

Comparative Study of N-Butyl Cyanoacrylate Glue versus Prolene Suture Method of Mesh Fixation in Inguinal Hernia Repair. A Randomized Clinical Trial

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Abstract

There are various methods for any hernia repair. They can be broadly classified in two main types (i) without prosthetic mesh or (ii) with prosthetic mesh. Prosthetic mesh repair gives better strength and so less recurrence. There are many methods for fixing the prosthetic mesh. In this study the result of fixing mesh by N-Butyl Cyanoacrylate Glue is compared with prolene suture method in inguinal hernia cases. 100 patients were randomised in two groups, 50 patients in each group for hernioplasty with glue or prolene sutures. Longer time required in surgery, lengthier duration of hospital stay and more analgesia needed in prolene group patients.

Keyword: N-Butyl Cyanoacrylate Glue, Inguinal Hernia, Prolene

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Introduction

A hernia occurs when a part of internal organ (e.g. intestine, omentum protrudes through the weak point of tissue that normally contain it like abdominal wall. Inguinal hernias are the most common of abdominal wall hernias accounting for almost 75% with a life time risk of 27% in men & 3 % in women.(Kingsnorth A, et al 2003). Inguinal Hernia typically develops in the groin area on one or both sides (Schumpelick V et al, 1990). [1-5]

During the repair of an inguinal hernia, sutures or tacks are generally used to secure the prosthetic mesh in place. In trans abdominal pre-peritoneal repairs the

peritoneum is closed using sutures or tacks. These mesh fixation or peritoneal closure techniques may contribute to postoperative chronic pain presumably due to nerve irritation or entrapment (HeiseCP et al, 1998). [6-9]

Intraoperative strategies to reduce pain include the non-fixation of mesh or the use of non-mechanical methods of mesh fixation other than tacking or suturing, which may be less traumatic to the local tissue and less likely to cause local nerve entrapment. These non-mechanical methods include self-fixating meshes or glue. Similarly, closing the peritoneum with sutures may be less

traumatic than the use of tacks, thus resulting in less postoperative pain. (Ross SW et al, 2015) [10,11]

Two types of glue, fibrin glue and N-butyl-2-cyanoacrylate, are the most commonly used glues for mesh fixation. Fibrin glue is a biodegradable adhesive that combines human-derived fibrinogen and thrombin. In addition to its haemostatic action, the fibrinogen component gives the product tensile strength and adhesive properties. N-butyl-2-cyanoacrylate is a new generation of cyanoacrylate that has been used as a surgical tissue adhesive since the 1960s. Self-fixating mesh has a large number (>5000) of micro grips that help secure the mesh to tissue without the need for tacks or sutures. When the mesh is placed in between layers of the abdomen it is kept in place by intra-abdominal pressure the rationale behind non-fixation of the mesh. (Campanelli G et al, 2016) [12-14]

Prolene or polypropylene was developed in 1970 as a first synthetic nonabsorbable suture. It is a monofilament suture. Prolene is made of isotactic crystalline stereoisomer of polypropylene with few unsaturated bonds. Polypropylene has a tensile strength more than nylon. It can easily pass through tissues and induces minimal host response. It does not adhere to the tissues and can be used as an intradermal suture. It is available as dyed or undyed form. It has good plasticity and it expands with tissue swelling to accommodate the wound. High memory, poor knot security and lack of elasticity are the few disadvantages with Prolene. (Meinel L etl, 2005) [16-20]

Objective:

- To compare the outcome of fixation of mesh with prolene suture v/s N-butyl cyanoacrylate glue in inguinal hernia mesh repair in patients with inguinal hernia.
- To determine whether N-butyl cyanoacrylate glue can reduce postoperative complications, especially chronic pain, with no increase in recurrence rate, compared with prolene

sutures for mesh fixation in inguinal hernia repair.

Material & Method:

Study Design: Prospective cross sectional study

Study Centre: K.D. Medical College & Hospital, Mathura and K.M. Medical College & Hospital Mathura.

Duration of Study: Eighteen Month

Methodology

1. Over an accrual period of 18 months, patients were prospectively randomized between using the n-butyl cyanoacrylate glue (3ml) and prolene suture to fix the mesh.
2. Patient's demographic and medical history was recorded.
3. They were consented for trial, immediately preoperatively an opaque envelope was opened which dictated the type of fixation technique randomized for each hernia side.
4. Inguinal canal was prepared, alongside with the anatomical landmarks- pubic tubercle conjoined tendon, inguinal ligament, the hernia sac were prepared and reduced.
5. The mesh was shaped according to shape and size of the inguinal canal and put in place.
6. In group A the mesh was fix with two running sutures both starting from the first stitch passed on the tissue above the pubic tubercle (avoiding periosteum and with a 2cm overlap of the mesh above the tubercle) and were passing on the conjoined area and the inguinal ligament.
7. The two posterior wing of the mesh were sutured together with two single prolene stitches.
8. In group B the mesh was fixed with n-butyl cyanoacrylate tissue adhesive on pubic tubercle, the inguinal ligament and the conjoined tendon.
9. Attention was paid to avoid dripping the glue on the nerves. only one vial of glue was used for each patient. The two posterior wings of the mesh was stitched with a single vicryl paying attention to take only the mesh.

10. Same polypropylene kind of mesh were used in all patients , irrespective of the fixation method. The fascia was closed in both groups with a vicryl running suture .skin will be closed with a subcuticularvicryl running suture.
11. Nerves were never prepared or cut ,in either group.
12. All operations were performed with spinal block. No postoperative analgesic device was used .
13. postoperative analgesic treatment were just intramuscular diclofenac upon request of the patient when patient was still in hospital, as required oral paracetamol were prescribed after discharge.
14. Postoperative pain was measured by direct interview or by phone call at 3hrs ,24hrs,48hrs,7 days,15 days,1 month,3months and 6 months after the operation .

Inclusion criteria

1. All patients with evidence of primary uncomplicated inguinal hernia
2. Patients above 18 years age.
3. Patients undergoing elective Lichtenstein mesh hernioplasty.

Exclusion criteria

1. Age less than 18 years

2. Patients with recurrent and complicated hernias.
3. Emergency inguinal hernia repair
4. Laparoscopic inguinal hernia repair

Sample Size:

- On the basis of number of patients admitted during course of study, minimum 100 patients to be studied, 50 patients in each group Procedure Hernioplasty with glue or prolene suture

Investigations

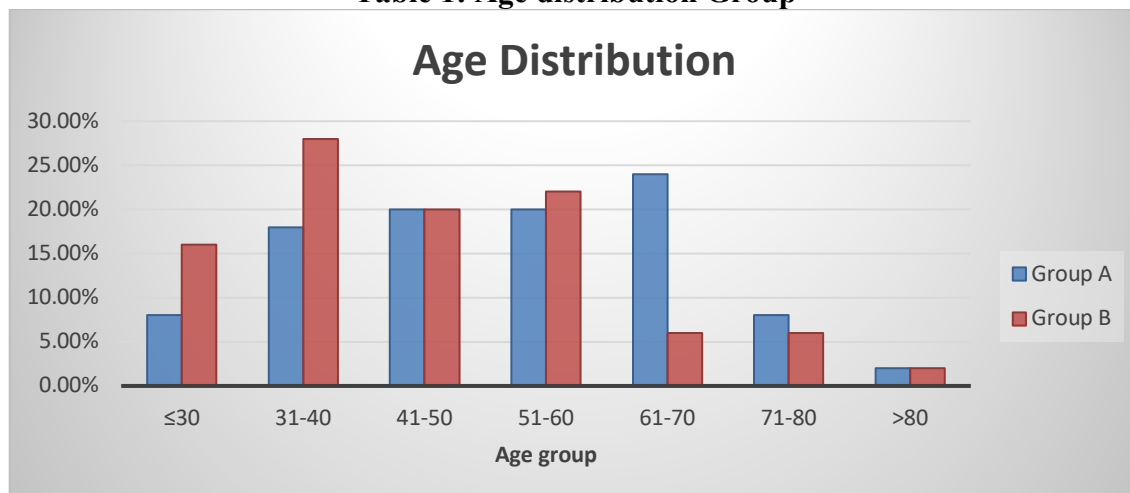
- OT profile (cbc, blood group, RBS, serum creatinine, blood urea, urine r/m, BT/CT ,HIV, HBsAG)
- Chest xray
- ECG
- USG inguino-scrotal region

Statistical analysis

All the data analysis was performed using IBM SPSS ver. 20 software. Frequency distribution and cross tabulation was used to prepare the tables. Quantitative variables were expressed as the mean and standard deviation. Categorical data was expressed as percentage. PRISM and Microsoft office was used to prepare the graphs. Student t- test and ANOVA was used to compare the means. Chi Square test was used to compare the categorical data. P value of < 0.05 is considered as significant.

Observation& Result:-

Table 1: Age distribution Group



In present study, majority of the patients in Group A had age between 61-70 years

followed by41-50 years (20%) and 51-60 years (20%), whereas in Group B, majority

of the Hernia patients had age between 31-40 years (28%) followed by 51-60 years (22%) and 41-50 years (20%). The age distribution

between both the groups was comparable as revealed by the insignificant p value of 0.237.

Table 2: Sex distribution

| | | | Group | | Total | P value |
|--------|---|-------|-------|-------|-------|---------|
| | | | A | B | | |
| Gender | F | Count | 1 | 1 | 2 | 0.603 |
| | | % | 2.0% | 2.0% | 2.0% | |
| | M | Count | 49 | 49 | 97 | |
| | | % | 98.0% | 98.0% | 97.0% | |

In present study, in group A, majority of the hernia patients were males (98%) similarly in Group B, majority were males (98%). The age distribution between groups was comparable as revealed by the insignificant p value of 0.603.

Table 3: Types of Hernia

| | | | Group | | Total | P value |
|----------------|----------|-------|-------|-------|-------|---------|
| | | | A | B | | |
| TYPE OF HERNIA | DIRECT | Count | 29 | 27 | 56 | 0.678 |
| | | % | 58.0% | 54.0% | 56.0% | |
| | INDIRECT | Count | 21 | 23 | 44 | |
| | | % | 42.0% | 46.0% | 44.0% | |

In present study, in both Group A (58%) and Group B (54%), majority had direct type of hernia. In both the groups, type of hernia were equally distributed as revealed by the insignificant p value of 0.678.

Table 4: Duration of surgery

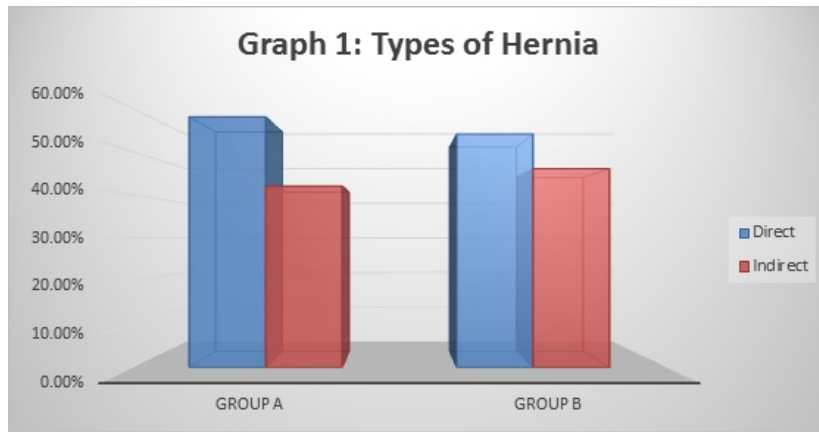
| | Group | N | Mean | Std. Deviation | P value |
|---------------------|-------|----|------|----------------|---------|
| DURATION OF SURGERY | A | 50 | 1.37 | .08524 | <0.001 |
| | B | 50 | 1.11 | .05055 | |

In present study mean duration of surgery was longer in Group A (1.37) as compared to Group B (1.11). That means in Group A patients surgery time of longer as compared to Group B patients. The comparison was highly significant as revealed by the p value of <0.001.

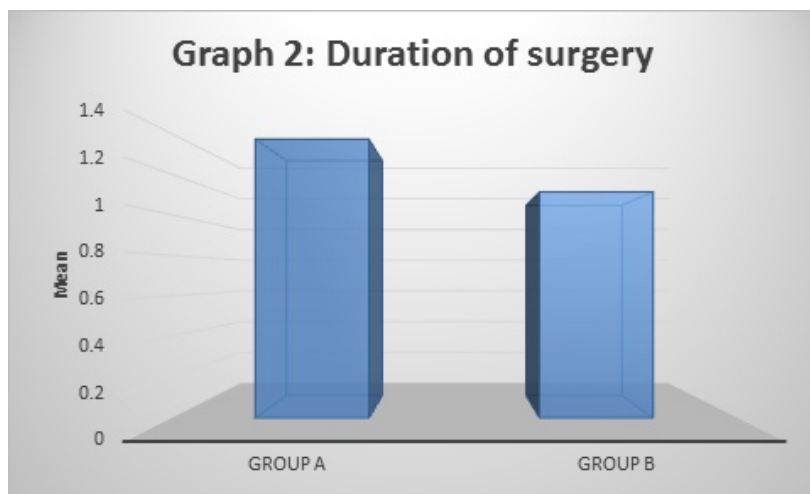
Table 5: Duration of stay

| | Group | N | Mean | Std. Deviation | P value |
|------------------|-------|----|------|----------------|---------|
| DURATION OF STAY | 1 | 50 | 2.50 | .505 | <0.001 |
| | 2 | 50 | 1.62 | .530 | |

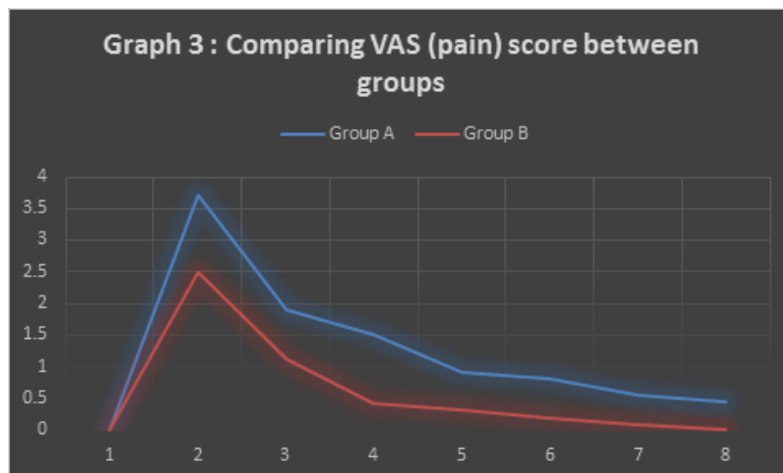
In present study mean duration of stay was longer in Group A (2.50) as compared to Group B (1.62). That means in Group A patients stayed for longer time as compared to Group B patients. The comparison was highly significant as revealed by the p value of <0.001.



In present study, in both Group A (58%) and Group B (54%), majority had direct type of hernia. In both the groups, type of hernia were equally distributed as revealed by the insignificant p value of 0.678.



In present study mean duration of surgery was longer in Group A (1.37) as compared to Group B (1.11). That means in Group A patients surgery time of longer as compared to Group B patients. The comparison was highly significant as revealed by the p value of <0.001.

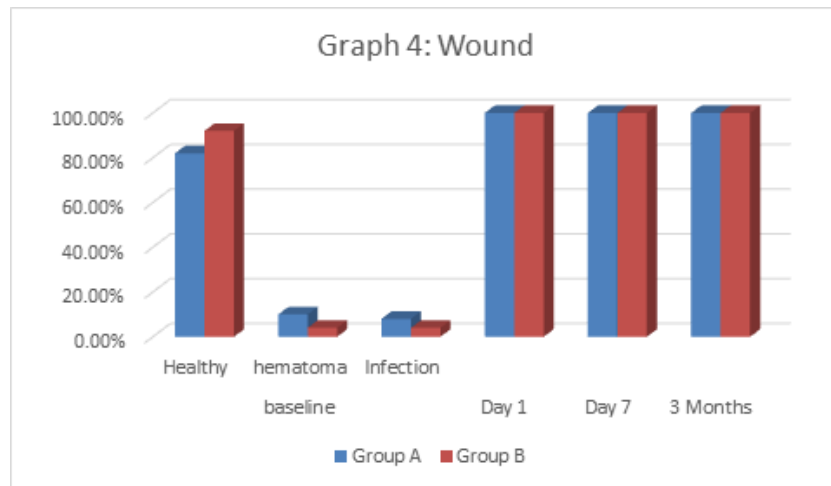


In present study, on comparing the pain using the VAS score it was found that VAS score in Group A and Group B at 3 hours (0.00 vs 0.040) was similar, at 24 hours (3.72 vs 2.50) was significantly higher in Group A as compared to Group B ($p < 0.001$), at 48 hours

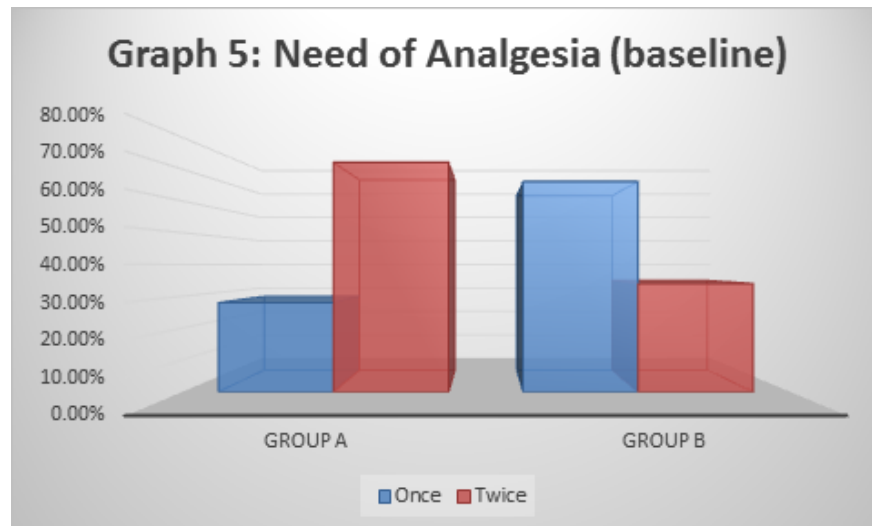
(1.90 vs 1.12) was significantly higher in group A and Group B ($p = 0.005$), similarly at 7 day, VAS score was significantly higher in Group A (1.52) as compared to group B (0.42) ($p < 0.001$), at the end of 15 days VAS score was significantly higher in Group A

(0.92) as compared to group B (0.32) ($p=0.004$), at the end of 1 month VAS score was significantly higher in Group A (0.82) as compared to group B (0.20) ($p=0.001$), at the end of 3 month VAS score was significantly higher in Group A (0.56) as compared to group B (0.10) ($p=0.008$) and at the end of 6 months VAS score was significantly higher

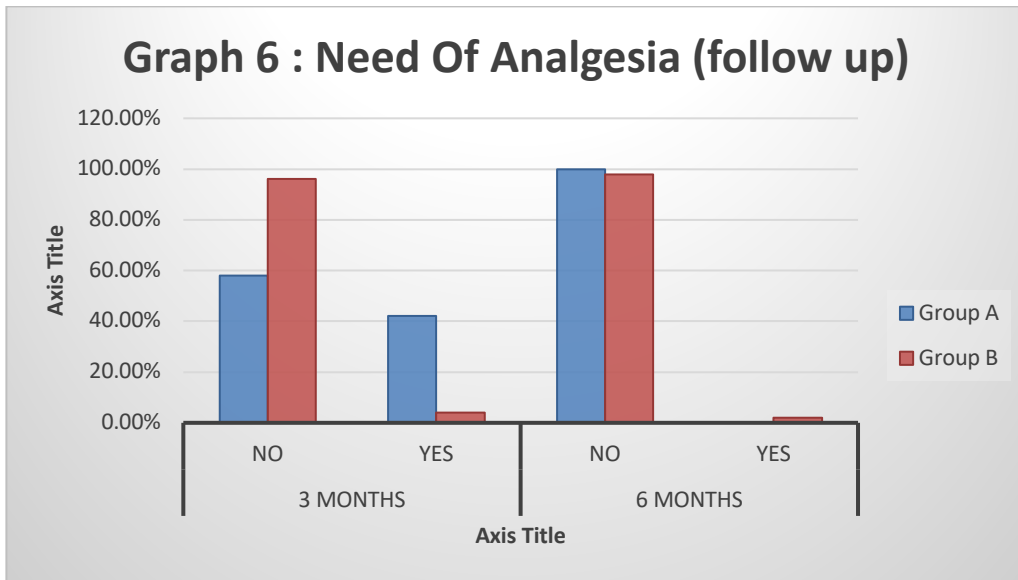
in Group A (0.46) as compared to group B (0.00) ($p=0.001$). In conclusion group A patients felt more pain as compared to Group B patients across all the follow up time (24 hours, 48 hours, 7 days, 15 days, 1 month, 3 months and 6 months) except at 3 hours where VAS score was similar in Both the groups.



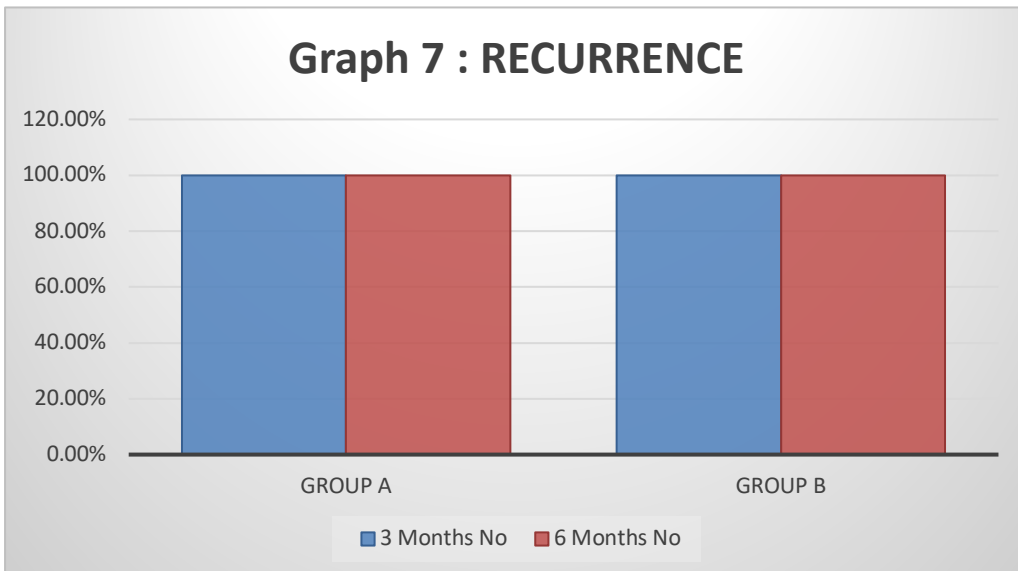
In Present study on comparing the wound type between both the groups we found that at baseline hematoma was seen in 10% of the Group A patients and 4% of the Group B patients ($p=0.326$). On follow up on Day 1, day 7 and after 3 months, all the patients were healthy in both the groups



On comparing the need of analgesia we found that In Group A majority required analgesia twice (72%) whereas 28% required it once only. Whereas in Group B, majority required analgesia only once (66%). That means that in group B patients required less analgesia as compared to Group A.



In present study, at the end of 3 months, majority in Group A required analgesia (42%) as compared to 4% in Group B ($p < 0.001$). However, analgesia requirement was similar in both the groups at the end of the 6 months ($p = 0.315$).



In Present study, In None of the group's recurrence was seen at 3 months and 6 months follow up.

Conclusion

Results of the present study shows that the hernia is more prevalent in male population, duration of surgery was longer in prolene suture compared to N-butyl cyanoacrylate glue, mean duration of hospital stay was more in prolene suture patients than N-butyl cyanoacrylate glue patients. Analgesia was more required in prolene suture compared to N-butyl cyanoacrylate glue. Present study

conclude that the use of prolene suture for mesh fixation in hernia repair is associated with more complications and causing significant postoperative pain while N-butyl cyanoacrylate glue showed benefits in terms of shorter surgery, chronic pain of groin. With these benefits it can be concluded that use of butyl cyanoacrylate glue in mesh fixation is safer and effective in the treatment of hernia.

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