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Study to compare self-gripping mesh (Pro Grip) versus sutured mesh in open inguinal hernia repair: A prospective study

Bhavana Verma[1], Anurag Anand[2], KB Singh[3]
[1] Assistant Professor, Department of Surgery, S.N. Medical College, Agra, Uttar Pradesh, India
[2] Senior Resident, Department of Surgery, S.N. Medical College, Agra, Uttar Pradesh, India
[3] Medical Superintendent, Police Hospital, Agra, Uttar Pradesh, India

Abstract
Introduction: With the introduction of Lichtenstein mesh repair, common postoperative problem was chronic pain which is mainly due to the fixation techniques for which, many modifications had been done to deal it. Subsequent to this, a new self-gripping mesh that provided a Velcro like adherence to underlying tissues was developed. Several randomised controlled trials are published in the recent past comparing self-gripping mesh with sutured repair to assess perioperative and long term outcomes.
Material and Method: This prospective study "Comparative study of self-gripping mesh (ProGrip) versus sutured mesh in open inguinal hernia repair" was conducted in Department of Surgery, Sarojini Naidu Medical College & Hospital, Agra from Jan. 2018 to Jan. 2021 in 240 patients, who were randomized in two groups of 120 patients each in study group and control group respectively.
Discussion: There is statistically significant result indicating that self-gripping mesh reduces the operating time , less Post-Operative pain (early as well as chronic phase) , early discharge from hospital, early return to normal activity. There is no statistically difference in recurrence, infection, any intra operative injury, and any anaesthetic complication.
Conclusion: Mesh repair is the ideal way to handle the inguinal hernias, but chronic pain is most troublesome complication related with mesh repair. We found self-gripping mesh superior to suture mesh and recommend it use.

Keywords: inguinal hernia, hernia open repair, progrip, sutureless mesh, chronic groin pain

Introduction

Inguinal hernia is one of the most common diseases that a surgeon has to manage. Inguinal hernia repair evolve vastly in past 130 years and beautifully evolved in last decade with the introduction of the tension-free repair, the laparoscopic repair and with the introduction of specialized hernia clinics. Lichtenstein presented his open mesh repair technique for inguinal hernia in 1986. The Lichtenstein technique has since become the most frequently used one [1, 2] Lichtenstein mesh repair is widely considered the gold standard technique for open inguinal hernia repair [3]. With the introduction of Lichtenstein mesh repair, overall hernia recurrence rates have fallen to 2% or less.

But in today's time the common postoperative problem was chronic pain which is mainly due to the fixation techniques, for which many modifications had been done to deal with it. Modifications started from the non-absorbable sutures to absorbable sutures, Glue and now self-fixating systems [4]. Although hernia recurrence rates have significantly reduced over the years, but the levels of chronic groin pain after elective hernia repair have not reduced to the same extent, ranging between 19 and 29%. [5, 6] Chronic groin pain can be debilitating with impact on convalescence and return to work [7]. Several factors can affect the incidence of groin pain such as type of mesh used [8] and fixation of mesh [9]. A recent study comparing conventional sutured fixation of the mesh with mesh fixation with fibrin glue has shown a reduction in chronic pain at 12 months with fibrin glue fixation [9]. A further meta-analysis comparing glue versus sutured mesh fixation for Lichtenstein inguinal hernia repair has shown glue mesh fixation compared with sutures is faster and less painful, with comparable hernia recurrence rates [10]. This suggests that the pain after mesh repair may be related to suture fixation of the mesh. Subsequent to this, a new self-gripping mesh that provided a Velcro like adherence to underlying tissues was developed with significant improvement in recurrence rates and chronic groin pain [11]. Several randomised controlled trials are published in the recent past comparing self-gripping mesh with sutured repair to assess perioperative and long term outcomes.

Material and Method

This prospective study "Comparative study of self-gripping mesh (Pro Grip) versus sutured mesh in open inguinal hernia repair" was conducted in Department of Surgery, Sarojini Naidu Medical College & Hospital, Agra from Jan. 2018 to Jan. 2021 in 240 patients, who were randomized in two groups of 120 patients each in study group and control group respectively.

Recurrent hernia, bilateral hernias, emergency cases and female patients were excluded from the study.

Written consent of all the patients was taken. The inguinal region of the patients was shaved just before the operation. Antibiotic prophylaxis was applied to the patients by using cefazolin sodium 1 g intravenous (IV) half an hour before the operation. The study was carried out as a double blinded procedure. Pain inquiries of the patients were performed on

the postoperative 1st, 7th, 4thweek, 2 mth, 6monthly for 3yr by using the visual pain scale (VAS).
The inquiries were maintained as face to face during the hospitalization and by means of phones or in OPD during the post-discharge period.

Group S: suture mesh (Prolene) (n= 120) was applied with repair by using prolene graft.

Group P: self-gripping (Pro Grip) mesh (n= 120) was applied with repair by using a Pro grip self-fixating graft.
Post-operative analgesia was performed on the first day by using paracetamol i.v. tds and later by oral route, in case of severe pain tramadol per oral sos was given.
Pain assessment was performed using visual pain scale (VAS). Comparisons were made using the Independent Samples Test, the Mann-Whitney U test and student t-Test. For all tests, type 1 error margin was selected as alpha: 0.05 and the difference between the groups was considered statistically significant if the value of p was less than 0.05.
The objective of this study is to compare self-gripping mesh and sutured mesh in regards operative time, wound related complications and peri and post-operative complications, chronic groin pain and hernia recurrence.

Observation and Result

Following observation was made

Table 1: Age distribution

Demographic status	Pro Grip mesh	Prolene mesh
Age in years		
50 – 80	94	80
20 – 50	26	40

Table 2: Type of hernia

Demographic status	Pro Grip mesh	Prolene mesh
Type of hernia		
Indirect	80	72
Direct	40	48

Table 3: Operative time

Operative detail	Pro Grip mesh	Prolene mesh
Operative time	24.89 ±4.20 min	58.31±15.22 min

Table 4: Length of hospital stay

Operative detail	Pro Grip mesh	Prolene mesh
Length of stay		
Day 2	104	12
More than 2 days	16	108

Table 5: Days in return to normal activity

	Pro Grip mesh	Prolene mesh
Return to normal activity	4 days	10 days

Table 6: Pain in early and late postoperative period

	Pro Grip mrsh		Prolene Mesh		
	Min-max	Mean ± SD	Min-max	Mean ± SD	P value
VAS 1 day	0-3	1.43±1.04	0-4	2.07±1.20	0.052
VAS 7 days	0-3	1.53±0.97	0-8	4.40±2.48	0.001
VAS 4 weeks	0-4	0.60±1.10	0-6	1.33±1.58	0.036
VAS 2mth	0-1	0.50±0.50	0-3	0.73±0.90	0.023
VAS 6mth	0-1	0.40±0.5	0-3	0.66±0.81	0.054
VAS 1yr later	No case complaining pain		No case complaining pain (mild discomfort in 3 patient)		

Table 7: Complication

	Pro Grip mesh	Prolene mesh
Recurrence	0	0
Vessel injury	0	0
Hematoma / seroma	1	2
Infection	0	1
Complication of anaesthesia	0	0

Discussion

The ideal result in inguinal hernia surgery is to provide a recurrence-free repair while minimising the morbidity, disability and both acute and chronic pain that the patient may experience. With the introduction of meshes surgeons achieved a recurrence rate of less than 5%. On the contrary, chronic pain, of neuralgic origin, has emerged as one of the most important negative clinical sequel which can follow inguinal hernia repair.
The hernia recurrence rates have been significantly reduced over the years, but the incidence of chronic groin pain remains high. Although the precise cause for chronic groin pain is difficult to ascertain, a combinations of factors such as type of mesh used and technique of mesh fixation. Recent studies including a met aanalysis comparing fixation with glue and sutures have shown a significant reduction in the incidence of early chronic groin pain with glue fixation suggesting suture fixation may predispose to increased groin pain [10]. On this back ground, Chastan devised a new mesh that provided Velcro like adherence to underlying tissues, and preliminary studies showed good results at 2 years with no chronic pain or recurrence [11].
Significant reduction of early postoperative pain which helped the patient for early return to day to day activities in this study is also comparable to the earlier studies [12, 13, 14]. and same is seen in our study , pain control is easy and patient became pain free very early in self-gripping mesh and have early return to normal activity and less duration of stay in hospital when compare with suture mesh , which is statistically significant. However, when we see in long term; patients ultimately became pain free (with very mild discomfort) even in suture mesh.
Five randomised trials comparing self-gripping mesh and sutured mesh have been published comparing short [15] and long term outcomes [16, 19]. All the trials have shown a significantly shorter operative time with the self-gripping mesh compared to sutured mesh [15, 19]. A significant heterogenicity was noted amongst the included trials. The reduction in operating time with self-gripping mesh is attributed to lack of need for suturing during hernia repair reducing the operative time. This also reflectes in our study, with mean operating time in self-gripping mesh of 24.89±4.20min. and with sutured mesh of 58.31±15.22 min. which is statistically significant. Similar conclusion drawn

by Zhang et al and Fang et al [20, 21]. This may translate to overall cost effectiveness by increasing the number of hernia repairs performed on a specific operating list, however, to date no cost effectiveness study has been performed comparing the 2 mesh repair techniques.

In our study, the 3 cases of wound infection and 5 case of seroma formation seen with suture mesh in early Post-Operative days and only 1 case of seroma formation with self-gripping mesh with no case of wound infection in self-gripping mesh group although the results were not statistically significant. A recent study [22] on abdominal wall hernia repair has shown that operative time is a significant factor predisposing to mesh infection, however we should be cautiously interpreted as the cause for wound infections are multifactorial and abdominal wall hernia repair is a significantly longer operation compared to inguinal hernia repair.

The suture less Pro Grip mesh is a revolutionary mesh as it can be secured without a suture, avoiding any risk for nerve entrapment, and preserving anatomical structures [23, 12]. Moreover, the Resorbable PLA micro-grips of the Pro Grip mesh are substantially blunt to prevent damage to the surrounding tissues. A study examined the impact of Pro Grip mesh on fertility in rat models and found that self-gripping mesh posed no harm to the ductus deferens [24]. Given the larger dimensions of the human ductus deferens, there is little or no risk for a detrimental effect on fertility by application of a Pro Grip mesh on exposed tissue and no such case occur in our study. Another study Fan et al, there is no recurrence with comparison to present study in self grippng group [25]. In our study no recurrence seen in any of the mesh repair, with no any complication of anaesthesia as well.

Summary and Conclusion

Mesh repair is the ideal way to handle the inguinal hernias, but chronic pain is most troublesome complication related with mesh repair

In our study “Comparative study of self-gripping mesh (Pro Grip) versus sutured mesh in open inguinal hernia repair”, 240 patient was enrolled; 120 in each group, and following conclusion is drawn. There is statistically significant result indicating that self-gripping mesh reduces the operating time , less post-operative pain (early as well as chronic phase) , early discharge from hospital, early return to normal activity. There is no statistically difference in recurrence, infection, any intra operative injury, and any anaesthetic complication. We found self-gripping mesh superior to suture mesh and recommend its use.

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