Comparative Study of Postoperative Complications in Sutures and Cyanoacrylate Glue Mesh Fixation in Inguinal Hernia Repair

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ABSTRACT

Introduction: Postoperative pain is the consequence of tissue dissection and post operative local inflammation. As a result, the surrounding nerves become damaged and nociceptive stimulation occurs. Surgeon's experience, local complications, synthetic material implantation are considered to be dominant causative factors. Inflammation appears with the ligation of the hernia sac, neurectomy, when a nerve gets captured into a suture or scar around the implant and with ischemic testicle. This study attempts to compare mesh fixation by N-butyl-2-cyanoacrylate glue comparing with suture fixation, in Lichtenstein technique of inguinal hernioplasty

Material and Methods: This was a prospective study, conducted over a period of 18 months. After obtaining detailed history, complete general physical and systemic examination, the patients were subjected to relevant investigations. The complete data was collected in a specially designed case recording form.

Results: The postoperative pain is significantly lesser in patients who underwent Glue fixation of mesh compared to patients who underwent Suture fixation of mesh in the early (POD1, POD3, POD7, POD15) and late post-operative period (1 month, 3 months). Among the postoperative complications encountered in the present study seroma rate was lesser in G group, whereas wound gap rates were similar in both the groups.

Conclusion: The postoperative pain is significantly lesser in Glue fixation of mesh compared patients who underwent to patients who underwent Suture fixation of mesh. Glue fixation of mesh is easy to perform and is easily reproducible. It is not associated with needle related complications.

Keywords: Pain, Complication, Hernia

INTRODUCTION

Postoperative pain is the consequence of tissue dissection and post operative local inflammation. As a result, the surrounding nerves become damaged and nociceptive stimulation occurs. Surgeon's experience, local complications, synthetic material implantation are considered to be dominant causative factors. Inflammation appears with the ligation of the hernia sac, neurectomy, when a nerve gets captured into a suture or scar around the implant and with ischemic testicle. Sutures applied behind the periosteum of the pubic tubercle lead to chronic periostitis, another source of the chronic pain. Surgical access and the way implant is sutured are irrelevant.1,2

Other tissue repairs like such as modified Bassini, Iliotibial tract repair, Shouldice, Nylon-Darn, Halsted-Tanner, McVay and many others either require good surgical experience or are tension repairs fraught with recurrences. Shouldice method which closely compares with the mesh repair is rarely used probably because of the complexity involved in tissue dissection and repair. Recurrences vary from surgeon to surgeon and centre to centre owing to complexity of the procedures.3

Success of groin hernia repair is measured primarily by the permanence of the operation, fewest complications, minimal costs, and earliest return to normal activities. To validate the use of cyanoacrylate glue in fixation of mesh, its comparison to the Lichtenstein's repair with suture fixation of mesh in these outcomes must be established. The purpose of this study is thus to attempt to establish the influence of this new technique on early clinical outcomes of inguinal hernia repair, and limited study of long term outcomes. If proved to be effective it will be a basis for the promotion of its use globally.

This study attempts to compare mesh fixation by N-butyl-2-cyanoacrylate glue comparing with suture fixation, in Lichtenstein technique of inguinal hernioplasty, in terms of pain, operative time, post- operative analgesia requirement within 24 hours, hematoma, seroma, chronic pain, sensation of extraneous body, recurrence, time to return to work / normal activity following hernia repair

MATERIAL AND METHODS

This prospective study was conducted at MBS hospital, Govt Medical College Kota Rajasthan .Total 50 cases were enrolled in study and divided into 2 groups, with 25 patients nin each group. After obtaining detailed history, complete general physical and systemic examination, the patients were subjected to relevant investigations. The complete data was collected in a specially designed case recording form. The data collected was transferred into a master chart which was

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then subjected for statistical analysis. Patients were selected with following inclusion and exclusion criteria.

Inclusion criteria

- All patients with evidence of primary uncomplicated inguinal hernia admitted in Maharao Bhim Singh Hospital.
- Patients above 18 years age.
- Patients undergoing elective Lichtenstein mesh hernioplasty.

Exclusion criteria

- Age less than 18 years
- Patients with recurrent and complicated hernias.
- Emergency inguinal hernia repair.
- Laparoscopic inguinal hernia repair.
- Chronic steroid treatment
- Coagulation disorders
- Ongoing Chemotherapy
- Connective tissue disorders
- Psychological or physical disorders that could affect the ability to feel and elaborate pain

A total of 50 patients were included in study .An informed consent form was taken and patients were counselled about the detailed procedure, merits and demerits of operation. Patients were randomized into two groups (group A and B). Each having 25 patients.

- A. Classical Lichtenstein technique
- B. Lichtenstein technique with mesh gluing with cyanoacrylate.

The first part of the operation was same in the two groups, according to the original description by Lichtenstein. Inguinal canal was prepared, alongside with the anatomical landmarks — pubic tubercle, conjoined area, inguinal ligament. The hernia sac identified and reduced. The mesh was shaped accordingly and placed in place. In group A the mesh was fixed with one running suture starting from the first stitch passed on the tissue above the pubic tubercle (avoiding the periosteum and with a 2 cm overlap of the mesh above the tubercle) and passed on the inguinal ligament and few interrupted sutures in conjoined area. The two posterior wings of the mesh sutured together using single vicryl stitch to the inguinal ligament.

In Group B the mesh was fixed with n-butyl-2-cyanoacrylate tissue adhesive on the pubic tubercle, the inguinal ligament and the conjoined area. Attention paid to avoid dripping the glue on the nerve. The two posterior wings of the mesh were fixed with glue one by one. All patients had the same polypropylene kind of mesh, irrespective of the fixation method. The fascia closed in both groups with a vicryl running suture. Skin closed with nylon simple/mattress interrupted suture.

All operations performed with spinal block.

The operative time recorded by an operation theater nurse. The operative details recorded in proforma.

During postoperative period pain was measured by visual analogue scale (VAS). This compared at Day 1, Day 7, Day 15, 1st month, 3rd month. Approval to carry out the study was

sought from the Department of Surgery, M.B.S. Hospital and Govt. Medical College, Kota and Ethics Committee.

Statistical analysis

Descriptive and inferential statistical analysis has been carried out in the present study. The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS:

The patients were followed up at 15 days, one monthly and three monthly intervals for any complication or recurrence. Any recurrence of hernia or death of patient was regarded an end point. The Observations made during the course of the study were as follows.

1. Comparison of postoperative pain

On POD 1 the mean VAS Score in Suture Group was 3.48 ± 0.77 , while that in Glue Group was 1.68 ± 0.69 . This difference in mean vas score is statistically significant with a P value of < 0.001.(Table 1)

On POD 3 the mean VAS Score in Suture Group was 2.48±0.77, while that in Glue Group was 0.84±0.80 which was statistically significant with a P value of <0.001.(Table 1)

On POD 7 the mean VAS Score in Suture Group was 1.84 ± 0.69 , while that in Glue Group was 0.60 ± 0.71 , this difference is statistically significant with a P value of <0.001. (Table 1)

On POD 15 the mean VAS Score in Suture Group was 1.36 ± 0.76 , while that in Glue Group was 0.16 ± 0.73 , this difference is statistically significant with a P value of <0.001. (Table 1)

Overall Glue Group experienced significantly less pain compared to Suture group. Graphical presentation is shown below (Figure 2 and 3)

2. Distribution of post-operative pain severity in both groups

In Suture group around half of the patients had pain in range of 4-6 in POD 1 (48%). In POD 3 only few (8%) of the patients reported pain in range of 4-6. However during POD 7(96%) and POD 15 (88%) majority of the patients reported pain scores in the range of 1-3.(Table-2)

However in Glue group though all the patients had pain in range of 1-3 in POD 1 (100%). Pain showed significant decrease by POD 3 (40%) of patients reported pain score 0.(TABLE 2)

Important outcome to be noted is the POD 7 pain scores 0 among patients which are (2.5%) in Suture group compared to (52%) in Glue group.(TABLE 2)

3. Comparison of postoperative complications

There were 2 cases of seroma in Suture group whereas there was 1 case of seroma in Glue group. There were no cases of wound Infection/ Mesh infection in either of the groups. (Table 3)

There was one recurrence in glue group in our study. In this patient of glue group there was history of appendicectomy

which resulted in weakness of abdominal wall muscles of that area due to possible nerve injury during appendicectomy. In this patient Lichtenstein repair using cyanoacrylate glue was performed in standard way. The Mesh was extending few cms beyond the deep ring. In immediate postoperative period the patient developed a direct hernia. On exploration the hernia was lateral to previously placed mesh which was otherwise found snugly fixed at all sites. So this recurrence was considered due to improper mesh size. Hence it was a technical error during primary surgery rather than failure of glue fixation. After the final statistical analysis it was found that there was no statistically significant difference between

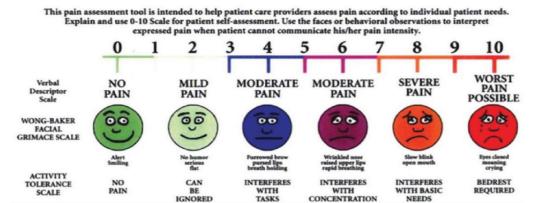


Figure-1: Visual analog scale used for pain assesment in the study

VAS Score	Suture Group	Glue Group	Total	P value
POD1	3.48±0.77	1.68±0.69	2.58±1.16	<0.001**
POD3	2.48±0.77	0.84±0.80	1.66±1.14	<0.001**
POD7	1.84±0.69	0.60±0.71	1.22±0.93	<0.001**
POD15	1.36±0.76	0.16±0.37	0.76±0.85	<0.001**
* POD- (Post operative Day), Student t test (Two tailed, Independent)				
Table-1: Comparison of mean VAS scores between the two groups in post operative days				

VAS Score	POD1	POD3	POD7	POD15
Suture Group (n=25)				
0	0	0	1 (4%)	10 (40%)
1-3	13 (52%)	23 (92%)	24(96%)	15 (60%)
4-6	12 (48%)	2 (8%)	0	0
7-10	0	0	0	0
Glue Group (n=25)				
0	0	10 (40%)	13 (52%)	21 (84%)
1-3	25(100%)	15 (60%)	12 (48%)	4 (16%)
4-6	0	0	0	0
7-10	0	0	0	0
P value	<0.001**	<0.001**	0.001**	<0.001**
**Chi-Square test/Fisher l	Exact test			
	Table-2: VAS score distrib	oution of pain severity in two	groups of patients studied	

(n=25) 8(32%) 0	(n=50) 18(36%)
, , , , , , , , , , , , , , , , , , ,	18(36%)
0	
	0
1(4%)	3(6%)
3(12%)	6(12%)
1(4%)	2(4%)
2(8%)	6(12%)
0	0
1 (4%)	1 (2%)
·	•
_	0

Pain	Suture Group (n=25)	Glue Group (n=25)	Total (n=50)	P value
1 month				
No	10(40%)	24(96%)	34(68%)	< 0.001
Yes	15(60%)	1(4%)	16(32%)	
3 months				
No	17(68%)	25(100%)	42(84%)	0.002
Yes	8(32%)	0	8(16%)	
Chi-Square test/fisher E	xact test			

Table-4: Chronic pain assessment in two groups of patients studied

Comparative Parameter (S vs G)	Present Study	Testini et al	Giovanni et al
Seroma Rate	4% vs 2%	0% vs 0%	5.2% vs 0%
Rate of Wound Infection	0% vs 0%	0% vs 0%	5.2% vs 0%
Induration& Swelling	8% vs 4%	8.4% vs 3.7%	
Hematoma	0% vs 0%	6.77% vs 1.8%	0% vs 0%
Table-5: Comparison of complications in different studies			

	Chronic pain	Recurrence		
	(glue group vs suture group)	(glue group vs suture group)		
Present study	16% vs 0%	4% vs 0%		
Campanelli ²⁰ et al	14.5% vs 7.5%	0.7% vs 0.7%		
Kim fuchset ²² al	15.7% vs 8.1%	3.39% vs 3.35%		
Nowobiliski ¹⁶ et al	_	1.75% vs 1.25%		
Testini ¹⁸ et al	6.67% vs 0%	1.32% vs 1.3%		
Table-6: comparison of chronic pain and recurrence in different studies				

the two groups. (Table 3)

4. Comparison of incidence of chronic groin pain at 1 month, 3 months

Chi-Square test/fisher Exact test

The patients in both groups were followed up after discharge for a period of three months with regular OPD checkups at 1 month, 3 months.

The presence of chronic pain was based on history given by patients and use of analgesics to get rid of the pain.

At the end of 1 month 15 patients in Suture group complained of disturbing groin pain during activities at site of surgery while 1 patient in Glue group had similar complaints. (Table 4)

At 3 months after surgery 8 patients in Suture group and 0 patient in Glue group complained of groin pain which persisted despite pain medications. (Table-4)

Though the difference between the two groups is statistically significant in this small cohort group with incidence of chronic groin pain significantly higher in Suture group.

DISCUSSION

Postoperative pain is the consequence of tissue dissection and postoperative local inflammation. As a result, the surrounding nerves become damaged and nociceptive stimulation occurs. Surgeon's experience, local complications, synthetic material implantation are considered to be dominant causative factors. Inflammation happens with tissue dissection, neurectomy, when a nerve gets captured into a suture or scar around the implant.

Sutures applied behind the periosteum of the pubic tubercle lead to chronic periostitis, another source of the chronic pain. Development of postoperative chronic groin pain (CGP) is an area of growing interest and concern because it contributes to significant morbidity and threatens to offset the gains made in terms of reduction of recurrence rates. The etiology of CGP is multifactorial. Although there is a mix of nociceptive pain (related to tissue injury) and neuropathic pain (related to nerve injury), the latter is predominant and its intensity seems to be aggravated when numbness is also present.⁴

Chronic pain usually resolves with the passage of time, but in some cases it becomes chronic, persisting for more than 03 months.

According to recent studies the incidence of chronic groin pain (CGP) ranges from 9.7% to 11%.^{5,6} Chronic groin pain following inguinal hernia repair is a potentially incapacitating complication, and presents a diagnostic and therapeutic challenge to the surgeon.

This pain can be of two types, nociceptive and neuropathic. Nociceptive pain is the pain caused by tissue damage which is subdivided into somatic pain, caused by tissue damage and is further subdivided into somatic pain (caused by damage to ligaments, tendons and muscles, characterized as dull, aching,irritating pain) and visceral pain (related to a specific visceral function such as urination and ejaculation).⁶

Neuropathic pain is the pain caused by damage to a nerve in the groin region due to partial or complete division, stretching, contusion, crushing, suturing or electrocautery, and characterized as numbness, radiating/ shooting pain, pins and needles.7

The traditional method of penetrating mesh fixation in the groin has its flaws. Except for bleeding after femoral or epigastric vessels damage caused by a needle, sutures may cause tissue ischemia, muscle contracture and nerve damage. The change may be the source of immediate postoperative and chronic pain. Remissions of the chronic ailments after sutures are removed in the evidence of cause and effect reliance. 8 Attempts have been made to replace non-absorbable with absorbable sutures, but clinical trials did not show any significant differences. 9,10 Similarly, staples or tackers caused new dangers, but did not relieve pain. 11 There are numerous articles on the prevention and pain occurrence after inguinal hernia repair in the literature. Reports concerning chronic pain after hernia repair are especially disturbing. Pain is diversely defined. In the following report, the British Pain Society definition was accepted: chronic pain is continuous pain, lasting over 12 weeks or – in case of surgical procedures or damages – it is pain occurring after tissues have healed. According to the International Association for the Study of Pain (IASP), chronic pain is recognized when it occurs after the surgery and lasts minimum 2 months. This definition is criticized as it does not take into account changes occurring later on when the pain starts to decrease gradually e.g. due to the termination of inflammation. Such sequence of events may be expected in hernioplasty: after tissue structures have been strengthened by synthetic material. Those issues are recapped in the newest reports. 12 Apposition of tissues without excessive tension is a relatively new factor mentioned, which corresponds to the experience of the surgical team. Too energetic surgical maneuvers (the strength applied here amounts up to 20 N) causes micro damages of the surrounding tissue which activates painful sensations occurring regardless of other prophylactic treatment. Two groups of patients should be acknowledged in pain assessment: young people, professionally and physically active and middleaged or older patients with limited physical activity. The risk of chronic pain occurrence in the 2nd group is significantly lower.¹³ Recently, the methods of implant fixation have been discussed during meetings. Penetrating (staplers/tackers) and adhesive (sealants) methods of fixation are compared and situations when an implant does not have to be fixed to the surrounding tissues are defined. The first indexed report dates back to 1984. Russian doctors, Shapkina et al. used cyanoacrylic sealant in surgery in children. One hundred and eight herina repairs were performed with good results.¹⁴ The next trials were performed a decade later by Farouk et al. who modified Lichtenstein method by fixing the mesh with cyanoacrylic adhesive in grown-up patients. No recurrences were observed in the 1st year after the surgery. 15

1.Pain Assessment

In the present study the post operative VAS scores in the Glue group was significantly lower than the Suture group in post op days 1,,3,7 and 15 in the present study. While in study by Nowobilski et al ¹⁶, Paajanen et al ¹⁷, Testini et al ¹⁸, Wong et al ¹⁹, Campanelli et al ²⁰ the immediate post operative pain

was higher in the Suture group compared to Glue group. While in Giovanni Domenico Tebala et al ²¹ the post op VAS scores in day 1,3, and 7 were very similar to the present study.

2. Comparison of complications

Among the postoperative complications encountered in the present study seroma rate was lesser in G group, whereas wound gap rates were similar in both the groups.

3. Comparison of chronic pain

In the present study at the end of one month the percentage of patients with chronic pain in GLUE group was at 0% percent while that in SUTURE group was at 32%. At 3 months of follow up the percentage of patients with chronic pain in GLUE group was at 0% while that in SUTURE group was at 16%. In the studies the incidence of chronic pain in glue group in general was lesser than the incidence of chronic pain in the suture gp.

4. Recurrence

There was one recurrence in glue group in the present study and the recurrence rates in Suture Group and glue group are similar in many studies (Nowobilski et al¹⁶, Paajanen et al¹⁷, Testini et al¹⁸, Wong et al¹⁹, Campanelli et al²⁰). There was one recurrence in glue group in our study. In this patient of glue group there was history of appendicectomy which resulted in weakness of abdominal wall muscles of that area due to possible nerve injury during appendicectomy. In this patient Lichtenstein repair using cyanoacrylate glue was performed in standard way. The Mesh was extending few cms beyond the deep ring. In immediate postoperative period the patient developed a direct hernia. On exploration the hernia was lateral to previously placed mesh which was otherwise found snugly fixed at all sites. So this recurrence was considered due to improper mesh size. Hence it was a technical error during primary surgery rather than failure of glue fixation.

CONCLUSION

The present study comparing suture fixation of mesh in lichtenstein's repair with cyanoacrylate glue fixation of mesh in Lichtenstein's repair for inguinal hernia came out with that glue fixation of mesh is easy to perform and is easily reproducible, it is not associated with needle related complications. The postoperative pain is significantly lesser in patients who underwent Glue fixation of mesh. Hence Glue fixation of mesh is definitely a promising procedure and has a lot of potential to replace suture fixation of mesh in Lichtenstein repair.

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