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Cyanoacrylate glue as an alternate to sutures for mesh fixation in inguinal hernia repair: A randomised control trial

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Abstract

Background: Hernia is the “Protrusion of the viscous or a part of the viscous through an abnormal opening in the walls of its containing cavity”^[1]. Lichtenstein tension free mesh repair is the most commonly performed operation by a general surgeon. Postoperative pain can be due to multiple reasons like irritation from the suture used to fix the mesh, by the mesh itself, nerve entrapment etc. This study is used to compare the effectiveness of Cyanoacrylate glue in the fixation of mesh in elective inguinal hernia repair compared to conventional mesh fixation by sutures in terms of duration of surgery, post operative pain and analgesia requirement and return to normal activity.

Objectives: The primary objective of this study is to compare the postoperative pain score and analgesia requirement in patients who underwent Lichtenstein tension free hernia repair with cyanoacrylate glue versus conventional surgery using polypropylene sutures. Secondary objective is to compare the duration of surgery and the time taken for return to normal activity.

Methodology: This study was conducted between October 2017 and September 2019 and included 50 patients who were randomly assigned into two groups of 25 patients each, glue group and suture group respectively. All cases were followed up for a period of 3 months.

Results: In our study, patients who underwent Lichtenstein tension free mesh repair using cyanoacrylate glue had reduced postoperative pain score and required less analgesia compared to conventional suture repair with reduced time taken for surgery and a early return to normal activity.

Conclusion: This study concludes that cyanoacrylate glue is an effective alternate to conventional sutures for mesh fixation in Lichtenstein tension free hernia repair as the postoperative complications: Pain and analgesia requirement with an early return to normal activity.

Keywords: Cyanoacrylate glue, mesh, hernia

Introduction

Hernia is defined as an “Protrusion of the viscous or a part of the viscous through an opening in the walls of its containing cavity”^[1]. It is derived from the latin word- to mean “rupture”. “The lifetime risk for men is 27% and for women is 3%”^[2]. An inguinal hernia is a protrusion of abdominal cavity contents through the inguinal canal. Most commonly referred are the Groin hernias to the surgeons over the world. Abdominal wall, particularly the inguinal region is most commonly involved, but it can occur at any site of the body. Inguinal, femoral and umbilical regions are more commonly involved including the site of previous incisions. Surgery being the definitive treatment for hernia, Inguinal hernia repair being the most commonly done surgery worldwide, has developed to tension free repairs and Laparoscopic repairs. If the hernias are not operated, there are chances that they may go for complications such as obstruction and strangulation, resulting in morbidity and mortality. Since Edward Bassini had published his landmark research paper on the technique of tissue repair in 1887, various modifications have been proposed. “The concept of Tension Free Open Hernial Mesh Repair Surgery was first described by Lichtenstein in 1989”^[3]. The most commonly performed inguinal hernia repair today is the Lichtenstein tension free mesh repair. A flat mesh is placed on the top of the defect, it is a “tension free” repair that does not put tension on the muscles. Following Lichtenstein tension free hernia repair, up to 25% of patients experience prolonged postoperative pain. Postoperative pain can be due to multiple reasons like irritation from the suture used to fix the

mesh, by the mesh itself, nerve entrapment etc. Prevention of postoperative pain can be done by meticulous handling of tissues and safeguarding the structures present in the inguinal canal.

Sealants such as cyanoacrylate glue are used primarily for sealing and hemostatic purposes. Their exceptional safety record is attributable to their complete biodegradability and also physiological mechanism of action. Both clinical and experimental studies demonstrate the cyanoacrylate glue is a feasible option for mesh fixation in hernia repair.

This study will be used to compare the effectiveness of cyanoacrylate surgical sealant in the fixation of mesh in elective inguinal hernia repair compared to conventional sutures in terms of duration of surgery, post-operative pain, analgesia requirement, and return to normal activity at 3 months.

Materials and Methods

1. Study Design- Randomised control trial
2. Study Place- Department of general surgery, JSS Hospital Mysuru
3. Study Duration- One and a half year
4. Sample Size- Assuming relative proportion as 80% and alpha error as 5%, sample size is taken as 50, which will be divided into two groups respectively
5. Sampling Technique and study Design- Simple randomisation. Patients will be assigned into 2 Groups, suture and glue group respectively

Inclusion Criteria

1. Patients above 18 years
2. Patients presenting with uncomplicated inguinal hernia admitted at JSSH
3. Patients undergoing elective open inguinal hernia repair

Exclusion Criteria

1. Laparoscopic inguinal hernia repair
2. Emergency inguinal hernia repair

Study Setting and Method of Collection of Data

- A. Patients admitted in general surgery wards at JSSH Mysore
- B. Sample size will be taken as 50, will be divided into two groups of 25 each: Glue group and Suture group, by simple randomisation
- C. After detailed history and examination, and routine blood examination, randomisation will be done and patients will be allotted to respective groups

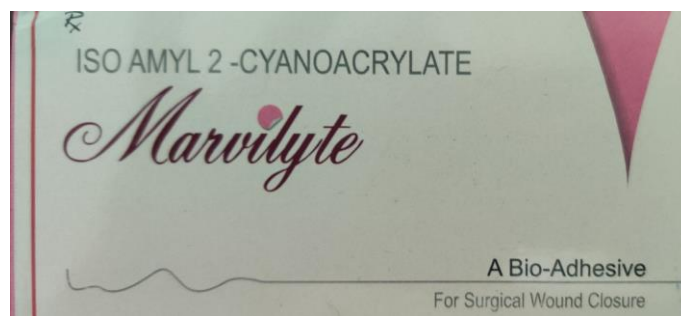
Procedure

All the 50 patients were admitted and a detailed history and clinical examination was carried out as per written proforma. Preoperatively the patients were randomised into two groups for Open inguinal hernia repair, with fixation of mesh either with sutures or glue and were educated about the advantages, disadvantages, and also the approximate cost of each of the procedure.

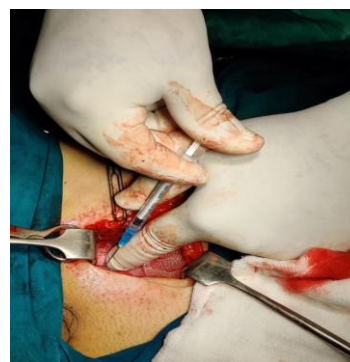
After taking consent for the procedure, the patient is investigated thoroughly. Following evaluation, once the patient is deemed fit for surgery, patients were grouped accordingly as per the simple randomisation technique.

A total of 50 patients were enrolled in this observational study and were divided into 2 groups of 25 patients each, in which one group had procedure done with suture fixation of mesh (group A) and the other group had procedure done with glue fixation of mesh (group B).

A dose of prophylactic antibiotic was given 30 minutes before surgery. Procedure was carried out with both methods, mesh fixation with glue and mesh fixation with sutures.



Cyanoacrylate Glue



Fixing The Mesh With The Glue

Postoperatively the patients were kept nil by mouth and advised complete bed rest till the effect of anesthesia is completely worn out, till then they are given supportive maintenance intravenous fluids. Patients were advised and encouraged to ambulate and start their activities of daily life as early as possible. Postoperative single dose of antibiotic was given. Post-operative analgesia was given as per the Visual analogue scale.

The postoperative pain scores are analysed and compared by visual analogue scale at 24hrs, 48hrs and 72hrs in both groups. Pain intensity had been assessed by a Visual Analogue Scale – VAS [0 (no pain) to 10 (worst pain)].

The patients were followed up for return for normal activity at 3 months interval.

Statistical Methods

The data obtained were documented and entered in excel sheet. The data was analysed using

1. Descriptive statistics
2. Chi square test
3. "T" test independent

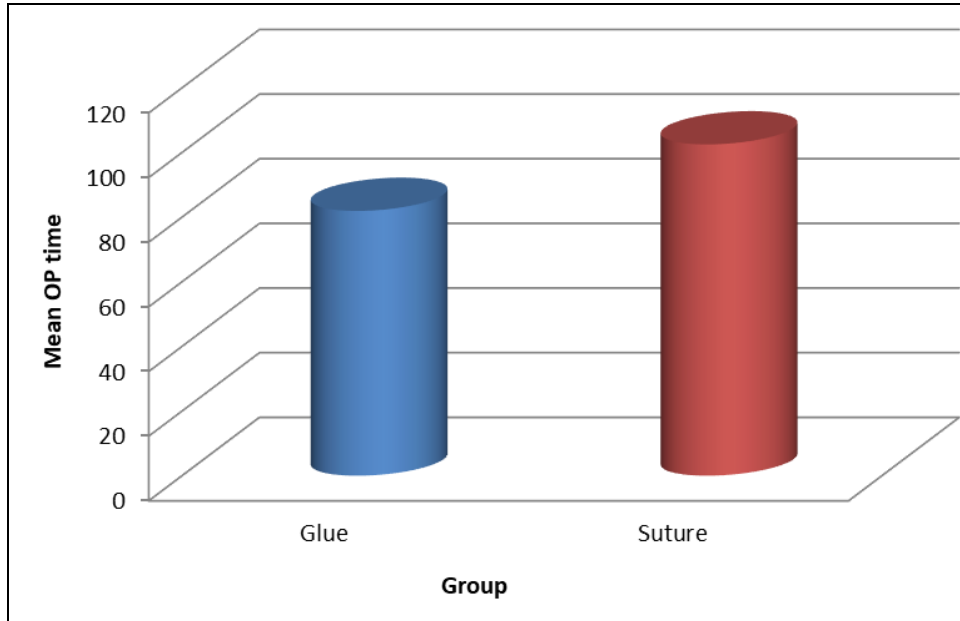
All measurements were done using SPSS 21

Results

In our study, out of 50 patients who were allocated into two groups of 25 each, in glue group 18 patients (73.1%) were male and 7(26.9%) patients were females. Similarly in suture group, 20 patients (83.3%) were male and 5 patients (16.7%) were females (Table 1). In our study Mean age in glue group is 44.6 years and in suture group is 56.29 years, p value=0.017, it is statistically significant. Mean operative time in glue group is 81.92 minutes and in suture group is 102.5 minutes (Graph-1), p value= 0.011- it is statistically significant

Table 1: Table Comparing Mean Age, Operative Time and Return to Normal Activity

	Group	N	Mean	Std. Deviation	Std. Error Mean
age	Glue	25	44.6923	16.55722	3.24714
	Suture	25	56.2917	16.56208	3.38072
OP time	Glue	25	81.9231	27.49825	5.39285
	Suture	25	102.5000	27.62324	5.63857
Return TO Normal Activity	Glue	25	16.3462	4.12739	.80945
	Suture	25	19.2917	3.50750	.71596

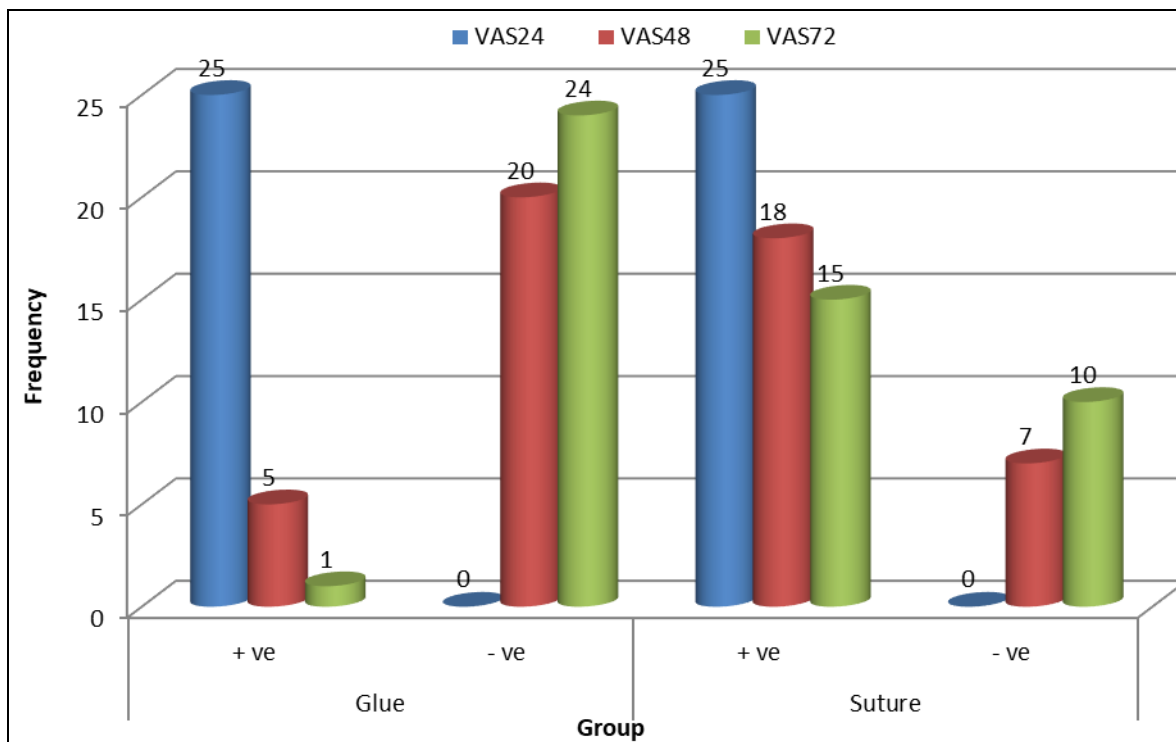


Graph 1: Figure Showing Mean Operative Time

In glue group mean VAS Score (Graph-2) at 24 hours in glue group is 5.57, 3.03 in 48 hours and 1.69 in 72 hours. In suture group mean VAS Score at 24 hours is 5.79, 3.91 at 48 hours and 3.16 in 72 hours. In our study, in the first 24 hours all 50 patients of both the groups required analgesia. Whereas at 48 hours 5 patients (19.2%) in glue group and 18 patients (75%) in suture

group required analgesia. At 72 hours, 1 patient (3%) in glue group required analgesia and 15 patients (58%) in suture group required analgesia.

In our study mean return to normal activity in glue group is 16 days and in suture group is 19 days. p value =0.009 It is statistically significant



Graph 2: Comparing Mean Vas Score

Discussion

Lichtenstein tension free mesh hernioplasty is the most commonly performed hernia surgery worldwide because it is better than the other surgeries in many ways". However "iliodynia" also called chronic groin pain is defined as the pain in the groin lasting more than 6 months post mesh hernioplasty. Chronic groin pain depends upon multiple factors like the subjective threshold of pain, type of mesh used and also the method used for mesh fixation. Pain developing after mesh hernioplasty can be classified into neuropathic and non neuropathic pain. Neuropathic pain post mesh hernioplasty can be due to involvement of the nerves like genitofemoral, ilioinguinal and iliohypogastric nerve. The pain can be due to nerve entrapment, impingement or neuroma formation. This type of pain can be prevented by many techniques like use of a light weight mesh, careful identification and safeguarding the nerves, use of glue to prevent traumatic fixation of mesh etc. Non-neuropathic pain in the inguinal region post mesh hernioplasty is due to excessive scarring of the posterior wall. Periosteitis of the pubic tubercle due to mesh fixation by sutures can be one of the cause. Another cause may be due to presence of mesh itself causing a sensation of foreign body causing pain "Use of surgical glue has shown a reduced inflammatory response at the site according Losi P *et al.*"^[4]. "Tebala *et al.* in their study have established that the pain from 48 hours to 1 month (immediate post operative pain) post-surgery is lower in the glue group as compared to suture"^[5]. However, no significant difference could be appreciated between the 2 methods in terms of chronic pain.

"Silvestro *et al.* have not found any difference in the pain in both the groups after 6 months, although there was major difference in the pain up to 6 months with the use of tissue glue"^[6]. In this study, mean operative time is lesser (81.92 minutes) in glue group compared to suture group (102.5 minutes) p value (0-011) being statistically significant. In this study it is found that the postoperative pain and analgesia requirement is lesser in glue group compared to suture group. Immediate pain in the postoperative pain is lesser in the glue group. Patients in the glue group required little amount of postoperative analgesia compared to suture group.

Patients who underwent mesh fixation using glue had a early return to normal activity (16 days) compared to suture group (19 days), p value (0.009) being statistically significant. "According to us cyanoacrylate surgical glue can be used as an alternative to sutures for mesh fixation in open uncomplicated inguinal hernia surgery". But sutures have turned out to be a more cost effective option compared to cyanoacrylate glue.

Conclusion

In the present study, 50 cases underwent hernioplasty, 25 cases who underwent the surgery with cyanoacrylate glue, following observations were made. Comparing the operative time between the groups it was found that the mean operative time in glue group is faster than in suture group. Patients in glue group required less analgesia and had an early recovery compared to patients who underwent surgery with conventional suture repair. Thus this study concludes that cyanoacrylate glue is a better alternative to conventional sutures for mesh fixation in open inguinal hernia repair in terms of operative time, postoperative complication and early recovery.

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