

A comparative study of Isoamyl-2-cyanoacrylate with sutures

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Abstract

Introduction: Closure of wounds with bioadhesives was proved to be efficacious and well tolerable. Therefore it is necessary to do a study which should compare the bioadhesives and sutures. **Aim:** To compare the efficacy of Isoamyl-2-cyanoacrylate with sutures in patients with bilateral inguinal hernia. **Methodology:** it is a comparative study of Isoamyl-2-cyanoacrylate with sutures in patients of bilateral inguinal hernia in the age group of 18 – 65 years who were admitted in the surgical ward of Government General Hospital, Chennai. **Result and Conclusion:** The scar obtained with bioadhesive is of better quality in the 3rd month and 6th month for the test group than that of suture. Though more expensive than sutures where economically feasible Isoamyl 2 cyanoacrylate offers a well acceptable alternative to suture.

Keywords: Bioadhesives; Isoamyl-2-cyanoacrylate; Bilateral Inguinal hernia; comparative study.

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INTRODUCTION

Conventional closure of wounds with sutures is time consuming and inflicts undersigned trauma. With advancement of surgical methods came the need to use better methods of wound closure like staples and tapes. The recently invented method of wound closure technique is by using bio-adhesive, which aims to decrease the time duration of wound closure and to avoid the pain of local anaesthesia. The adhesives are moreover expected to improve the cosmetic appearance of the scar. Isoamyl 2-cyanoacrylate is a new bio-adhesive synthesized with the aim to make a tissue adhesive of good quality. Preclinical studies to ascertain its efficacy on incisional, lacerated and visceral wounds were conducted in the Madras Medical College using parameters such as histopathological, biochemical and physical tests (Tear test

using Instron). After that toxicological tests were done in Trivandrum. A combined Phase I and II clinical trial on Isoamyl-2-cyanoacrylate was conducted in Madras Medical College and its efficacy and tolerability were confirmed and now ready for comparison with sutures.

AIM OF THE STUDY

To compare the efficacy of Isoamyl-2-cyanoacrylate with sutures in patients with bilateral inguinal hernia.

JUSTIFICATION FOR THE STUDY

When bilateral hernia patients are selected between patients variables are excluded and be absolute efficacy of the bioadhesive against sutures can be monitored. Comparison with sutures was done because silk sutures are the standard material used for skin closure after performing Herniorrhaphy. When pharmaco-economic factors are to be considered sutures are cheaper than bioadhesives. Moreover the suture material in one suture pack can be used for several patients. If bioadhesives are to be useful in the Indian scenario it is imperative that they are cost effective. If the cosmetic effect is better it may be useful to use a bioadhesive in patients who can afford it. In order to do this it was necessary to carry out an efficacy study between Isoamyl-2-cyanoacrylate and sutures.

METHODOLOGY

Study design

Comparative study of Isoamyl-2-cyanoacrylate with sutures. Study population included 6 male patients with bilateral inguinal hernia in the age group of 18 – 65. Patients associated with other systemic illness like, Diabetes mellitus, Systemic hypertension, Chronic renal failure, on steroid therapy, inguinal hernia associated with Epididymo Orchitis, Obstructed and Strangulated Hernia were excluded from the study. The total duration of study was 1 year. The ethical committee’s permission to conduct the trial was obtained to conduct the trial in this college. The informed consent to participate in the trial was obtained from the patient in the regional language after explaining the entire trial to them. The patients were monitored on day 8th, 90th, 180th and 365th day. The follow up period for this phase was one year. For a total there are 6 visits for a patient. The right side wound was closed with suture and the left side wound was closed with Isoamyl-2-cyanoacrylate.

Visit 1

The patients who fulfilled the inclusion and exclusion criteria were admitted in the surgical ward of Government General Hospital, Chennai. Fitness for giving anaesthesia was obtained and informed consent to close the wound using bio adhesive was obtained in the regional language and registered for the study. Herniorrhaphy was performed and the patient was discharged on the 4th POD.

Visit 2 and 3

Happened on the 8th and 42nd POD respectively. Here the wounds were examined for any signs of infection and photographed.

Visit 4, 5, and 6

happened in the 3rd, 6th months and 1 year after surgery. Here healing was ascertained and the assessment of the quality of scar was done. Cosmesis was evaluated using Judd E Hollander Scale. The 6 parameters of the scale are, 1. Step off border. 2. Contour irregularity 3. Scar width 4. Edge inversion 5. Inflammation 6. Overall cosmesis were carefully noted and the wounds were photographed. To grade each of these parameters the following scores were used. 0-poor, 1-fair, 2-good.

Statistical analysis

Students’ paired ‘T’ test: This was used to analyse the difference in the cosmesis assessment between the 3rd, 6th and 12th months within a group Students’ unpaired ‘T’ test: this was used to analyse the between group assessments.

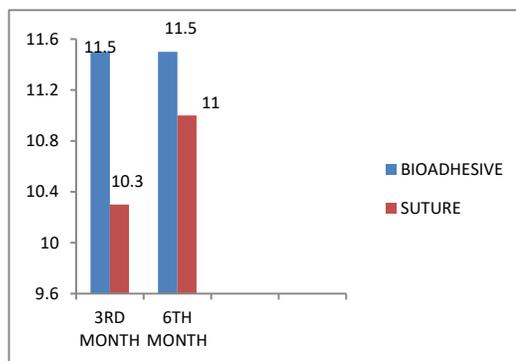
RESULTS



Figure 1: The results of cosmesis assessment for 3rd, 6th and 12th month are given in tables

According to the scale,

1. The scar obtained with bioadhesive is of better quality in the 3rd month and 6th month for the test group than that of suture.
2. The better score obtained with adhesive was statistically significant in the 3rd month using unpaired student’s t-test. P<0.05



DISCUSSION

Advantages

The time required for wound closure with the tissue adhesive is half that of the suture. There is also significant cost savings using adhesives due to reduced physician, ancillary services and reduced equipment needs. Furthermore the effect of the bioadhesive wears off after 48-72 hours without local allergic or other reactions.

Disadvantages

1. Usage of bioadhesive over the joints is not advisable as joint movement may disrupt the wound.
2. Bleeding wounds may require haemostatic sutures.
3. Carefully applied around the eye as it may cause conglutination of the cornea or the conjunctiva.
4. Cannot be used for infected wounds
5. Cannot be used to close wounds without well approachable margins.

6. Cannot be used on hands.
7. The wound bursting strength of bioadhesive is less than that of sutures.

CONCLUSION

The statistically significant superiority of the adhesive over suture was well made out in this study. Though more expensive than sutures where economically feasible Isoamyl 2 cyanoacrylate offers a well acceptable alternative to suture.

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