

Clinical evaluation of Isoamyl 2- cyanoacrylate: a novel tissue adhesive

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Abstract

Even in present day surgical practice, closure of wounds with sutures consumes more time. With advancement of surgical methods like staples and tapes which are used in closure of wounds leave a disfigured scar. Therefore it is necessary to minimise the scar as well as the time consumption with use of newer methods like bioadhesives. **Aim:** To study the effect of Isoamyl-2-cyanoacrylate on patients with surgical wounds (combined phase I and II) **Methodology:** it is a combined Phase I and II clinical trial conducted in patients of inguinal hernia in the age group of 18 – 40 years who were admitted in the surgical ward of Government General Hospital, Chennai. **Result and Conclusion:** the wound closure using bioadhesive is excellent with minimal scar formation and the difference is significant at 95% level of confidence. It is well tolerated.

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INTRODUCTION

A wise physician skilled our wounds to heal are more than armies for the common weal- HOMER

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 alternative 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 and the bio-adhesive was ready for clinical trial. So the purpose of the study is to find out the efficacy and tolerability of Isoamyl -2- cyanoacrylate in closure of wounds.

AIM OF THE STUDY

To study the effect of Isoamyl-2-cyanoacrylate on patients with surgical wounds (combined phase I and II)

METHODOLOGY

Study design: Combined phase I and II clinical trial.

Study population included 20 male patients with inguinal hernia in the age group of 18 – 40. 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 2 years. 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.

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

The results of cosmesis assessment for 3rd, 6th and 12th month weretaken. The results were analysed using students paired t-test and the difference is significant at 95% level of confidence.



After 6 weeks

After 3 months

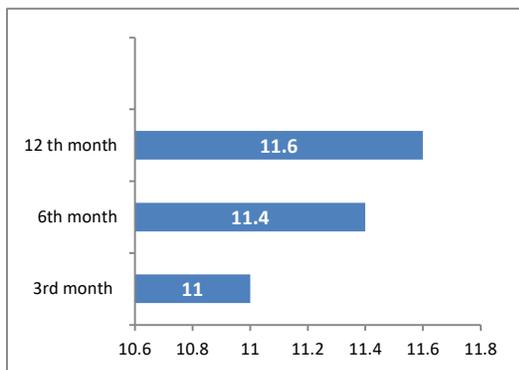
After 6 months

After 1 year

Case 1: Combine Phase I and II ISO AMYL 2-CYANO Acrylate

According to the scale,

1. The wound closure using bio-adhesive is excellent
2. The quality of scar is better at 6th month when compared to the 3rd month by using unpaired student’s t-test.
3. But there is no significant change in between one year group and 6th month group by using unpaired student’s t-test.



DISCUSSION

The time required for wound closure with the tissue adhesive is less than that required for 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. This study correlates with the study of Singer AJ *et al*, PJB Murray *et al* and Thomas B Burns, MC *et al*.

CONCLUSION

The present study confirms that Isoamyl-2-cyanoacrylate is an efficacious material for wound closure and was well tolerated. This study also generates a scope to compare the bioadhesives with sutures.

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