Research Article

A double blind randomised controlled clinical trial of Isoamyl-2-cyanoacrylate with N-butyl cyanoacrylate

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Abstract

Introduction: Closure of wounds with bioadhesives was proved to be efficacious and well tolerable. It also produces scar thinner than the sutures. Now it is require comparing the efficacy of various bioadhesives available in the market by a phase III clinical trial. **Aim:** To compare the efficacy and tolerability of Isoamyl-2-cyanoacrylate bya control clinical trial using n-Butyl cyanoacrylate as the control. **Methodology:** it is a double blind, randomised controlled clinical trial of Isoamyl-2-cyanoacrylate with n-butyl cyanoacrylate 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 scar was of better quality in the 3rd month for the test group. The increase in the scar scale was statistically significant for Isoamyl and n-butyl cyanoacrylate using paired student 't' test $p<0.05$. The difference in the scar quality between the two groups using unpaired 't' test was not statistically significant.
Keywords: Bioadhesives; Isoamyl-2-cyanoacrylate; N-butyl cyanoacrylate; Inguinal hernia; double blind.

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INTRODUCTION

When Preclinical studies were done to ascertain the efficacy of Isoamyl-2-cyanoacrylate on incisional, lacerated and visceral wounds in the Madras Medical College using parameters such as histo-pathological, biochemical and physical tests (Tear test using Instron),Followed by 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 its efficacy was also compared with sutures. Now it is the time to compare the efficacy of Isoamyl-2-cyanoacrylate with other bioadhesives commercially available.

AIM OF THE STUDY

To compare the efficacy and tolerability of Isoamyl-2-cyanoacrylate bya control clinical trial using n-Butyl cyanoacrylate as the control.

JUSTIFICATION FOR THE STUDY

Phase III clinical trials are controlled clinical trial carried out as Multicentric trial. The clinical pharmacology unit of Madras Medical College was selected by TIFAC (TECHNOLOGY INFORMATION FORECASTING AND ASSESSMENT COUNCIL, GOVERNMENT OF INDIA) to be the first centre for this study. The control selected for this trial was N-Butyl cyanoacrylate which was also a product of TIFAC and was available in the Indian market.

METHODOLOGY

It is a double blind, randomised controlled clinical trial comparing the test drug namely Isoamyl 2 cyanoacrylate with that of the available standard used as control, namely, N-butyl cyanoacrylate in order to assess its

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relative merits and demerits. Study population included 14 male patients with bilateral 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 6 months. 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 and 180th day. The follow up period for this phase was 6 months. For a total there are 5 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

Happened in the 3rd and 6th months 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 3rdand 6th months within a group. Students' unpaired 'T' test: this was used to analyse the between group assessments.

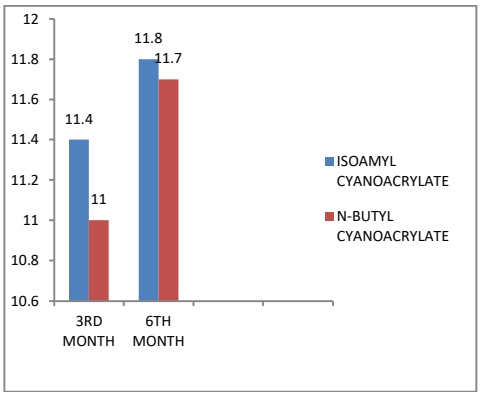
RESULTS

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

According to the scale,

1. The scar was of better quality in the 3rd month for the test group.
2. The increase in scar scale is statistically significant for Isoamyl 2 cyanoacrylate and N-butyl cyanoacrylate by using paired student's t test $p<0.05$.
3. The difference in the scar quality between the groups was not statistically significant by using unpaired student's t test.

The cosmetology scale never decrease showing that the quality always maintained. Among these patients hairline scar was obtained in 12 patients.



DISCUSSION

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. The cost of an ampoule of Isoamyl as it is locally made is not totally out of reach of the Indian public especially those who could afford it, as it finally works out cheaper when the return to hospital wound dressing suture removal are taken into consideration (indirect cost). Furthermore the effect of the bioadhesive wears off after 48-72 hours without local allergic or other reactions. However usage of bioadhesive over the joints is not advisable as joint movement may disrupt the wound.

CONCLUSION

Isoamyl 2 cyanoacrylate is proved to be an efficacious material for wound closure. The wound obtained with it is comparable with that of the existing bioadhesive namely n-butyl cyanoacrylate. In fact after 3 months the cosmetic appearance seems to be much better that that of N-Butyl cyanoacrylate even though not statistically so.

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