



TO STUDY THE EFFICACY OF ISO AMYL 2-CYANOACRYLATE GLUE FOR SUTURE LESS CIRCUMCISION OVER THAT OF THE TRADITIONAL WAY OF USING SUTURES.

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KEYWORDS :

INTRODUCTION:

Circumcision, surgical procedure documented since 2500 BC, is practised for social, cultural and medical reasons. It is the most common surgical procedure performed globally by paediatric surgeons, general surgeons, urologists and family physicians.

Circumcision is technically the removal of the foreskin from the human penis.[1] WHO estimated 33% of adult males worldwide are circumcised.[2] And out of this One-sixth of the population are circumcised on religious grounds.[3]

Circumcision may be used to treat pathological phimosis, refractory balanoposthitis and chronic or recurrent urinary tract infections (UTIs).[4,5] The finding that circumcision significantly reduces female-to-male HIV transmission has prompted medical organisations serving communities affected by endemic HIV/AIDS to promote circumcision as an additional method of controlling the spread of HIV.[6]

Conventionally circumcision wounds are approximated by absorbable sutures. This method is associated with complications. The most common ones being bleeding, post-op pain, wound infection, poor wound healing and inadequate cosmesis.

Recently alternative methods are being utilised to overcome the shortcomings of the traditionally used method for circumcision. One of them being the use of cyanoacrylate glue, a tissue adhesive.

Cyanoacrylate adhesives (patent filed 19427) are monomers that polymerise and form strong bonds via exothermic reaction in the presence of body fluids. They are bactericidal, chemically stable, easily stored making them clinically useful.[7] Approximation via cyanoacrylate glue is less time consuming, gives finer cosmesis and reduces risk of postoperative infection.

Adhesive glue is especially useful for day care surgery like circumcision. Cyanoacrylate is a better alternative to sutures and gained increased clinical popularity due to the ease of application, decreased scarring, decreased pain and better cosmetic results with no discomfort as seen with sutures getting to or snagging the clothing and dressing.

Care of wounds in its simplest form and based on contemporary knowledge evolved along with the evolution of mankind. From that time till date, enormous innovative measures and techniques in the management and closure of wounds have evolved.

A new technology that is available for wound closure is surgical adhesive. Cyanoacrylate provides patients the option of suture less skin closure and its use is fast catching up. Presently iso amyl 2-cyanoacrylate, a longer chain polymer which gives a stronger bond is in use. Several other compounds from the same family of cyanoacrylates have been developed, such as methyl cyanoacrylate, ethyl cyanoacrylate, isobutyl cyanoacrylate, and butylcyanoacrylate. Histotoxicity responsible for the degree of inflammatory response, is related to the chain length of these compounds, the last generation of these adhesives is iso amyl cyanoacrylates, which results in less heat when applied, lower inflammatory reaction and relatively higher tensile strength than the previous compounds.[9]

The Cyanoacrylates are safe for clinical use with no reports of adverse effects or carcinogenicity. [10,11,12]

The Cyanoacrylates were first synthesised in 1949 by Airdis and since then they have been applied for medical use Coove et al described their adhesive properties and suggested their possible use for surgical adhesives. In the early 1960s, various surgical applications were investigated for these adhesives. Cyanoacrylates can be synthesised by reacting formaldehyde with alkyl Cyanoacetate to obtain a prepolymer which, by heating, is depolymerized into a liquid monomer. This monomer can then be modified by altering the alkoxy carbonyl (-CooR) group of the molecule to obtain compounds of different chain lengths. Upon application to living tissues (water or base), the monomer undergoes an exothermic hydroxylation reaction that results in polymerization of the adhesive. The shorter chain derivatives. Cyanoacrylates may be very simplistically defined as solvent free, synthetic adhesives. They are reactive monomer liquids that polymerize into a film when initiated by moisture or certain chemicals. A key property of cyanoacrylates is that the monomer liquid actually polymerizes directly on the surface where it is applied, creating a high quality and a very tenacious polymer film. Cyanoacrylates typically fix within a minute and achieve full bond strength in 24 hours. [13,14]

Iso amyl 2 cyanoacrylate adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying adhesive onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimised. [21,22] If adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort. Extra caution should be taken to avoid depositing any adhesive in the wound; the adhesive will not seep into the wound since it starts to polymerize instantaneously. A common mistake is to inadvertently deposit the adhesive in the wound by pushing the tip of the vial into the wound and separating the wound edges.

METHODS AND MATERIALS

This is a hospital based observational study to be carried out in the Department of General Surgery at Smt. Kashibai Navale Medical College and General Hospital, Pune between the period September 2019-September 2021.

Type of study: Clinical investigations by randomised control trial
Study population: 100 patients (paediatric+adult)

Subject area: Surgery
Duration of study: 2 years

This study will be an open labelled randomised control trial and will be conducted in the Major Operation Theatre of Surgery Department of SKNMC and GH, Pune.

An informed consent will be taken from all patients prior to inclusion in the study. Detailed history, physical examination and laboratory workup will be done in all patients and findings will be recorded.

The sample size has been decided by the paediatric surgery unit of SKNMC based on the number of patients attending paediatric surgery OPD for circumcision. Patients will be investigated in the Out Patient Department and will be called on the day of surgery. Surgery will be done on a daycare basis. All patients included in the study will be given standard of care. It is proposed to enrol 100 patients in the study who are indicated for circumcision. This is a comparative study in which patients were studied in two groups. In the control group, the

mucocutaneous approximation was done by interrupted 3/0 (adults) or 4/0 (paediatric) chromic catgut. In the study group, iso amyl 2-cyanoacrylate glue was used for wound approximation. Mucocutaneous approximation was achieved by using a pair of toothed forceps holding the two edges of the wound firmly together.

Instructions given to patients:

- Patient should come on the day of examination with nil by mouth from 4 am on the day of surgery
- Patients will be instructed to come for follow up on 7th, 14th post op day.

Facilities and equipment used:

- Iso Amyl 2-Cyanoacrylate glue.
- Catgut 4-0/ 3-0
- Instruments required for circumcision.
- Major Operation Theatre set up.
- General and local anaesthesia

INCLUSION CRITERIA

- Paediatric patients
- Recurrent balanoposthitis
- Religious

EXCLUSION CRITERIA

- Patients less than 2 years (physiological phimosis)
- Patients with hemolytic disorder
- Patient with co-existing congenital urological problems

OBSERVATIONS AND RESULTS

Table 1) The distribution sample size studied across two study groups.

Group Code	Group Description	No. of cases	% of cases
Group 1	Glue	50	50.0
Group 2	Suture	50	50.0
Total		100	100.0

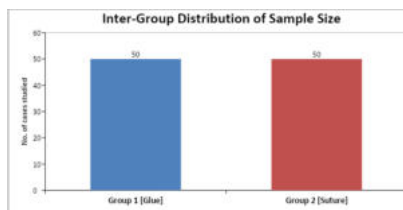


Figure 1) The distribution sample size studied across two study groups.

Table 2 Inter-group comparison of median age.

Age (years)	Group 1 [Glue] (n=50)		Group 2 [Suture] (n=50)		P-value
	Median	Min –Max	Median	Min –Max	
Age (years)	8.5	2 – 61	6.5	2 – 51	0.538N

Values are median and min - max, P-value by Mann-Whitney U test. P-value<0.05 is considered to be statistically significant. NS – Statistically non-significant.

Inter-group comparison of median age

The median age of cases in Group 1 and Group 2 was 8.5 years and 6.5 years respectively. The minimum – maximum age range in Group 1 and

Group 2 was 2 – 61 years and 2 – 51 years respectively. Distribution of median age did not differ significantly between two study groups (P-value>0.05).

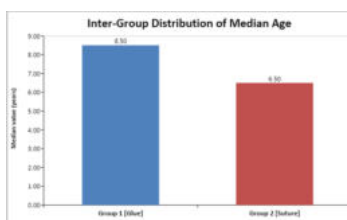


Figure 2 Inter-group comparison of median age.

Table 3 Inter-group distribution of presenting symptoms among the cases studied.

Presenting symptoms	Group 1 [Glue] (n=50)		Group 2 [Suture] (n=50)		P-value
	n	%	n	%	
Fever	0	0.0	0	0.0	0.999NS
Burning micturition	2	4.0	3	6.0	0.999NS
Ballooning of prepuce	3	6.0	2	4.0	0.999NS
Recurrent balanoposthitis	9	18.0	8	16.0	0.999NS

Values are n (% of cases), P-value by Chi-Square test. P-value<0.05 is considered to be statistically significant. NS-Statistically non-significant.

Inter-group distribution of presenting symptoms

Distribution of presenting symptoms such as fever, Burning micturition, Ballooning of prepuce and Recurrent balanoposthitis did not differ significantly between two study groups (P-value>0.05 for all).

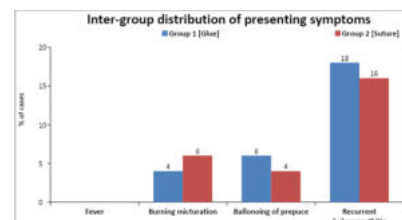


Figure 3 Inter-group distribution of presenting symptoms among the cases studied.

Table 4 Inter-group distribution of duration of symptoms among the cases studied.

Duration of symptoms	Group 1 [Glue] (n=50)		Group 2 [Suture] (n=50)		P-value
	n	%	n	%	
Since birth	29	58.0	32	64.0	0.823NS
Up to 1 year	20	40.0	17	34.0	
>1 year	1	2.0	1	2.0	
Total	50	100.0	50	100.0	

Values are n (% of cases), P-value by Chi-Square test. P-value<0.05 is considered to be statistically significant. NS-Statistically non-significant.

Inter-group distribution of duration of symptoms

Distribution of duration of symptoms among the cases studied did not differ significantly between two study groups (P-value>0.05).

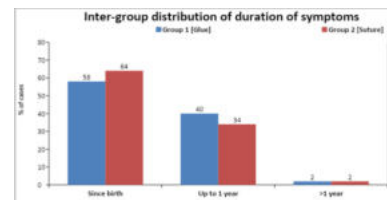


Figure 4) Inter-group distribution of duration of symptoms among the cases studied.

Table 5 Inter-group comparisons of mean duration of procedure.

Duration of procedure (mins)	Group 1 [Glue] (n=50)		Group 2 [Suture] (n=50)		P-value [Inter-group]
	Mean	SD	Mean	SD	
Duration of procedure (mins)	13.12	1.52	23.48	2.25	0.001***

Values are mean and SD, P-value [Inter-group] by independent sample t test. P-value<0.05 is considered to be statistically significant.***P-value<0.001.

Inter-group comparison of mean duration of procedure

The mean duration of procedure in Group 1 [Glue] and Group 2

[Suture] was 13.12 mins and 23.48 mins. Distribution of mean duration of procedure is significantly higher in Group 2 [Suture] compared to Group 1 [Glue] (P-value<0.05).

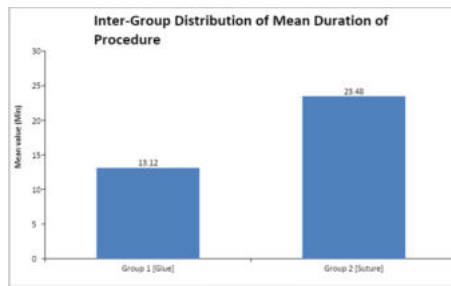


Figure 5 Inter-group comparisons of mean duration of procedure

Table 6 Inter-group distribution of incidence of post-operative complications among the cases studied.

Post-op complications	Group 1 [Glue] (n=50)		Group 2 [Suture] (n=50)		P-value
	n	%	n	%	
Seroma	3	6.0	4	8.0	0.999NS
Wound dehiscence	2	4.0	2	4.0	0.999NS
Stitch abscess	0	0.0	1	2.0	0.999NS
Stitch granuloma	0	0.0	4	8.0	0.117NS

Values are n (% of cases), P-value by Chi-Square test. P-value<0.05 is considered to be statistically significant. NS-Statistically non-significant.

Inter-group distribution of incidence of post-operative complications

Of 50 cases studied in Group 1 [Glue], 3 (6.0%) had seroma, 2 (4.0%) had wound dehiscence and none had Stitch abscess and Stitch granuloma. Of 50 cases studied in Group 2 [Suture], 4 (8.0%) had seroma, 2 (4.0%) had wound dehiscence and 1 (2.0%) had Stitch abscess and 4 (8.0%) had Stitch granuloma.

Distribution of incidence of post-operative complications such as seroma, Wound dehiscence, Stitch abscess and Stitch granuloma did not differ significantly between two study groups (P-value>0.05 for all).

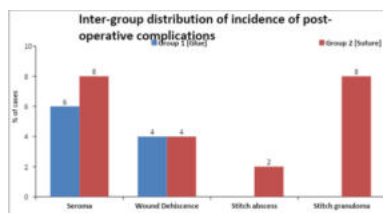


Figure 6 Inter-group distribution of incidence of post-operative complications among the cases studied.

DISCUSSION

It's tempting to suggest that infant (or at least pre-pubertal) circumcision should be encouraged to reduce the risk of penile infections and HIV, but this seems a drastic way of doing so, even if it is found that the findings of tropical Africa Are applicable to other ethnic groups. Better hygiene and safer sex can be encouraged to lessen infections. Doing Millions of circumcisions to lessen penile carcinoma seems a drastic way of reducing the incidence of an already uncommon malignancy. No-one would suggest that crude, mutilating circumcisions performed by untrained men in unsuitable surroundings are desirable, but appropriate preparation for manhood certainly is, and ways must be found of providing it in today's developing countries, as much as we need it in the West.

Traditionally, needle skin suturing with suture material is the commonest method of surgical wound closure that is being practised by surgeons because of its cost effectiveness. No doubt the cost consumed by suture material to close one unit of surgical incision is cheaper than the one consumed by adhesive glue. But if we consider the other aspects like, frequency of post operative wound care, the

length of postoperative hospitalisation and the number of postoperative consultations with the doctor which build up the cost of the procedure, it can be concluded that adhesives bring down the total cost of the surgical procedure.

In addition, nowadays surgeons are looking for faster, more comfortable and cosmetically best technique for skin closure and this obviously has thrown attention on the adhesive glues like iso amyl 2-cyanoacrylate. Iso amyl 2-cyanoacrylate provides a flexible, water resistant, sealed skin closure and also a needle free method of wound closure. This being a needle free method, guards against blood borne viral infections like HIV, HBV etcetera.

Further iso amyl 2-cyanoacrylate has some antimicrobial properties and hence bandaging can be avoided which contributes to reduction of total cost of the procedure. Iso amy 2-cyanoacrylate provides a water resistant closure and hence patients can have the comfort of having showers in the postoperative period which is not available with skin suturing method of wound closure. Patients with glue closure do not need to come back for suture removal which is not the case with skin suturing methods. Though suture removal is rarely painful, patients will have a high degree of anxiety for these procedures.

CONCLUSION

Iso amyl 2-cyanoacrylate provides an effective and reliable means of circumcision and yields similar cosmetic results as with sutured circumcision. The incidence of infection and wound complications are comparable in both the groups. In addition, iso amyl 2-cyanoacrylate provides certain practical advantages to the patients and surgeon. The advice as to which method is used for closure of wounds may come down to economics and operator preference.

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