groin region after 7th postoperative day and managed by giving analgesic. Most of the patients 46(95.8%) returned to normal activity, at the end of 1 month. 18(37.5 %) patients complained of mild pain and 2(4.2%) patients complained of moderate pain when they did more than normal activity after one month and pain was localized to port site. No patient developed pain after 3 months (Table 3 & Figure 10).

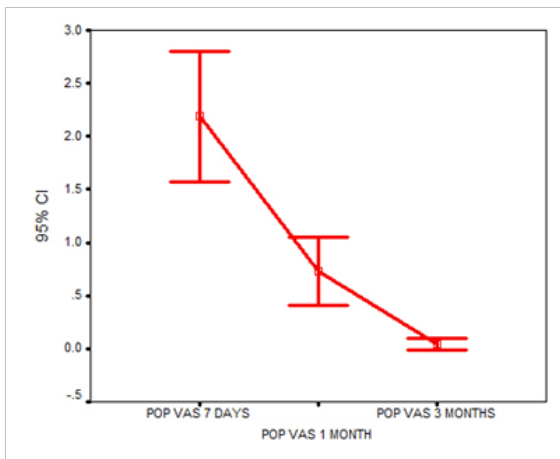


Figure 6 Error bar showing difference in pain score over a period of 3 month.

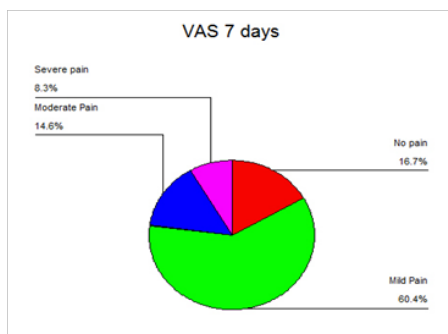


Figure 7 Showing distribution of grades of pain after 7 day.

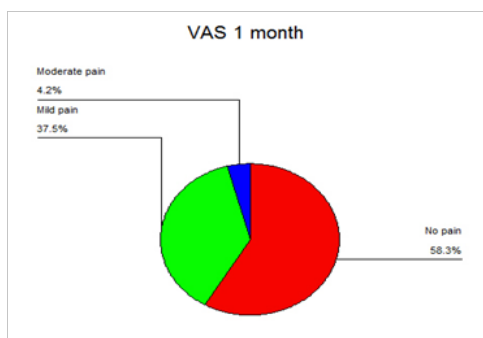


Figure 8 Showing distribution of grade of pain after 1 month.

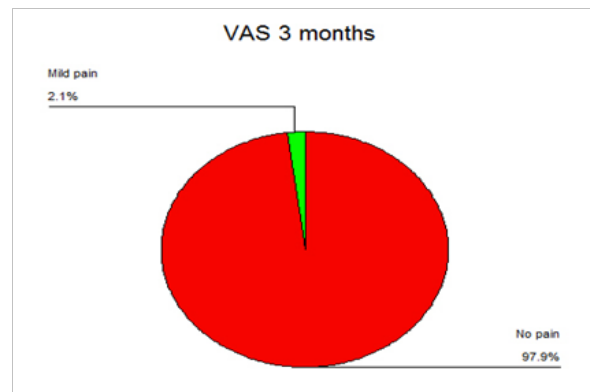


Figure 9 Showing distribution of grades of pain after 3 month.

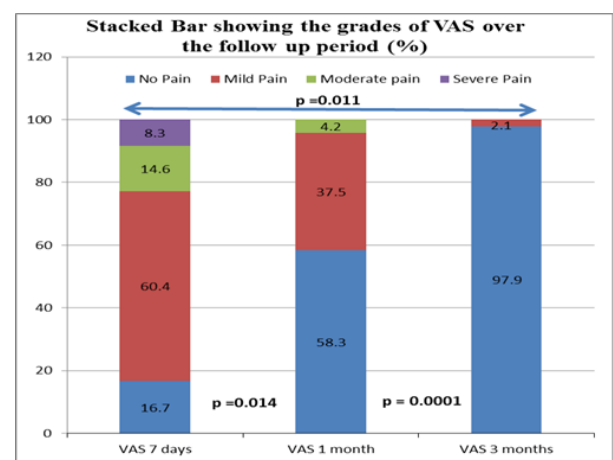


Figure 10 Stacked bar showing grades of VAS over the follow-up of 3 month.

There was highly significant difference in VAS score in male and female patients on the 7th (p=.004) and 1st postoperative month (p=.001). Female were having more perception of pain then in comparison to male, this may be because of their emotional and psychological factors.⁵ In our study there was no difference in VAS score in male and female after 3rd postoperative month (p=.201) (Table 4 & Figure 11).

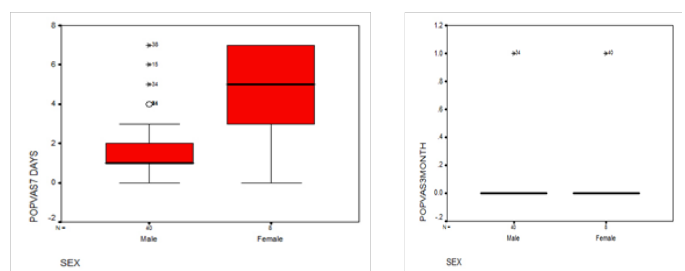


Figure 11 Showing Difference in VAS score in male and female patients in 3 months.

Recurrence: In our study no patient had persistent swelling after 3 month and symptomatic recurrence of inguinal hernia was 0% in 3 month.

Postoperative morbidity: The mean duration of stay in hospital was

2days.95.8% (n=46) patients returned to normal activity in 1month. No major morbidity and mortality was present after 3month (Table 4).

Table 3 Showing comparison grades of pain, having mild, moderate and severe pain

Days	No pain (VAS 0)	Mild pain (VAS 1-3)	Moderate pain (VAS 4-6)	Severe pain (VAS>7)
1-7 th Day	16.7%(8)	60.4%(29)	14.6%(7)	8.3%(4)
1Month	58.3%(28)	37.5%(18)	4.2%(2)	
3Month	97.9%(47)	2.1%(1)		

Table 4 Showing comparison of VAS score in male and female patients

	Gender	Mean vas score	P value
1-7 th day	Male	1.70+1.66	0.004
	Female	4.62+2.55	
1Month	Male	0.47+0.87	0.001
	Female	2.00+1.3	
3Month	Male	0.02+0.15	0.201
	Female	0.12+0.35	

Patient satisfaction: Overall, 100% patients were satisfied with their hernia operation and would recommend this operative technique to friends or relatives with an inguinal hernia. There were no statistically significant differences in satisfaction based on the side of surgery, gender, or the presence or absence of postoperative pain.

Table 5 Analysis of studies showing end points, pain, recurrence and morbidity.

Author	Year	Type of repair	Type of mesh	Number of patients	Fixation or nonfixation of mesh	Pain	Recurrence	Morbidity	Mean follow-up	Length of stay in hospital
Bell et al. ⁹	2003	LapTAPP	3D contoured mesh	146	Fixation with 3 helical tacks	0-1%	0.42%	0-1%	23months	
Alberto Meyer et al. ¹¹	Mar. 2013	lapTEP	3d Mesh	157	Non fixation of mesh	Not calculated	0.0%	5.7%	26months.	less than 12hours
Ahmed et al. ⁵	2014	Lap TAPP	Prolene mesh	45	Fixation with tackers	4.4-6.6%	0%		21Months	
Mir et al. ⁸	2015	LapTEP/TAPP	3D MESH	53	TEP nonfixation, tapp tacker fixation	3.7% mild pain	(0%)	Nil	12Months	24hours
Dario et al. ¹⁴	2015	Lichtenstein	Self fixating 3d implant Proflor	44	Nonfixation	0% pain	0%		24 months	

Discussion

In this study 48patients of inguinal hernia were evaluated for 3month after laparoscopic hernia repair with 3D mesh. The mean operative time was 83.58±19.94min.

When we compare the results of our study with previous literature there was a significant difference was present in background of pain, recurrence and morbidity.

The end points that we have analysed were pain, recurrence and morbidity.

Extraction of data and analysis of end points

We searched the literature published in English from 1990 to 2016. The databases searched include Pubmed, Medline , clinical key with the key words used for the search strategy were “ Lap TAPP ”, “ VAS score ”, “ 3D Mesh”, “ Recurrence ”. We searched the literature for selection of studies. We searched 500 studies and finally included 16studies for references. The following data were extracted from each study.

- Type of repair
- Type of mesh
- Number of patients
- Fixation and no fixation of mesh
- Pain (VAS Score)
- Recurrence
- Length of stay in hospital
- Follow -up
- Morbidity

All studies varied with respect to these baseline characteristics thus the necessary data was extracted from the selected studies^{5,9,11,14} for analysis (Table 5).

Pain

In various studies with the Self-fixating mesh reduction in the incidence of chronic pain down to 0% has been reported.^{8,9,11,14} Localization of pain varied in studies, because of the various methods of fixation techniques. Tolver et al.¹⁵ compared the port incision site pain and abdominal pain including groin pain in TAPP repair and it was found that abdominal pain was more significant than port site incision pain (p<0.001).¹⁵ In our study, only one patient developed mild pain at port incision site and no patient complained of groin pain at the end of 3months (p=0.011). This difference in pain localization

is because of minimal fixation and better incorporation of mesh in the groin region because of its three dimensional shape that prevent its migration and shrinkage without any fixation device. Thus we can conclude that it is the self-gripping nature of mesh and lack of need for a fixation device as well as better incorporation of these meshes reduced the incidence of pain.¹⁶

Recurrence

In various studies recurrence rates varied from 0%–3.33%, (mean follow up of 12-26month) using 3D mesh and in our study recurrence rate was 0% at 3months. The results of our study are not truly comparable to previous studies^{8,9,11,13} as recurrence is a late phenomenon which can be best determined by further long term follow-up studies.

Secondary outcome

Data from secondary outcomes analysis showed that all the patients in our study were discharged from the hospital on 1st postoperative day that is truly comparable to the study of Mir et al.,⁸ in their study 88.67% patient were discharged with in 24hour of surgery. In our study 46(95.8%) patient returned to normal activity in 1month then

in comparison to Bell et al.⁹ study; in which 94% patients returned to normal activity by 3weeks. In our study, 2patients developed moderate ($p=0.008$) pain after one month, limiting their return to normal activity.⁹

The results of our study comparable in terms of postoperative pain, recurrence and hospital stay. This conclusion is further supported by several other studies (Table 6). As the trend of self fixing meshes in inguinal hernia repair is now a day's popular, so non fixation of mesh is coming in advanced surgical practices. The use of an anatomically configured three-dimensional mesh (3-D Max) enables laparoscopic TAPP and TEP repairs of inguinal hernias with only the rare requirement of mechanical fixation, resulting in a minimal risk of complications and an extremely satisfactory success rate.

Thus, laparoscopic inguinal hernia repair with 3D mesh has demonstrated a clear advantage in unilateral as well as bilateral hernias, in elderly patients and even in female patients with regard to pain, recurrence and shorter stay in the hospital. (Table 1) In laparoscopic inguinal hernia repair techniques, 3D mesh is used because it better incorporated and easy to place with minimal fixation and less postoperative complications .

Table 6 Showing comparison of results of our study and various other groups in literature

	3D contoured mesh	Historical group 1 bell et al. ⁹	Historical group 2 mir et al. ⁸	Historical group 3 ahmed et al. ⁵
Pain	2.10%	0-1%	3.70%	2.5% mild pain
Recurrence	0%	0.42%	0%	0%

Conclusion

Laparoscopic TAPP inguinal hernia repair using 3D contoured meshes has the technical advantage of easy insertion in an anatomically correct position with minimal fixation. Early follow-up results from our study has shown a significant reduction in the incidence and prevalence of pain, hernia recurrence and postoperative morbidity. Long term data regarding their use is lacking primarily due to its cost prohibitiveness in developing countries. Our observational study shows that by preventing post-operative co morbidities, readmissions and redo surgeries, the benefit of 3D mesh may outweigh the costs and that there is a vital need for further longitudinal studies with this technique and prosthesis. The patient-reported postoperative pain scores compared very favorably with the published literature, which may indicate that the use of a self-gripping mesh is associated with reduced postoperative pain.

Need for future research

Well designed randomised clinical trials with low risk of systematic error and random error and those that include long-term analysis for the recurrence and quality of life as important outcomes may be necessary. Such trials ought to stratify patients according to the likely cause of inguinodynia well as to report both short-and long-term outcomes such as quality of life, recurrence, serious complications as seroma, mesh infection and mortality. Well designed long term trials should also compare the preoperative and postoperative pain that is not the part of our study. Reporting of such trials will enable transparent evaluation of the intervention.

As our study is short term prospective study using 3D CONTOURED MESH including the n=48patients. The inferences that we have calculated can be studied with this sample size. As our study is not a comparable study, and long term results of the variables as recurrence, mesh complications were not analysed, so to analysed these results large sample size should be necessary.

Acknowledgements

None.

Conflict of interest

The author declares no conflict of interest.

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