A Prospective Randomized Study Comparing Fibrin Glue Versus Prolene Suture for Mesh Fixation in Lichtenstein Inguinal Hernia Repair

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Abstract The aim of this study is to assess the advantages of fibrin glue over Prolene suture in fixation of the mesh in open inguinal hernia repair. Sixty-four cases of inguinal hernia underwent hernia repair by the Lichtenstein method in the department of surgery in PGIMER & Dr. RML Hospital, New Delhi. The patients were randomized prospectively into group A (fibrin glue group) and group B (Prolene suture group). In group A, fibrin glue was used for mesh fixation, and in group B, Prolene suture was used for mesh fixation. The mean age of patients in group A was 44.5 years and that of group B patients was 44.2 years. There was a significant difference in the duration of surgery, with the mean duration in fibrin glue group being 30.6 min and that of the suture group was 43.3 min. The mean visual analogue pain score of postoperative pain at 1, 6, 12, and 24 h was significantly higher in the suture group than in the fibrin glue group ($p < 0.001$). The mean total dose of analgesia in ampoules of tramadol was significantly less in the fibrin glue group (1.56 ampoules) than that in the suture group (4.125 ampoules) with $p = 0.000$. At the end of the first month, 25 % of subjects in the suture group presented with mild groin pain (p value = 0.0048). At the end

of the second and third month, 22 % (p value = 0.0048) and 12.5 % (p value = 0.1132) of subjects respectively presented with mild groin pain in the suture group. The present study demonstrates that the use of fibrin glue in place of Prolene suture for mesh fixation in open inguinal hernia repair can help decreasing the time required for surgery, reduce the intensity of postoperative pain, shorten the duration of hospital stay, and prevent the incidence of chronic groin pain.

Keywords Inguinal hernia · Chronic groin pain · Fibrin glue · Prolene suture · Mesh

Introduction

Repair of hernia, minimizing the intraoperative and postoperative complications, early return to normal routine, and minimizing the chance of recurrence are the main goals of inguinal hernia surgery. Understanding the physiology and anatomy of the inguinal area and to know how to use most effectively the currently available surgical techniques and materials hold the key to successful surgery.

In hernia repair surgery, the use of mesh has reduced the recurrence, but the presence of foreign material can induce strong chronic inflammation which can result in chronic pain and foreign body sensation [1, 2].

Chronic pain or persistent neuralgia has been recognized as a complication after inguinal hernia repair but was reported in the 1980s as a rare and infrequent condition [3]. Studies from the mid-1990s have reported a higher frequency of patients reporting pain after hernia repair more than 1 year after surgery [4–6]. Estimates of chronic pain vary considerably from 0 to 53 % [7]. It can be mild to severe, can even be disabling, and can adversely affect the quality of life [8].

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The “pain complex syndrome” after hernia repair includes three different aspects: (1) numbness and burning sensation (hypoesthesia, hyperesthesia, and paraesthesia)—the incidence was observed in 10 to 23 % in open inguinal hernia repair in Cochrane review [9]; (2) groin discomfort—its incidence is reported in most studies to be from 11 to 27 % [10, 11]; (3) neuralgia [7, 12], with radiation of pain to the skin of the corresponding hemi-scrotum, labium majus, and Scarpa’s triangle. The consensus of the European Hernia Society, in the Tl.ME.LI. Trial, has defined pain complex syndrome as the presence of one of the three or all of these aspects 1 year after surgery. In terms of percentage, the incidence of pain complex syndrome is assumed to be about 25 % of patients undergoing inguinal hernia repair.

The etiology of this problem includes non-neuropathic and neuropathic causes or a combination of both. Non-neuropathic causes include mechanical pressure of folded or wadded mesh, periosteal reaction, and scar tissue formation. Neuropathic pain can be caused by compression of one or more nerves by perineural fibrosis, suture material, staples and tacks, or nerves injuries. So if it is possible to limit the use of suture and fixation devices, chronic groin pain could be reduced [13, 14].

Studies have also shown that fibrin glue does not increase the risk of these outcomes and may, in fact, decrease the risk compared with tissue-penetrating fixation methods. When used in the repair of incisional hernias, fibrin glue significantly decreased both postoperative morbidity and duration of hospital stay. Based on above assumptions, we took up the study to make the hernia repair suture-less by using fibrin glue which is more biological.

The aim of this study is to assess the advantages of fibrin glue over Prolene suture in fixation of the mesh in open inguinal hernia repair.

Materials and Methods

A prospective randomized study involving 64 patients of inguinal hernia, who underwent hernia repair by the Lichtenstein method, was done in the department of surgery in PGIMER & Dr. RML Hospital, New Delhi, with the approval of an ethical committee. The patients were randomized prospectively into group A (fibrin glue group with 32 patients) and group B (Prolene suture group with 32 patients). In group A, fibrin glue was used for mesh fixation, and in group B, Prolene suture was used for mesh fixation. All the patients

included in the study were aged more than 25 years with recurrent, obstructed, and strangulated hernia being excluded from the study population. The potential candidates for this study were educated preoperatively regarding the use of visual analogue pain scale. A written informed consent was taken from all the patients.

Before giving anesthesia, patients were randomized prospectively into group A and group B. The inguinal hernia repair was performed according to the standard Lichtenstein tension-free repair method.

The duration of surgery, postoperative pain, duration of hospital stay, and chronic groin pain were recorded.

During the postoperative period, all patients were prescribed intravenous tramadol (100 mg) for analgesia if required. The time of the first dose of postoperative analgesic as well as the total requirement of postoperative analgesic was recorded for each patient. The degree of postoperative pain was assessed by means of visual analogue pain scale (VAS) at 1, 6, 12, and 24 h postoperatively.

The inferences were drawn with the use of appropriate tests of significance.

Results

Of 64 patients included in study, the mean age of patients in the fibrin glue group was 44.5 years and that in the suture group was 44.2 years. There was a significant difference in the duration of surgery, with the mean duration in the fibrin glue group being 30.6 min and that in the suture group being 43.3 min (Table 1).

The mean visual analogue pain score of postoperative pain at 1, 6, 12, and 24 h was significantly higher in the suture group than in the fibrin glue group (Table 2). The first dose of analgesia required was significantly earlier in the suture group than in the fibrin glue group ($p < 0.001$) (Table 3).

The mean total dose of analgesia in ampoules of tramadol was significantly less in the fibrin glue group (1.56 ampoules) and that in the suture group (4.125 ampoules) with a $p = 0.000$ (Table 4).

The mean duration of hospital stay was the same in both the groups.

About 47 % of subjects in the suture group and 6.2 % of subjects in the fibrin glue group presented with mild to moderate degree of chronic groin at the end of the first week (p value = 0.0010). At the end of the first month, 25 % of subjects in the suture group presented with mild groin pain (p value =

Table 1 Comparison of duration of surgery

Material	Number	Duration of surgery (in minutes), mean $\pm$ SD	p value
Fibrin glue	32	30.6 $\pm$ 2.6	0.000
Prolene suture	32	43.3 $\pm$ 2.2	

Table 2 Comparison of postoperative pain assessed by VAS between the two groups

	Mean rank for pain		<i>p</i> value
	Fibrin glue group	Suture group	
At 1 h	21.88	43.13	0.000
At 6 h	18.73	46.27	0.000
At 12 h	18.17	46.83	0.000
At 24 h	20.31	44.69	0.000

0.0048). At the end of the second and third month, 22 % (p 68 value=0.0048) and 12.5 % (p value=0.1132) of subjects respectively presented with mild groin pain in the suture group (Table 5). There was no chronic groin pain in the fibrin group at the end of the first, second, and third month.

Discussion

The Lichtenstein tension-free method of hernia repair is the preferred surgical technique for open inguinal hernia repair. Conventionally, the Prolene suture is used to fix the mesh. Fixing mesh with suture is a tedious, time-consuming, and invasive method. It can also increase the incidence of postoperative pain and can lead to other long-term complications such as chronic groin pain due to nerve entrapment. This can lead to longer duration of hospital stay and postoperative

medical consultation which can be a physical and financial burden to the patient.

For a common pathology such as inguinal hernia, the goal is to have “no defects.” Thus, for primary inguinal hernia by the Lichtenstein’s operation, we should aim for the following: (a) mesh repair; (b) tension-free and suture-less; (c) early ambulation; (d) decreased duration of hospital stay; (e) rapid return to work; (f) recurrence rate of <1 %; and (g) absence of patient discomfort, numbness, or neuralgia.

In order to overcome these abovementioned limitations, we have conducted a prospective randomized study using fibrin glue for mesh fixation in the Lichtenstein method of open inguinal hernia repair. Fibrin glue is a two-component material consisting of fibrinogen and thrombin. In the presence of small amounts of calcium and factor XIII, the thrombin converts fibrinogen into insoluble fibrin, the final stable form of the agent. Fibrin sealant now has over a century of development and use. The Food and Drug Administration (FDA) approved liquid fibrin sealant in 1998 as well as a fibrin sealant patch in 2010.

The present prospective trial has confirmed the observation of the earlier studies that the use of fibrin glue for mesh fixation significantly decreases postoperative pain as evidenced by the marked difference in the mean visual analogue pain scale score of the two groups. The pain perceptions were significantly higher in the suture group as compared to the fibrin glue group (p value <0.001). The study by Negro et al. [15] also showed that the mean pain score was significantly lower in the fibrin glue group than the suture group (2.5 vs. 3.2,

Table 3 Time duration for requirement of the first dose of analgesia after surgery in the two groups

First dose requirement in minutes	No. of subjects		Total	<i>p</i> value
	Fibrin glue group	Suture group		
40	0	3	3	0.000
45	0	3	3	
50	0	6	6	
55	0	4	4	
60	0	7	7	
65	0	4	4	
70	2	1	3	
75	0	1	1	
80	2	2	4	
85	3	1	4	
90	2	0	2	
95	6	0	6	
100	6	0	6	
105	3	0	3	
110	3	0	3	
120	4	0	4	
130	1	0	1	
Total	32	32	64	

Table 4 Requirement of total dose of analgesia (in ampoules) in the two groups

Total dose in ampoules	No. of subjects		Total	<i>p</i> value
	Fibrin glue group	Suture group		
1	18	3	21	0.000
2	11	4	15	
3	2	4	6	
4	1	6	7	
5	0	8	8	
6	0	4	4	
7	0	3	3	
Total	32	32	64	

$p<0.001$) and fibrin glue group patients also experienced less intense pain (0.6 vs. 1.2; $p=0.001$).

A study by Fortelny et al. [16], whose results were in concordance with our results, showed that less postoperative pain was reported in the fibrin sealant group compared to the suture group at 6 weeks ($p=0.035$), 6 months ($p=0.023$), and 1 year ($p=0.011$) postoperatively. Additionally, trends toward a higher postoperative quality of life, a faster surgical procedure, and a shorter hospital stay were seen in the fibrin glue group.

The perception of postoperative chronic groin pain was significantly high at the end of the first week and after the first month and the second month ($p=0.0048$) in the suture group, but was statistically not significant at the end of the third month ($p=0.1132$). The study by Liu et al. [17] also showed that there was a lower incidence of chronic pain (RR 0.42, 95 % CI 0.22–0.79, I^2 11 %; $p<0.01$) in the fibrin glue group.

This study also showed that the time at which the first dose of analgesia was given was much earlier in those in the suture group when compared to those in the fibrin glue group ($p<0.001$). The total dose of analgesia requirement was also significantly higher in the suture group as compared to the fibrin glue group ($p=0.000$).

The duration of surgery was significantly shorter in the fibrin glue group as compared to the suture group ($p=0.000$), thus making fibrin glue the safe and suitable alternative to Prolene suture for mesh fixation in open inguinal hernia repair. A systematic review of randomized control trials

assessing mesh fixation in open inguinal hernia repair in 2014 by Sanders et al. [18] also showed that there was a significant reduction in operative time, ranging from 6 to 17.9 min with non-suture fixation, in five of the studies. Although infrequently measured, there were no significant differences in length of hospital stay or quality of life between fixation methods.

Conclusion

The use of Prolene suture for mesh fixation in open inguinal hernia repair is associated with many distressing complications for both surgeons and patients such as longer duration required for surgery, significant postoperative pain, and higher incidence of chronic groin pain. These complications can be reduced to some extent by meticulous dissection and prevention of entrapment and careful preservation of nerves.

But the safe and suitable alternative to Prolene suture is the fibrin glue. Being the non-invasive method of mesh fixation, it can help prevent nerve entrapment and tissue injury, which ultimately decreases the incidence of postoperative pain and chronic groin pain with the additional benefit of lesser duration of time required for surgery.

Thus, from our study, we can conclude that the fibrin glue can be a safe, easy, and suitable alternative to Prolene suture for mesh fixation in open inguinal hernia repair.

Table 5 Comparison of the number of subjects having postoperative chronic groin pain in the two groups

	At 1 week			At 1 month			At 2 months			At 3 months		
	No pain	Mild pain	Moderate pain	No pain	Mild pain	Moderate pain	No pain	Mild pain	Moderate pain	No pain	Mild pain	Moderate pain
Fibrin glue group	30	2	0	32	0	0	32	0	0	32	0	0
Suture group	17	11	4	24	8	0	25	7	0	28	4	0
<i>p</i> value	0.0010			0.0048			0.0108			0.1132		

Compliance with Ethical Standards A written informed consent was taken from all the patients.

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

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