Mediterranean BioMedical Journals
International Journal of Medicine and Surgery
Volume 6, 2019, ID 248
DOI: 10.15342/ijms.v6ir.248

ORIGINAL RESEARCH

SELF-RETAINING FREEDOM PROFLOR VS. LICHTENSTEIN MESH REPAIR FOR THE REDUCTION OF POSTOPERATIVE PAIN IN INGUINAL HERNIA: A 1-YEAR RANDOMIZED CONTROLLED STUDY

Dr. Kannikanti Nageswara RAO[1], Dr. A.S. GOGATE[2]

[1] Department of General Surgery, K.L.E. University's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi 590003, Karnataka, India.

[2] Department of General Surgery, K.L.E. University's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi 590003, Karnataka, India.

ABSTRACT

Introduction: Lichtenstein tension-free mesh repair (LMR), surgical procedure for inguinal hernia, associated with postoperative pain. The study was aimed to compare self-retaining Freedom ProFlor versus LMR for the reduction of postoperative pain in inguinal hernia.

Methodology: A total of 60 patients with inguinal hernia undergoing mesh repair were randomized into two groups of 30 each: group A (Freedom ProFlor mesh repair) and group B (LMR). Demographic data and clinical findings of all the patients including duration of pain, lump size, cough impulse, and the position of hernia were noted. Recorded findings such as postoperative pain and operative time were subjected to statistical analysis.

Results: Most (31) of the patients had hernia on the right side. The operative time was significantly less in group A when compared to group B ($P < 0.05$). Significantly lower pain scores were observed in group A than in group B ($P < 0.05$). The mean post-operative pain was significantly lower in group A compared with group B during the fifth follow-up visit (0.2 ± 0.41 vs. 1.07 ± 1.28; $P < 0.0001$).

Conclusion: The Freedom ProFlor mesh repair was better than the LMR regarding postoperative pain. Moreover, the dose of the analgesic needed in Freedom ProFlor mesh repair group was less and for a shorter time when compared to LMR group. However, further long-term studies are required for documenting hernia recurrences.

KEY WORDS: Freedom ProFlor mesh, Lichtenstein tension-free mesh repair, inguinal hernia, self-retaining mesh, postoperative pain.

CORRESPONDING AUTHOR:

Dr. A.S. GOGATE, Department of General Surgery, K.L.E. University's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi 590003, Karnataka, India. Email: gogatebhijit@gmail.com, Tel: 9844001879

INTRODUCTION

Inguinal hernia repair, accounting for 10% to 15% of all surgical procedures, is the second most common surgical procedure after appendectomy [1, 2]. It has been predicted that each year over 20 million inguinal hernia repairs are performed worldwide [3]. Any condition that either weakens the anterior abdominal wall or increases the intraabdominal pressure may contribute to the appearance or progression of an inguinal hernia. Known risk factors of inguinal hernia are smoking, patent processus vaginalis, positive family history, collagen disease, previous open appendectomy, prostatectomy, patients with ascites, peritoneal dialysis, long-term heavy work, and chronic obstructive pulmonary disease [4].

Swelling/lump or pain in the groin region are the most typical symptoms in patients with inguinal hernia. An untreated hernia may sometimes become incarcerated, which can no longer be reduced or pushed back into its place resulting in strangulation [5]. The management of inguinal hernia poses a therapeutic challenge to surgeons practicing in resource-limited countries. Late presentation of the disease and lack of modern therapeutic facilities (laparoscopy and mesh) are the hallmarks of the disease in developing countries [6, 7].

Bassini first described inguinal hernia repair in 1887, later many techniques such as shouldice, darning, desarda, modified Bassini, Lichtenstein tension-free mesh repair (LMR), and more recently laparoscopic repair are performed for hernia repair [2, 3]. Amongst these, laparoscopy and LMR have gained remarkable popularity in recent days [8]. Low recurrence rate, ease to perform, and rapid return to regular activities are the most common advantages associated with these procedures [9]. However, postoperative pain ensuing inguinal hernia repair is the major complication. Recently, several studies have concentrated on aspects of postoperative chronic pain and quality of life/recurrence rate after hernia repair. LMR and similar procedures introduced in the management of inguinal hernia showed a dramatic decline in recurrence rates [10]. However, mesh fixation with sutures to avoid dislocation has been stated as a cause of postoperative pain and discomfort. The main causes of postoperative groin pain include postoperative fibrosis, perioperative nerve damage, and mesh-related fibrosis [11]. The Freedom ProFlor mesh is a specifically designed 3D autostatic prosthetic device placed without any suture. This is achieved using its inherent radial recoil, vertical buffering, and friction within the hernia edge. The procedure is based on the centrifugal expansion of the device, wherein the device converts the ejection forces into gripping forces and avoid the need for suturing the implant [12]. The present study was conducted as an initiative to compare the postoperative pain after conventional Lichtenstein's meshplasty against Freedom ProFlor hernia repair.

METHODS

The 1-year randomized controlled study was conducted at the Department of General Surgery, from January 2015 to December 2015. A total of 60 patients were randomized into two groups: group A (30, Freedom ProFlor self-retaining mesh repair) and group B (30, conventional LMR). Randomization of the groups was done using computer-generated random scheme method. Ethical approval was obtained from the Institutional Ethical and Research Committee, prior to the commencement of the study. An informed written consent was obtained from the patients before their participation in the study.

Inclusion criteria was patients with inguinal hernia undergoing mesh repair. Exclusion criteria comprised of immunocompromised patients, patients with pulmonary tuberculosis, recurrent hernia, and benign prostatic hyperplasia. Selected patients were informed about the nature of the study, specifically, the benefits of using Freedom ProFlor self-retaining mesh repair and LMR.

Data collection

Demographic data such as age, gender, and history were obtained through an interview. All the patients were subjected to clinical examination and the details including duration of pain, lump size, cough impulse, and the position of hernia were noted on a predesigned proforma. Routine investigations such as blood counts (hemoglobin, total leucocyte count, differential count, red blood cell count, and erythrocyte sedimentation rate), blood urea nitrogen, serum creatinine, bleeding and clotting time, urine tests (routine and microscopy), chest X-ray, electrocardiogram, and ultrasonography (to rule out benign prostatic hyperplasia) were also performed.

Intervention

All the patients in group A underwent Freedom ProFlor self-retaining mesh repair. The skin and subcutaneous tissue were treated same as LMR standard procedure [13]. Further the procedure was performed as reported by John *et al*., (2016) [14]. The Freedom ProFlor self-retaining mesh is available in two sizes of dynamic core (25 mm and 40 mm). Depending on the size of the defect, appropriately sized Freedom ProFlor mesh was delivered into the opening of fascia transversalis with the applicator. The closing of subcutaneous tissue and skin was also done according to standard LMR procedure [13]. (Figure 1)

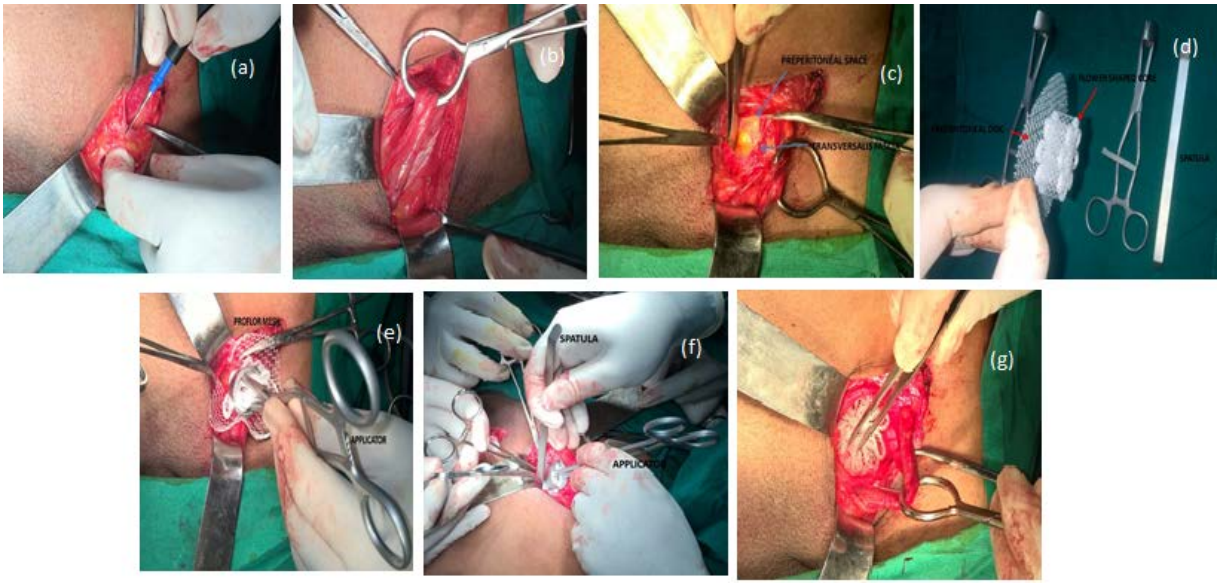

Figure 1 : Placement of Freedom ProFlor mesh

(a) Opening of external oblique aponeurosis (b) Identifying cord and cord holding with forceps (c) Preperitoneal space (d) Freedom ProFlor mesh (e) Deployment of Freedom ProFlor mesh in preperitoneal space with the applicator (f) Spreading preperitoneal disc into preperitoneal space with spatula (g) Freedom ProFlor mesh holding the defect in fascia transversalis.

All the patients in group B underwent LMR with a standard Lichtenstein procedure [14] using flat polypropylene mesh (7 × 15 cm), sutured to the pubic tubercle.

In postoperative period for the pain management, intramuscular diclofenac 50 mg twice daily was administered to patients in both the groups. Oral diclofenac 50 mg was given, if needed. The pain was assessed based on visual analogue scale (VAS) ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain. Further, the range of pain was divided into three categories: mild (VAS score ≤ 3), moderate (VAS score between 4 and 6), and severe (VAS score ≥ 7). Postoperatively, all the patients were followed-up for three months: on day one, day three, first week, fourth week, and after three months.

Statistical analysis

SPSS 20.0 was used to analyze the data. The categorical data were expressed as rates, ratios, and percentages. The comparison was done using Mann–Whitney test and t-test. Continuous data were expressed as mean ± standard deviation. $P \leq 0.05$ was considered statistically significant.

RESULTS

Demographic and clinical characteristics of the patients are summarized in Table 1. All sixty patients in the study were men. Out of 60 hernia patients, most of the patients had direct hernia (43) and on right side (31). All the patients in group A were operated within 30 minutes. While, in group B, only one patient was operated within 30 minutes. And, the difference observed was statistically significant ($P < 0.05$). However, no significant difference was observed between the two groups in terms of gender, mean age, mean duration of symptoms, vital signs, side of hernia, and diagnosis ($P > 0.05$).

Table 1: Demographic and clinical characteristics of the study population

Variables	Group A (n = 30)	Group B (n = 30)	*P* value
Gender			
Men	30 (100%)	30 (100%)	1
Mean duration of inguinal hernia (months)	13.07 ± 9.6	56.47 ± 13.85	0.428
Vitals			
Pulse rate (per min)	77.73 ± 4.81	78.73 ± 4.99	
Systolic BP (mm Hg)	116.67 ± 8.64	118.67 ± 10.16	> 0.05
Diastolic BP (mm Hg)	74.2 ± 5.34	74.2 ± 5.34	
Side of hernia			
Right	16 (53.33%)	15 (43.33%)	0.691
Left	9 (30%)	11 (40%)	
Bilateral	5 (16.67%)	5 (16.67%)	
Diagnosis			
Direct hernia	22 (73.33%)	21 (70%)	0.774
Direct hernia and Indirect hernia	8 (26.67%)	9 (30%)	
Duration of surgery (minutes)			
0–30	30 (100%)	1 (3.33%)	< 0.05*
30–60	0	29 (96.67%)	

*Data is expressed as n (%) and mean ± SD; *Significant; BP*, Blood pressure

The comparison of the VAS scores in all the five follow-ups is shown in Table 2. Significantly lower pain scores were observed in group A than in group B ($P < 0.05$). During the first and second follow-ups, most of the patients in group A reported mild pain. While, most of the patients in group B reported moderate pain.

Table 2: Comparison of the visual analogue scores during the follow-up period

Follow-up	Score	Group A, n (%)	Group B, n (%)	*P*-value
On day 1	Mild	16 (53.33)	6 (20.0)	0.001*
	Moderate	14 (46.67)	15 (50.0)	
	Severe	0	9 (30.0)	
On day 3	Mild	25 (83.33)	8 (26.6)	< 0.001*
	Moderate	5 (16.6)	20 (66.6)	
	Severe	0	2 (6.66)	
After 1 week	Mild	30 (100.0)	25 (83.3)	0.02*
	Moderate	0	5 (16.6)	
	Severe	0	0	
After 4 weeks	Mild	30 (100.0)	26 (86.6)	0.035*
	Moderate	0	4 (13.33)	
	Severe	0	0	
After 3 months	Mild	30 (100.0)	26 (86.6)	0.035*
	Moderate	0	4 (13.33)	
	Severe	0	0	

**Statistically significant*

The mean postoperative pain scores during the follow-up period are shown in Table 3. The mean post-operative pain was significantly lower in group A compared with group B during the fifth follow-up visit (0.2 ± 0.41 vs.

1.07 ± 1.28; $P < 0.0001$). Moreover, the mean reduction of pain scores from the first to the fifth follow-up was also statistically significant between the groups (3.3 ± 1.24 vs. 4.4 ± 2.04; $P = 0.029$).

Table 3: Mean postoperative pain scores during the follow-up period

Follow-up visits	Group A	Group B	*P*-value
First	3.53 ± 1.36	5.47 ± 2.11	< 0.0001*
Second	1.37 ± 1.5	4.3 ± 1.51	< 0.0001*
Third	0.47 ± 0.57	2.37 ± 1.47	< 0.0001*
Fourth	0.3 ± 0.47	1.53 ± 1.43	< 0.0001*
Fifth	0.2 ± 0.41	1.07 ± 1.28	< 0.0001*

*Data is expressed as mean ± SD; * Statistically significant*

DISCUSSION

Postoperative pain is a major complication following open inguinal hernia repair [15-17]. Therefore, the present study attempted to compare self-retaining Freedom ProFlor mesh repair (group A) versus LMR (group B) for reduction of postoperative pain in inguinal hernia.

In our study, the operative time was significantly less in group A compared to group B. The significant reduction of operative time in group A is due to minimal anterior dissection and specifically designed mesh, which does not require point fixation. Similarly, a study conducted by *John et al., (2016) reported t*he average operation time of 43 min for the LMR, whereas 24 minfor the Freedom ProFlor repair *[14]*. This represents an average reduction in skin-to-skin surgical time of 19 min, which is comparable to our study. Studies showed that the mean duration of surgery was shorter in patients in whom the mesh was placed behind the fascia transversalis [16].

The lower pain scores reported in group A were due to its self-retaining property of the mesh (no fixing sutures), lesser tissue dissection, and placement of mesh behind the fascia transversalis, which is free of nerves. The complications—bleeding, nerve entrapment, hematoma, pain, and discomfort—that arise owing to direct fixation of the implants were absent in our study. Similarly, a study conducted by Paliwal *et al*., (2016) followed-up 260 cases with a new 3D ProFlor self-retaining implant for a period of 2 weeks to 3 years and observed mild to moderate pain during first three days, which became nil to mild after 4 days [18]. Furthermore, all the patients resumed the normal activities within three days to one week, postoperatively. Moreover, only one case of recurrence was observed.

In our study, the patients in-group A required less pain medication for a shorter period than group B. All the patients were followed-up for the study period of one year. There are no recurrences seen in both the groups till the study period of one year. During the present study, one individual complained of feeling the core of implant in the groin region in-group A. However, the patient was thin and did not complain any pain or discomfort. Similar study conducted by John *et al*., (2016) also reported requirement of less pain medication (average: 1.72 tablets vs. 10.09 tablets; P < 0.01) and a shorter length of time (7 days for Freedom ProFlor group vs. 14 days for LMR group) for ProFlor than the LMR procedure [14].

This technique gained widespread acceptance due to its advantages, such as tension-free, less pain, and less recurrence rate as compared to other techniques [19]. However, the present study is only limited to postoperative pain and operative time. Therefore, further long-term multicentric studies should be conducted to assess the rate of recurrences.

CONCLUSION

The Freedom ProFlor hernia repair significantly reduced the postoperative pain compared to LMR. Furthermore, the Freedom ProFlor mesh repair group required less pain medication for a shorter duration of time when compared to LMR group, postoperatively. In this study, there were no recurrences observed during one-year study duration. Hence, the use of this new Freedom ProFlor mesh repair can be an alternative technique to reduce chronic postoperative inguinal hernia pain. However, further long-term studies are required to establish it as the gold standard treatment technique.

AUTHORS' CONTRIBUTIONS

The participation of each author corresponds to the criteria of authorship and contributorship emphasized in the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals of the International Committee of Medical Journal Editors. Indeed, all the authors have actively participated in the redaction, the revision of the manuscript and provided approval for this final revised version.

SPONSORSHIP

Declared none.

COMPETING INTERESTS

The authors declare no competing interests.

REFERENCES

[1] Osilli D, Awori M, Ojuka D. Factors Influencing Choice of Inguinal Hernia Repair Technique. Ann Afr Surg. 2017;14:3-9.

[2] Schoots IG, van Dijkman B, Butzelaar RM, van Geldere D, Simons MP. Inguinal hernia repair in the Amsterdam region 1994-1996. Hernia. 2001;5:37-40.

[3] Kingsnorth A, LeBlanc KA. Management of abdominal hernias: Springer Science & Business Media; 2013.

[4] Simons M, Aufenacker T, Bay-Nielsen M, Bouillot J, Campanelli G, Conze J, et al. European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. Springer; 2009.

[5] Chiow AKH, Chong CK, Tan S-M. Inguinal hernias: a current review of an old problem. Proceedings of Singapore Healthcare. 2010;19(3):202-11.

[6] Mabula JB, Chalya PL. Surgical management of inguinal hernias at Bugando Medical Centre in northwestern Tanzania: our experiences in a resource-limited setting. BMC research notes. 2012;5(1):585.

[7] Rao SS, Singh P, Gupta D, Narang R. Clinicoepidemiologic profile of inguinal hernia in rural medical college in central India. J Mahatma Gandhi Inst Med Sci. 2016;21(2):116.

[8] Chan M, Poon C, Chan K, Leong H. Laparoscopic Total Extraperitoneal Versus Open Lichtenstein Inguinal Hernia Repair In Outpatient Setting. Surg Pract. 2009;13(1):A1.

[9] Collaboration EHT. Repair of groin hernia with synthetic mesh: meta-analysis of randomized controlled trials. Ann Surg 2002;235(3):322-32.

[10] Kingsnorth A, Wright D, Porter C, Robertson G. Prolene Hernia System compared with Lichtenstein patch: a randomised double blind study of short-term and medium-term outcomes in primary inguinal hernia repair. Hernia. 2002;6(3):113-9.

[11] de Jonge PvH, Lloyd A, Horsfall L, Tan R, O'Dwyer P. The measurement of chronic pain and health-related quality of life following inguinal hernia repair : a review of the literature. Hernia. 2008;12:561-9.

[12] Amato GI, Agrusa AN, Romano GI. Fixation-free inguinal hernia repair using a dynamic self-retaining implant. Surg Technology Int. 2012;22:107-12.

[13] Amid PK, Shulman AG, Lichtenstein IL. Open" tension-free" repair of inguinal hernias: the Lichtenstein technique. Eur Journal Surg. 1996;162:447-53.

[14] John WM, Ashwin P. Comparison of Lichtenstein and Proflor™ Open Inguinal Hernia Repair in Regards to Immediate Post-Op Pain: A Randomized Double Blinded Registered Clinical Study. J Surg Transplant Sci 2016;4:1040.

[15] de Jonge PV, Lloyd A, Horsfall L, Tan R, O'Dwyer PJ. The measurement of chronic pain and health-related quality of life following inguinal hernia repair: a review of the literature. Hernia. 2008;12:561-9.

[16] Bansal VK, Misra MC, Babu D, Victor J, Kumar S, Sagar R, Rajeshwari S, Krishna A, Rewari V. A prospective, randomized comparison of long-term outcomes: chronic groin pain and quality of life following totally extraperitoneal (TEP) and transabdominal preperitoneal (TAPP) laparoscopic inguinal hernia repair. Surg Endosc. 2013;27:2373-82.

[17] Brescia A, Tomassini F, Berardi G, Pezzatini M, Cosenza UM, Castiglia D, Dall'Oglio A, Salaj A, Gasparrini M. A new fixation-free 3D multilamellar preperitoneal implant for open inguinal hernia repair. Can J Surgery. 2017;60(1):66.

[18] Paliwal CK, Jindel DK, Garg KM. Minimal Dissection: No Fixation Technique For Inguinal Hernia Repair. IOSR Journal of Dental and Medical Sciences. 2016;1(15):34-42.

[19] Bülbüller N, Çetinkaya Z, Kirkil C, Ayten R, Aygen E, Girgin M, et al. Inguinal Hernia Repair via Application of Mesh in Front of and behind the Fascia Transversalis. Ind J Surgery. 2014;76:124-6.