

Tissue Glue As an Alternative Method of Skin Approximation in Patients Undergoing Circumcision – A One Year Randomized Controlled Trial

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Abstract

Background and objective: Traditionally, the circumcision wound was closed by absorbable sutures. Recently the use of tissue adhesive had evoked immense interest in the field of wound healing. This study was planned to compare tissue glue approximation with conventional suture method in terms of time consumed and incidence of infection in patients undergoing circumcision.

Methodology: This one year randomized controlled trial was performed on a total of 70 patients undergoing circumcision at Department of Urology, SS Institute of medical sciences & Research Centre, Davangere, from January 2014 to December 2014. Patients were randomized by assigning even numbers to patients in group B (skin approximation by cyanoacrylate tissue glue) and odd number to those in group A (skin approximation by suture method). Operative time was noted and patients were examined for infection and other complication on the post operative day three and seven.

Results: Majority of the patients were in the age group of three to six years (82.86% in group A and 80% in group B; $p=1.000$). The mean age was comparable in group A and B (5.51 ± 2.65 vs 5.32 ± 2.75 years; $p=0.771$). Further the clinical presentation, indications for circumcision, clinical examination findings and surgical characteristics were comparable in group A and B ($p>0.050$). Surgical time in group B was significantly less compared to group A with a difference of nearly more than five minutes (19.14 ± 5.54 vs 24.97 ± 3.93 minutes; $p<0.001$). On day three wound assessment, significantly lower rate of complications was noted among the patients with group B regard to tenderness and oedema ($p<0.050$). During day seven assessment also significantly lower number of patients had oedema and discharge in group B compared to group A ($p<0.050$).

Conclusion: Skin approximation by cyanoacrylate tissue glue results in significant reduction of surgical time with lower rates of complications compared to skin approximation by suture method.

Keywords: Circumcision; Cyanoacrylate tissue glue; Skin approximation; Suture;

I. Introduction

Circumcision is one of the most common surgical procedures carried out all over the world. It is performed for a number of therapeutic and non-therapeutic reasons. The normal penis consists of a cylindrical shaft and rounded tip (glans penis) separated by a groove, the coronal sulcus. The fold of skin (foreskin) covering the glans is removed during the circumcision procedure to a point near the coronal sulcus. Earliest description of circumcision was found in cave drawings and Ancient Egyptian tombs.^{1,2}

According to the World Health Organization (WHO), global estimates suggest that 30% of males are circumcised.³ Ritual circumcision is common in Jewish and Islamic faiths and in sub Saharan Africa. Also, it was estimated that 69 to 97% of all males in the USA are circumcised, in comparison with 70% in Australia, 48% in Canada and 24% in the United Kingdom. The reported prevalence of the procedure in the United States increased from about 30% in the 1930s to nearly 80% in the early 1970s.⁴ Nelson et al⁵ noticed a significant increase in the rate of newborn circumcision in USA, according to data taken from the nationwide inpatient sample. The increased incidence is attributed to perceived health benefits, particularly improved hygiene and reduced penile cancer.¹³ In India incidence of circumcision in general population is approximately 33%.⁶ Most circumcisions are performed during adolescence for cultural or religious reasons. The prevalence of circumcision varies mostly with religious affiliation, and sometimes due to culture.¹

Circumcision is usually performed for social, religious or medical reasons. The common medical indications for circumcision are usually seen in adults. Medical reasons for circumcision include phimosis, paraphimosis, trauma, recurrent skin infections and lesions, like preputial cysts, redundant foreskin, and dyspareunia due to short frenulum. Phimosis which means narrowing of the preputial orifice is the most common medical indication for circumcision in all age groups. Severe phimosis may cause pain on voiding, urinary retention, urinary tract infections, localized skin infections, and calculi, and later in life may be

associated with sexual dysfunction and squamous-cell carcinoma. Adhesions developing between the foreskin and the glans and preventing it to become retractile is another indication for circumcision. Secretions may collect under the foreskin producing infections and subsequent balanitis, or it may produce phimosis. Adult and adolescent circumcision in India is commonly carried out using dorsal slit method or sleeve method under local anesthesia. All the methods of adult and adolescent circumcision require suturing and dressing and absorbable sutures have traditionally been used for closure.⁷

Surgical complications of male circumcision can include excessive bleeding, hematoma formation, sepsis, unsatisfactory cosmetic effect, lacerations of the penis and injury to the glans, too little or too much of foreskin excised, meatal stenosis, urinary retention, phimosis and buried penis. Among all these complications, hemorrhage and infection are the most common complications.¹

In the modern time with the advent of elective surgery, more energy has been directed for achieving an efficient and uncomplicated healing of the deliberately inflicted wound. Every surgeon dreams of perfect wound healing while performing surgeries. Although spectacular achievements are made in science and technology in recent years, yet the oldest problem of perfect wound closure still persists. The use of tissue adhesive as an attractive alternative to sutures has recently evoked immense interest in the field of wound healing.¹

The present study was an attempt to compare tissue glue approximation with conventional suture method in terms of time consumed and incidence of infection in patients undergoing circumcision.

II. Materials and methods

The present one year randomized controlled trial was conducted in the Department of Urology, SS Institute of medical sciences and Research Centre, Davangere, over a period, from 1st January 2014 to 31st December 2014. A total of 70 patients posted for circumcision aged from one year to 70 years were divided into two groups of 35 each were studied. Patients with malignancy, immunocompromised state and hypospadias were excluded. The study was approved from the Institutional Ethical Committee, SS Institute of medical sciences & Research Centre Davangere, prior to the commencement. The patients fulfilling selection criteria were informed in detail about the nature of the study and a written informed consent was obtained. In case of children, parents / caregivers were explained about the study details and written informed consent was obtained.

Randomization was done by assigning even numbers to patients in group B (study group) and odd number to those in group A (Control group). Patients were randomized into two groups of 35 each as Group A (Patients undergoing circumcision with skin approximation by suture method) and Group B (Patients undergoing circumcision with skin approximation by cyanoacrylate tissue glue). Data such as age and history was obtained through an interview. Further these patients were subjected to clinical examination and the findings were noted on a predesigned and pretested proforma. Investigations such as Routine blood counts (Hemoglobin, total leucocyte counts, differential counts, red blood cell counts and ESR), Blood grouping, Blood urea nitrogen, Serum creatinine, Bleeding time and Clotting time were done

The operation was performed under spinal/caudal/general anaesthesia. The technique of dorsal slit followed by free hand cutting all around with sharp scissors was used in all the cases. The outer layer of the foreskin was retracted back and meticulous haemostasis was achieved.

Patients in group A underwent skin approximation by suture method using Plain Catgut 4-0 with round body needle, edge to edge, simple suture and in group B, skin approximation was done by cyanoacrylate tissue glue. The glue 2-octyl cyanoacrylate was applied in two thin layers to the cut edges and then approximated with the help of forceps on either side in arc like fashion. The glue was allowed to dry and polymerize for 20 seconds. Leakage of the glue between the edges was avoided so that hardened glue does not catch the undergarments. The time of start of skin closure and the time of finishing the skin closure were noted down using a stopwatch timer. The time taken for skin closure was noted. No liquid or antibiotic ointment applied after glue application.

All the patients in the both groups received a 5 day course of amoxycillin and ibuprofen and paracetamol in appropriate doses. Bathing of the operative site was permitted after the 5th day onwards. Patients were followed up at post operative day three and day seven. Patients were examined for infection and other complication on the post operative day three and seven. Patients were evaluated for infection by assessing redness, tenderness, oedema and discharge. Other complications like allergy and skin necrosis were noted.

III. Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean \pm standard deviation and the independent sample 't' test was used for comparison. A 'p' value of less than or equal to 0.05 at 95% confidence interval was considered as statistically significant.

IV. Results

Majority of the patients were in the age group of three to six years (82.86% in group A and 80% in group B; $p=1.000$). The mean age was comparable in group A and B (5.51 ± 2.65 vs 5.32 ± 2.75 years; $p=0.771$). Further the clinical presentation, indications for circumcision, clinical examination findings (vitals) and surgical characteristics were comparable in group A and B ($p>0.050$). Surgical time in group B was significant low compared to group A with a difference of nearly more than five minutes (19.14 ± 5.54 vs 24.97 ± 3.93 minutes; $p<0.001$). On day three wound assessment, significantly lower rate of complications was noted among the patients with group B with regard to tenderness and oedema ($p<0.050$). During day seven assessment also significantly lower number of patients had oedema and discharge in group A compared to group B ($p<0.050$).

V. Discussion

In the present study the commonest age group was three to six years comprised of 82.86% in group A and 80% in group B ($p=1.000$). The mean age of the study population was 5.51 ± 2.65 years in group A and in group B, it was 5.32 ± 2.75 years ($p=0.771$). These findings suggest that, the demographic characteristics of the study population were comparable in both the groups.

In this study the most common clinical presentation was inability to retract prepuce. In group A 80% of the patients and in group B 91.43% of the patients were unable to retract the prepuce ($p=0.172$). The ballooning of prepuce was present among 22.86% of the patients each in group A and B (1.000). Urinary tract infections were present in 14.29% of the patients in group A compared to 8.57% of patients in group B. ($p=0.452$). Few patients that is, 5.71% of children in group A and 8.57% of the children in group B were undergoing circumcision on religious ground ($p=0.673$). These findings indicate that presentation of the study population was comparable in both the groups.

In this study based on clinical examination findings, mean pulse rate, systolic blood pressure, diastolic blood pressure and respiratory rate were comparable in group A and B ($p>0.050$). In group A, 91.43% of patients and in group B 94.29% underwent circumcision under caudal plus spinal anaesthesia ($p=0.500$). Hence the study population in group A and B were comparable in terms of clinical and surgical characteristics.

In the present study mean surgical time in group A was 24.97 ± 3.93 minutes compared to 19.14 ± 5.54 minutes in group B showing a difference of nearly five minutes. This difference was statistically significant ($p<0.001$). These findings suggest that, skin approximation by cyanoacrylate tissue glue results in significantly lower operative time compared to skin approximation by suture method. In one of the first published studies evaluating octylcyanoacrylate, Quin J et al⁸ indicated that use of the skin adhesive was found to be significantly faster. Martin SF⁹ and Elmore JM et al⁹ also concluded that the skin adhesive technique is significantly faster. The findings of the present study were consistent with the results reported by Quin J et al⁸ Martin SF⁹ and Elmore JM.¹⁰ In India, Parmar HD et al¹¹ used 2-octyl cyanoacrylate for closing circumcision wounds and reported that, the mean time taken for skin closure by 2-octyl cyanoacrylate is much shorter. Recently Tiwari P et al¹² in their comparative study to compare cyanoacrylate as a better alternative to conventional suture material in terms of time consumed reported mean time taken for circumcision with tissue glue as 14.2 min (SD 2.42), whereas it was 24.4 min (SD 5.06) in case of the use of sutures. The tissue glue group took 10 min shorter than the control group. Arunachalam et al.¹³ showed that 2-octyl cyanoacrylate is cosmetically superior and its operative time is significantly less in comparison to suture group. In contrast, Cheng and Saing¹⁴ concluded that tissue glue has no significant advantage over suturing and time taken was longer in tissue glue group.

Coover et al.,¹⁵ has discovered the adhesive properties of cyanoacrylate adhesive and suggested their use as a surgical adhesive for the first time. 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 clothings and dressing.¹²

Now a day surgeons are looking for faster, comfortable and cosmetically best technique for skin closure, more over 2-octyl cyanoacrylate is easier to use and provides a flexible, water resistant, sealed skin closure. 2-Octyl cyanoacrylate provides a needle-free method of wound closure, an important consideration because needle stick injuries are avoided.¹⁶ It requires no bandaging due to its antimicrobial properties.¹⁷ For the patient side, it gives less pain during post-operative period, needs no suture or staple removal, disappears naturally as incision heals, leaves no marks and patients can even have a shower.¹⁸

In this study wound assessment on post operative day three revealed more complications in group A compared to group B. In group A, 85.71% of patients had tenderness and 42.86% had oedema compared to 31.43% and 14.29% in group B respectively. This difference was statistically significant ($p<0.050$). Though redness and discharge were high in (51.43% and 22.86% respectively) group A compared to group B (42.86% and 11.43% respectively) the difference was statistically not significant ($p>0.050$). Similar rate of complications

was noted during wound assessment on day seven that is, in group A oedema, tenderness, redness and discharge were present in 57.14%, 40%, 31.43% and 25.71% compared to 11.43%, 22.86%, 34.29% and 5.71%. However at this follow up oedema and discharge were significantly low in group B compared to group A ($p < 0.050$). These findings suggest lower rate of complications in patients who had skin approximation using cyanoacrylate tissue glue compared to suture method. Recently Tiwari P et al⁸⁹ in their comparative study reported that, tissue glue results in lower rate of wound inflammation, bleeding or hematoma rate compared to sutures. Singer AJ et al¹⁹ reported fewer cases of adhesive glue were erythematous at the end of 1st week after surgery and wound dehiscence rate of 1.6% in adhesive glue group and 0.9% in suturing group. In Toriumi DM et al¹⁰⁰ they had evaluated wound at 1st week and had not observed any complication. In a study Suture less Circumcision Using 2-octyl cyanoacrylate (Dermabond): appraisal after 18 months of experience by Elmore JM et al²¹ no patient developed wound complication.

Overall the present study showed that, skin approximation by cyanoacrylate tissue glue significantly reduces duration of operative time and reduces rate of complications significantly compared to skin approximation by suture method.

VI. Conclusion

Based on the findings of the present study it may be concluded that, skin approximation by cyanoacrylate tissue glue reduces duration of surgery and results in lower complications compared to skin approximation by suture method.

Table 1. Age distribution

Age group (Years)	Group A (n=35)		Group B (n=35)	
	Number	Percentage	Number	Percentage
3 to 6	29	82.86	28	80.00
7 to 9	3	8.57	3	8.57
10 to 15	3	8.57	4	11.43
Total	35	100.00	35	100.00

p = 1.000

Table 9. Mean surgical time

Variables	Group A (n=35)		Group B (n=35)		p value
	Mean	SD	Mean	SD	
Surgical time (minute)	24.97	3.93	19.14	5.54	< 0.001

Table 10. Wound assessment day 3

Variables	Findings	Group A (n=35)		Group B (n=35)		p value
		No	%	No	%	
Redness	Present	18	51.43	15	42.86	0.473
	Absent	17	48.57	20	57.14	
	Total	35	100.00	35	100.00	
Tenderness	Present	30	85.71	11	31.43	< 0.001
	Absent	5	14.29	24	68.57	
	Total	35	100.00	35	100.00	
Oedema	Present	15	42.86	5	14.29	0.008
	Absent	20	57.14	30	85.71	
	Total	35	100.00	35	100.00	
Discharge	Present	8	22.86	4	11.43	0.205
	Absent	27	77.14	31	88.57	
	Total	35	100.00	35	100.00	

Table 11. Wound assessment day 7

Variables	Findings	Group A (n=35)		Group B (n=35)		p value
		No	%	No	%	
Redness	Present	11	31.43	12	34.29	0.799
	Absent	24	68.57	23	65.71	
	Total	35	100.00	35	100.00	
Tenderness	Present	14	40.00	8	22.86	0.122
	Absent	21	60.00	27	77.14	
	Total	35	100.00	35	100.00	
Oedema	Present	20	57.14	4	11.43	< 0.001
	Absent	15	42.86	31	88.57	
	Total	35	100.00	35	100.00	
Discharge	Present	9	25.71	2	5.71	0.022
	Absent	26	74.29	33	94.29	
	Total	35	100.00	35	100.00	

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