



COMPARITIVE STUDY BETWEEN CYANOACRYLATE GLUE AND NON-ABSORBABLE SUTURE FOR MESH FIXATION IN LICHTENSTEIN INGUINAL HERNIA REPAIR.

General Surgery

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ABSTRACT

Methods: Prospective, randomized and unicentric study of patients undergoing primary, unilateral inguinal hernia, operated under the Lichtenstein technique; comparing the mesh fixation with n-butyl-2-cyanoacrylate (group I) versus non-absorbable suture (group II). The study variables in the postoperative period focused on the incidence of pain, complications and hernia recurrence.

Results: 240 patients have been included, from January 2018 to December 2019. 30 patients in each treatment group. In group I pain was recorded (EVA ≥ 3) at 24h in 38 patients, at 30 days in 18 patients and at 90 days in 2 patient, against 44, 30 and 12 patients in group II (p= 0, 56; p= 0.17, p= 0.048, specifically). The incidence of morbidity at 90 days was 15% in the cyanoacrylate group and 13.33% in the suture fixation group, p= 0.79. Repairs were 5.8 minutes faster in the glue group (p= 0.02). There were no early recurrences in either group.

Discussion: There were no differences in the incidence of acute pain evaluated at 24 hours after the intervention or at 30 days, but there was a lower incidence in favor of the glue at the 90-day assessment p= 0.048. There were no statistically significant differences in complications at 90 days, we objective reduction in surgical time of 5.8 minutes in favor of the cyanoacrylate. There were not early recurrence.

KEYWORDS

inguinal hernia, mesh fixation, postoperative pain

1. INTRODUCTION

The Lichtenstein technique is the method of open repair most widely disseminated for treatment of inguinal hernia, with which the incidence of recurrence has been remarkably reduced, as we know this fact has been the most important quality index in inguinal hernia repair. Although recurrence remains a relevant and mandatory indicator in the analysis of the results of these interventions, today it is necessary to include parameters related to the incidence of post-operative pain

In response to this problem, modifications have been made to the technique initially described by Lichtenstein, from the use of low weight meshes with the aim of implanting less material using resorbable sutures, self-adhesive meshes and tissue adhesives (biological or synthetic) The purpose of these methods of fixation is to achieve an anchorage of the safe and atraumatic prosthesis with which to reduce the incidence of pain associated with these procedures.

The aim of the present study is to determine if the fixation of the mesh with n-butyl-2-cyanoacrylate in the inguinal hernioplasty according to the Lichtenstein technique is equivalent from the point of view of patient safety, with the similar efficacy and providing advantages in the short and medium term (24 hours, 30 days and 90 days) in relation to post-operative pain, when compared with the suture with non-absorbable material.

2. MATERIALS AND METHODS

Prospective, randomized, controlled and unicentric study of patients over 18 years of age and under 70 years old, operated on electively for primary inguinal hernia, unilateral in the period between January 2018 to December 2019.

The patients were informed verbally in a complete and clear way about their participation in this study and also signed a specific informed consent that they accepted for inclusion. (Criteria for inclusion included in). All the patients met the inclusion criteria and none of the exclusion criteria (bilateral hernia, inguino-scrotal, recurrent, femoral, age over 70 years or the patient's rejection).

Table 1. Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|-------------------------------|-------------------------------------|
| Age over 18 years old | Age under 18 years old |
| Age younger than 70 years old | Age over 70 years old |
| ASA I, II AND III | ASA \geq IV |
| Elective surgery | Urgent surgery |
| Unilateral hernia | Bilateral or inguino-scrotal hernia |
| Primary hernia | Recurrent hernia |
| Acceptance by the patient | Not acceptance by the patient |

Antibiotic prophylaxis was administered with Amoxicillin/Clavulanic 2 gr. o Ciprofloxacin 500 mg. in case of allergy to beta-lactams in all cases and thromboembolic prophylaxis according to protocol.

Randomization was carried out for the assignment in one or another treatment arm (fixation with cyanoacrylate, group I or fixation with suture, group II, using the Randomizer computer program (<https://www.randomizer.org/>).

All patients had undergone surgery under spinal anesthesia + infiltration with local anesthesia with levobupivacaine (20ml) in the ilio-hypogastric and ilio-inguinal nerves.

In all the repairs, a low weight polypropylene mesh of 7.5x15cm was used. In indirect hernias, the hernia sacs were resected or invaginated into a cavity according to the surgeon's criteria. The mesh was placed, surpassing the pubis and fixed to the inguinal ligament and the aponeurosis of the minor oblique muscle, creating in the case of male patients a tie around the spermatic cord.

In patients of group I the prosthesis was fixed with n-2- butyl-cyanoacrylate ,following the same fixation points as in the traditional technique and avoiding applying excessive amounts (for each repair 1 vial of n-butyl-2-cyanoacrylate containing 1 ml). In patients of group II, the mesh was fixed with a non-absorbable suture of 3/0 to the inguinal ligament and with loose stitches to the aponeurosis of the minor oblique muscle, with preservation of the nerves of the inguinal region, following the classic description of the Lichtenstein technique (13). The greater oblique aponeurosis was closed by resorbable continuous suture type polyglycolic acid 2/0 (vicryl) and the skin with staples, without drainage placement in any case.

In order for the study to broadly reflect the reality of a surgical service, it was not exclusively performed by highly specialized abdominal wall surgeons, but by 4 surgeons and 3 supervised residents.

Oral NSAIDs were prescribed every 8h as postoperative analgesia in all cases. In no case was antibiotic treatment performed. The pain was evaluated at 24h using a form with visual analogic scale (collected in the first assessment in outpatient consultations). The postoperative control was carried out ambulatory 30 and 90 days after the intervention, with physical examination and pain assessment (VAS).

The statistical analysis of the data obtained was analyzed through the statistical program SPSS 7.5-Windows (SPSS, Chicago, IL). The χ^2 and Fisher's exact test were used for the qualitative variables expressed as frequencies and the t-Student test for the quantitative variables

expressed as mean and standard deviation, after checking the normal distribution. The statistical significance was established at $p < 0.05$.

3. Results

During the study period, a total of 240 patients were included (120 in each treatment arm), 112 men and 8 women in group I and 110 men and 10 women in group II $p = 0.72$.

Both groups were homogeneous with respect to the type of hernia (Table 2) and without statistically significant differences in relation to their body mass index (BMI), BMI 24.79 in group I and BMI of 25.92 in group II ($p = 0.49$). A total of 224 patients (93.33%) underwent surgery in ambulatory surgery and 16 (6.66%) required admission for an average of 1.2 days. The average time of repairs in group I with n-butyl-2-cyanoacrylate was 41.66 minutes, while in group II it was 47.48 minutes ($p = 0.02$).

Table 2. type of hernia according to the classification of the European Hernia Society (EHS)

| EHS Classification | Cyanoacrylate | Suture | Total |
|--------------------|---------------|--------|-------|
| M-I | 2 | 4 | 6 |
| M-II | 14 | 12 | 26 |
| M-III | 26 | 22 | 48 |
| L-I | 12 | 14 | 26 |
| L-II | 16 | 20 | 36 |
| L-III | 22 | 18 | 40 |
| ML-I | 10 | 14 | 24 |
| ML-II | 4 | 6 | 10 |
| ML-III | 14 | 10 | 24 |
| Total | 120 | 120 | 240 |

We performed the post-surgical pain assessing using the visual analog scale (VAS) observing in the group I at 24h, 30 days and 90 days was 2.21; 1.3 and 0.78 while in the group II it was 2.45; 1.88 and 1.21 respectively (and).

Table 3. Average scores in the visual analogue scale

| Average score in the VAS | Cyanoacrylate | Suture | P= |
|--------------------------|---------------|--------|-------|
| 24 hours | 2,21 | 2,45 | 0,23 |
| 30 days | 1,3 | 1,88 | 0,008 |
| 90 days | 0,78 | 1,21 | 0,009 |

Table 4. Number of patients with scores ≥ 3

| Number of patients with scores ≥ 3 | Cyanoacrylate | Suture | P= |
|-----------------------------------------|---------------|--------|-------|
| 24 hours | 19 | 22 | 0,56 |
| 30 days | 9 | 15 | 0,17 |
| 90 days | 1 | 6 | 0,048 |

There were no intraoperative complications in either group. Postoperative complications were assessed in external consultations by physical examination. The incidence of complications in the fixation group with cyanoacrylate was 18/120 (15%), while in the suture fixation group it was 16/120 (13.33%), without statistically significant differences $p = 0.79$ (). No patient presented allergic or foreign body reactions induced by the use of cyanoacrylate. There were also no differences when comparing the complications of the repairs carried out by tutoring residents with surgeons with experience $p = 0.4$. No early recurrences were observed in any group. They completed the initial follow-up in this 3-month period a total.

Table 5. Morbidity at 30 days

| Morbidity at 30 days | Cyanoacrylate | Suture | p= |
|--------------------------|---------------|--------|------|
| Complications in general | 18 | 16 | 0,79 |
| Wound infection | 0 | 2 | 0,31 |
| Hematoma | 2 | 0 | 0,31 |
| Ecchymosis | 4 | 6 | 0,64 |
| Seroma | 8 | 6 | 0,69 |
| Orchitis | 4 | 2 | 0,55 |
| Early recurrence | 0 | 0 | 1 |

4. DISCUSSION

As we know, the classic technique of Lichtenstein is a technique with great effectiveness and simplicity practically reproducible in any field, with these objectives fulfilled we focus on the identification of

technical variations that allow to improve the results, mainly reducing the postoperative pain. The initial results of this study show a shorter surgical time, with a mean of 41.66 minutes in the cyanoacrylate group and 47.48 minutes in the suture group ($p = 0.02$), a lower incidence of pain ($EVA \geq 3$) in the evaluation at 90 days in favor of the use of this adhesive $p = 0.048$, without relevant changes in acute pain in the measurements at 24 hours and 30 days ($p = 0.56, p = 0.17$ respectively). The incidence of complications observed in this period was 15% in group I and 13.33% in group II, without statistically significant differences, and no early recurrences were observed in either group.

These results have been obtained reflecting the reality of a general surgery service in which patients can be operated by professionals with different levels of experience, including residents in training, so we can conclude that both methods of fixation are at least equivalent from the point of view of patient safety and effectiveness of the procedure with the added benefit of a lower incidence of pain at 3 months in the n-butyl-2-cyanoacrylate group.

5. CONCLUSION

This kind of mesh fixation in Lichtenstein inguinal hernia repair is a safe technical variation, simple, and easily reproducible by surgeons with different levels of training, associated with reduction in the incidence of acute postoperative pain.

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