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To evaluate the efficacy of N-butyl cyanoacrylate glue for mesh fixation in laparoscopic inguinal hernia repair

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Abstract

Method: A Prospective observational study of Laparoscopic Repair of Inguinal Hernia by using N-Butyl Cyanoacrylate Glue for mesh fixation without tackers was conducted on 50 patients with Inguinal hernia admitted in Department of General Surgery, M.G.M Medical College and M.Y Hospital Indore (M.P.) during December 2017 to February 2019.

Result: There were very few procedure related complications: hematoma formation 2 (4%), wound infection 1 (2%), inguinal hernia recurrence 1 (2%), with significant reduction in postoperative pain and no incidence of chronic pain (beyond 6 months of surgery)

Conclusion: This prospective study shows that the use of N-butyl cyanoacrylate glue as an alternative to tacks for mesh fixation in laparoscopic inguinal hernia repair is extremely effective in overcoming the common complication of 'Chronic Inguinal Pain' associated with the use of tacks.

Keywords: Efficacy, N-ButylCyanoacrylate, Laparoscopic & Inguinal Hernia, post-operative pain

Study Design: Observational Study

Introduction

Hernias are among the oldest known afflictions of human-kind, and surgical repair of the inguinal hernia is the most common general surgery performed worldwide.^[1] The technical aspects of hernia repair continue to evolve despite its high incidence and expertise achieved in the various repair techniques. Advancements in perioperative anesthesia and operative technique have made this an outpatient ambulatory operation with low recurrence rates and morbidity.

The rapid changes witnessed in the open approach surgeries, prosthetic materials and with the advent of laparoscopic surgeries, the field of hernia repair has undergone a drastic transformation and has likewise attracted a lot research attention worldwide. Given the advancements made in this field, mere hernia repair is not the end point. Quality of life post hernia repair and the avoidance of chronic PND (pain, numbness and discomfort) has become the main prerogative.

Laparoscopic repair of inguinal hernia can be accomplished by either TEP or TAPP or IPOM techniques. It involves mesh fixation to avoid its displacement leading to recurrence of hernia. The correct fixation of the mesh, as well as the right size of the prosthesis are considered as the most important factors to prevent the risk of recurrence. The use of 10mm titanium staples or tackers to fix the mesh is the conventional approach. Tackers are associated with certain amount of surgical trauma and complications such as nerve injury (chronic PND, neuralgias, pubalgias) and hematomas in the Retzius space.

The complications associated with the use of tackers for mesh fixation which significantly affected the quality of life of the patient instigated the search for newer and effective alternatives for mesh fixation. Various methods were introduced with good effect like no fixation of mesh, use of fibrin sealant for mesh fixation, self-adhering mesh and the use of N-butyl cyanoacrylate glue for mesh fixation.

The use of N-butyl cyanoacrylate glue for mesh fixation in laparoscopic inguinal hernia repair is the topic of interest in this study. It is a cyanoacrylate ester, a synthetic sealant that provides a strong and fast polymerization when in contact with organic tissues and liquids. Its polymerization temperature is 45 degrees centigrade, so thermal injury is avoided as an undesirable effect. Full degradation of the glue takes place by hydrolysis in a variable time

depending on the type of tissue and quantity of glue, so permanent glue adherence is avoided unlike the case of tack staples. The polymerized form has excellent tensile strength and hence it is a main component of medical cyanoacrylate glues with uses in topical skin approximation, treatment of AVMs, etc. Extensive research and literature about the use of N-butyl cyanoacrylate glue for mesh fixation in laparoscopic inguinal hernia repair is lacking and thus this venture aims to seek the evidence of its efficacy for this purpose.

Material & Method

The study title “A Prospective observational study of Laparoscopic Repair of Inguinal Hernia by using N-Butyl Cyanoacrylate Glue formesh fixation without tackers” was an observational study conducted on 50 patients with Inguinal hernia admitted in Department of General Surgery, M.G.M Medical College and M.Y Hospital Indore (M.P.) during the study period December 2017th to February 2019.

Sample Size

50 cases of inguinal hernia (unilateral or bilateral)

Inclusion Criteria

1. Patients with age > 18 years.
2. Reducible inguinal hernia.
3. New cases of inguinal hernia.
4. Patients operated by a single surgeon.

Exclusion Criteria

1. Patients unfit for general anesthesia or laparoscopic surgery.
2. Patients with Irreducible, Obstructed, Strangulated Inguinal hernias.
3. Patients with recurrent Inguinal hernia
4. Patients operated by different surgeons.

Data Collection

- Data was collected on individual basis by filling of

proforma (annexure at the end) as well as by telephonic conversation.

- All the patients included in the study were asked about the existence of pain before the surgery, verifying they were not undergoing any analgesic treatment. Patients were given a card and were instructed to note every time they needed to take analgesics, the day this corresponded to with respect to surgery, and the day on which the pain disappeared.
- The primary end points were Pain and Recurrence.
- Acute pain was defined as pain reported by the patient in the first 3 months after operation, and Chronic pain was defined as pain persisting for more than 6 months. Pain scores were calculated using Numerical rating pain scale (0-10) where 0 meant no pain, 1-3 meant mild pain, 4-6 meant moderate pain, 7-10 meant severe pain. Hematoma was defined as the accumulation or drainage of blood, with ecchymosis of the adjacent tissues or of the scrotum with local discomfort.
- Wound infection was defined as the presence of any sign of infection in the wound (pain, fluctuation, redness, etc) whether or not it was associated with fever, or pus drainage via the wound, and always confirmed using bacterial culture. The frequency of infection was recorded 1 month after surgery.
- Recurrence was confirmed by clinical examination and when necessary by ultrasound.
- The secondary end points were Operating time (minutes) and the time to return to normal activities (days). This period was defined as the time needed to be able to perform household activities, drive, or walk without pain.

Results

50 patients underwent 56 TEP repairs (6 bilateral) for inguinal hernia over a period of 14 months (Dec 2017- Feb 2019). Patient characteristics and relevant findings are shown in Table 1. Hernia type is also documented but the hernia size was not recorded.

Table 1: (Patient characteristics and relevant findings of 50 patients who underwent TEP repair for inguinal hernia using NBCA glue for mesh fixation)

Characteristics	Findings
Sex	Male: 47, Female: 3
Age	Mean: 50 years, Range: 19-85 years
Hernia side	Right unilateral: 26, Left unilateral: 18, Bilateral: 6
Type of hernia	Indirect: 33, Direct: 11, Pantaloon: 6
Mesh used	15×10mm polypropylene mesh
Fixative used	N-Butyl Cyanoacrylate glue
Postoperative Morbidity	Hematoma formation: 2, Wound infection: 1, Hernia recurrence: 1, Pain Score (Numerical Rating Scale): 3,1,0,0,0 on day1, day 7, 1 month, 3 months and 12 months post-surgery
Operating time	Unilateral (mean) 72 min, Bilateral (mean) 100 min
Time to return to normal activity	Unilateral (mean) 18 days, Bilateral (mean) 20 days

The graph shows that the patients who underwent Laparoscopic TEP repair using NBCA as mesh fixative recorded the above pain scores after surgery. The median pain score (by Numerical Rating Scale) at day 1 was 3, at day 7 was 1 and was 0 on subsequent follow up at 1 month, 3 months and 12 months. None of the patients had chronic pain (pain beyond 6 months of surgery).

Discussion

A significant male preponderance was seen in Inguinal hernias with the ratio between male: female being 15.6:1. Garcia-Vallejo *et al.* (2014) [2] found that most of the patients of

inguinal hernia were males (88.5%) with females being 11.5%. It was found that majority of inguinal hernias occurred on the right side which accounted for 52% of the cases. Garcia-Vallejo *et al.* (2014) [2] also had similar observation with males being 51% of the cases. Most of the other studies also observed right side inguinal hernia to be more common than the left.

The present study observed that indirect inguinal hernia was more common. The ratio of direct to indirect inguinal hernia is 1:3. Garcia-Vallejo *et al.* (2014) [2] and most of the other studies also found indirect inguinal hernia to be more common. Hematoma formation was seen in 4% patients on follow up. Alfredo Moreno-Egea *et al.* [3] observed the percentage of

hematoma formation to be 2% in cases of open surgery with use of glue, 1% in the laparoscopic repair with use of glue. Wilson.P *et al.* [4] observed Groin seromas to be 2.4%. Testini Mario *et al.* [5] observed the hematoma rate to be same as the present study at 4%.

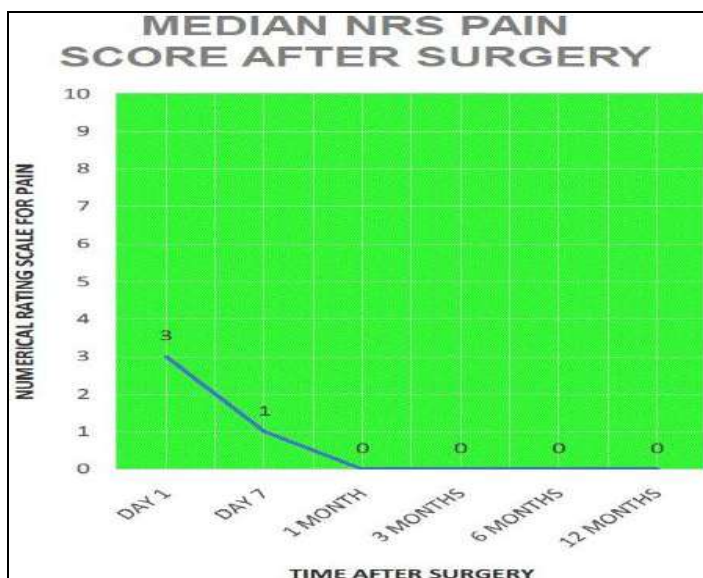
Wound infection was seen in 2% patients. Alfredo Moreno-Egea *et al.* [3] observed the percentage of wound infection to be 0%. Testini Mario *et al.* [5] also observed the percentage of wound infection rate to be 0 %.

Recurrence of inguinal hernia post Laparoscopic TEP repair with NBCA as mesh fixative was 2%. (1 /50). Garcia- Vallejo *et al.* (2014) [2] had no recurrence recorded in their study. Alfredo Moreno-Egea *et al.* [3], Khalil Alaa *et al.* [6], Kalpesh Jani *et al.* [7] had no recurrences. Lovisetto F *et al.* and Fine P Arthur *et al.* both had similar observations as the present study with 1 case of recurrence.

The median pain score (by Numerical Rating Scale) at day 1 was 3, at day 7 was 1 and was 0 on subsequent follow up at 1 month, 3 months and 12 months. None of the patients had Chronic Groin pain (i.e pain beyond 6 months after surgery). Liew W *et al.* [8] observed median VAS scores to be 3 at 4hours and 24 hours, 2 at 48 hours, 1 at 7 days and 0 at 3 months. They reported 6.3% patients who had a chronic groin pain after surgery. Garcia- Vallejo *et al.* (2014) [2] and Kalpesh Jani *et al.* [7] reported no cases of chronic groin pain. Alfredo Moreno-Egea *et al.* [3] recorded 5.6% cases of chronic groin pain. Fine P Arthur *et al.* [9] reported 7.9% chronic pain 12 to 18 months postoperatively.

Unilateral inguinal hernia operated by Laparoscopic TEP repair using NBCA as mesh fixative, had a mean time of 18.02 days to return to normal activity while the median time was 18 days with the range of 15-23 days.

For Bilateral inguinal hernia the mean time to return to normal activity was 20.66 days, the median time was 21 days with the range of 18-24 days. Testini Mario *et al.* [5] observed that mean time to return to normal activity was 19.8 days and there was no significant difference in this regard between sutures, fibrin glue and NBCA.



The graph shows that the patients who underwent Laparoscopic TEP repair using NBCA as mesh fixative recorded the above pain scores after surgery.

Conclusion

The field of inguinal hernia repair has undergone a paradigm shift over a period. Laparoscopic repair has become a preferred approach for inguinal hernia repair. The latest advancements in the field of prosthetic materials and various means of mesh fixation have brought about significant improvement in the quality of life of the patient who often suffered chronic pain post hernia repair. The use of tacks for mesh fixation in laparoscopic hernia repair is known to cause chronic pain to the patient which significantly hinders normal routine activities of the patient.

NBCA glue used as an alternative to tacks for mesh fixation in laparoscopic inguinal hernia repair in this study proved to be extremely effective in overcoming the common complication "Chronic Pain" associated with use of tacks. There were no reported cases of chronic pain after NBCA was used for mesh fixation in all cases of study. The incidence of other complication did not show any significant difference than those seen with the use of tacks.

Thus the use of NBCA definitely improves the quality of life of the patient post hernia repair by reducing chronic Groin pain.

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