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Research Article

Comparison of dermabond adhesive glue with skin suture for repair of episiotomy

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ABSTRACT

Background: The objective of the study was to compare perineal skin closure of episiotomy with cyanoacrylate adhesive glue with standard skin closure.
Methods: A prospective randomized controlled study was conducted in a tertiary care hospital. 100 primigravidae undergoing normal vaginal delivery were assigned to study and control groups. After completion of vagina mucosa and muscle suturing; in study group, skin closure was done with adhesive glue and in control group, conventional suturing done. Time taken to complete skin closure, pain perceived during and after procedure and postoperative wound healing and cosmesis of perineal area were studied.
Results: The mean time for skin closure with adhesive glue (1.16 minutes) was lesser than conventional skin suturing (3.52 minutes). 84% of study group patients perceived no pain (VAS score of 1) while 72% of patients in control group perceived mild pain during suturing. In all time intervals (during and after the procedure), pain intensity was lower in the study group (p value <0.05). The time for healing was around 4 days in the study group and around 8 days in the control group. There was no statistically significant difference in the rate of wound complications and cosmesis between the groups.
Conclusions: Findings of the study support the safe and efficacious usage of cyanoacrylate adhesive glue for episiotomy skin closure. Cyanoacrylate adhesive glue is a superior alternative to conventional skin suturing shorter time, less pain during and after the procedure. Wound healing and cosmesis are comparable with both adhesive glue and suturing.

Keywords: Episiotomy skin closure, Cyanoacrylate adhesive glue

INTRODUCTION

Episiotomy as a procedure needs no introduction to obstetricians. Though its restrictive use has been recommended in recent reviews, it continues to be a commonly performed procedure, and lies at the core of obstetric practice and a woman's experience of childbirth.[1]

In an effort to reduce procedure-related morbidity and improve cosmesis, there have been various attempts to modify and improve the technique of episiotomy.[1,2] These range from the use of hyaluronidase injections to non-suturing of perineal skin.[3] However, data has been insufficient and a Cochrane review in 2000 described the need for prospective studies involving cosmetic results of perineal skin.[1] Traditionally, the perineal skin is sutured using absorbable synthetic suture materials. However, recent advances have given us more options such as tissue adhesives, one of which is cyanoacrylate. Octyl-cyanoacrylate is a medical grade tissue adhesive that has been recently approved for closure of surgical incisions and lacerations. The reported advantages are negligible histotoxicity, improved cosmesis and shorter time for repair. A meta-analysis performed on all clinical trials using octyl-cyanoacrylate in a variety of surgical

indications and specialties showed a positive benefit. Though it has been used in other specialties extensively, its use in obstetrics is far more anecdotal.[4-6] This study was undertaken to find the utility of application of adhesive glue in episiotomy skin closure, and to compare it with the standard method of closure to find its superiority, if any, over the suture materials used today.

The objective of the study was to compare perineal skin closure of episiotomy with Dermabond® cyanoacrylate adhesive glue (CAG) with the standard skin closure using vertical mattress sutures of Polyglactin 910 (Rapide Vicryl® No1-0) with respect to following parameters:

- Time taken to complete the overall procedure and time taken to complete the skin closure.
- Pain perceived during and after the procedure.
- Post-operative healing of the wound, wound complications (if any), and cosmesis of the perineal area.

METHODS

This was a prospective randomized cohort study over a period 18 months from June 2012 to November 2013 in a tertiary care hospital, with 50 patients each in the study and control groups. The study was initiated after Institutional Ethics Committee permission.

The study included primigravidae of any age who had a full term normal delivery, with mediolateral episiotomy, with no extension or tears of the vagina or perineum. Exclusion criteria were patients who had an instrumental delivery, those with local infectious lesions, body mass index >35 kg/m2 or preexisting medical disorders.

Patients were enrolled in early labour; the study was explained to them and consent was taken. Medical and obstetric histories were noted, and labour records were maintained as per the usual institutional obstetric practice. Patients were allotted to study or control group by simple alternate randomization. In both groups, a mediolateral episiotomy was taken, and suturing of episiotomy was initiated as soon as the placenta was delivered. Skin closure was performed with CAG or vertical mattress sutures, as described below.

Study group

The episiotomy was repaired using the standard technique till subcutaneous tissues and hemostasis was confirmed. Skin was then cleaned and dried. Following this, CAG pen was removed from its pack under aseptic precautions. The cap of the pen was removed and tip of the glue pen was touched to the upper edge of the incision. The button on the glue pen was pressed to release the glue. Glue was applied from crown (upper edge) downwards to the tail (lower edge) of episiotomy. As the CAG pen is for single use application, the pen with any residual glue was discarded after use. Wound was allowed to air dry; typically this took around 2 to 3 minutes after the procedure. Time required to complete the suturing of the two inner layers (mucosa and muscle) and skin closure were separately noted.

Control group

The episiotomy was repaired using the standard technique. All the three layers of the episiotomy i.e. the mucosa, muscle and the skin were closed with Polyglactin 910 (Rapide Vicryl No.1-0). Skin was closed with vertical mattress sutures. Time required for completing the suturing of mucosa and muscle, and skin closure was separately noted.

Patients in both groups were explained about care of episiotomy, including the need to keep the area clean and dry. Standard antibiotics as per hospital policy and analgesia were given to both groups. Daily assessment of the patients till day 3 after procedure was done for pain, condition of wound, and healing of the wound.

Intensity of pain as perceived by the patient was assessed on visual analog scale (VAS), ranging from 0 - 5 in order of increasing severity, with 0 being no pain to 5 representing severe pain. This was noted at the completion of the procedure, and subsequently on days 1, 2 and 3 post-delivery. Patients from both groups were studied till discharge from hospital and subsequently followed up in OPD one week after discharge.

Statistical methods

Association between qualitative variables was assessed by chi-square test. Fisher exact test was used where p-value of chi-square test was not valid due to small counts. For change in quantitative variables over time, Wilcoxon signed rank test was used. Quantitative data was represented using mean±SD and median. Analysis of quantitative data between two groups was done using unpaired t-test and Mann-Whitney test. P-value of <0.05 was taken as significant. SPSS Version 17 was used for analysis.

RESULTS

Age: Majority of the patients in both the groups were between 22-25 years of age, with a mean age of 24.1 years.

Gestational age: 82% patients in the study group and 88% of patients in the control group were at term. The median gestational age was 39 weeks in both groups.

Time taken to initiate suturing: Episiotomy suturing was initiated within 5 minutes of delivery of placenta in more than 50% patients in both the groups. Mean time required for initiation of suturing after removal of placenta was 4.92 minutes in the study group and 5.32 minutes in the control group. There was no statistical difference in "time

taken to initiate suturing" in the two groups. (P-value 0.585).

Time taken to complete suturing of mucosa and muscle: Closure of mucosa and muscle in both groups ranged from 5 to 8 minutes; study and control group required mean time of 6.88 minutes and 5.94 minutes, respectively, which was not statistically significant. (P value 0.618).

Time taken for skin closure: The mean time for skin closure with CAG was 1.16 minutes while with suture it was 3.52 minutes. In 76% of study group, skin closure took 2 minutes or less, while in only 14% patients from control group skin suturing was completed within 2 minutes. The difference in mean time was 1.36 minutes, which was statistically significant (P value < 0.05) as shown in Table 1.

Table 1: Duration of skin closure.

Duration of skin closure in minutes	Study group	Control group
1 to 2	76%	14%
3 to 4	22%	66%
≥ 5	2%	20%

Pearson's chi-square test: p value <0.05

Table 2: Visual analog score for pain.

VAS	During procedure		Day 1		Day 2		Day 3	
	Study group	Control group	Study group	Control group	Study group	Control group	Study group	Control group
1 (least /no pain)	42	8	43	12	45	15	42	20
2	8	36	5	35	3	34	0	29
3	0	5	2	2	2	0	6	0
4	0	1	0	1	0	1	2	1
5 (severe pain)	0	0	0	0	0	0	0	0

Pain intensity during the procedure: Majority of study group patients (84%) perceived no pain during the CAG procedure (VAS score of 1) while majority of patients in control group (72%) perceived mild pain during suturing (VAS score of 2), as shown in Table 2. The mean pain intensity during the procedure and on days 1, 2 and 3 after procedure for both the study and control groups (Table 3) were compared. At all time intervals, pain intensity was lower in the study group, which was statistically significant (P value <0.05) as shown in Table 3.

Table 3: Pain intensity during and after the procedure.

	Study group		Control group	
	Mean	SD	Mean	SD
During procedure	0.16	0.37	0.98	0.59
Day 1	0.18	0.48	0.84	0.58
Day 2	0.22	0.71	0.74	0.57
Day 3	0.26	0.90	0.64	0.60

Mann-Whitney test applied: P value <0.05

The change in pain intensity over time in each of the groups was evaluated. In the study group, since the pain intensity was low during the procedure itself, the change over time was not statistically significant (Wilcoxon signed rank test; P-value 0.808). However, in the control group, since the pain intensity was high initially, the change over time showed statistical significance (P-value 0.002).

Wound healing and complications: Though the number of patients with wound disruption was more in the study group, there was no statistical difference (P-value 0.678) between the overall wound complications in the two groups. Four patients with disruption in study group and one in control group required secondary suturing which was done after readmission. Thorough debridement and daily dressing of the wound was done till it was healthy for re -suturing (Table 4).

Table 4: Wound complications.

Wound complication	Study group	Control group
Hematoma	0	2%
Wound disruption	8%	2%
None	92%	96%
Total	100%	100%

Fischer exact test applied. P value - 0.678

Cosmesis: Although two patients in control group had poor cosmesis (one mal-approximated wound and one thick scar, as identified visually by the examiner) as compared to none in study group, the overall cosmetic results were not statistically significant, as seen in Table 5 (p value 0.187).

Time for healing: As seen in Table 6, the average time for wound healing in majority of the patients in study group was 4 days while in control group it was 8 days. This difference was statistically significant (P value< 0.05).

Table 5: Cosmesis.

Cosmesis	Study group	Control group
Wound disruption	8%	2%
Thick scar	0	2%
Mal-approximation	0	4%
None	92%	92%
Total	100%	100%

Pearson chi square test: P value-0.187

Table 6: Time for wound healing.

Days for wound healing	Study group	Control group
1 to 2	10.9%	6.1%
3 to 4	89.1%	0.0%
5 to 6	0.0%	20.4%
7 to 8	0.0%	73.5%

Pearson chi square test: P value <0.05

DISCUSSION

A good material for skin closure is one which takes lesser time for application, causes less pain to the patient during and after the procedure and has good healing and cosmetic properties; this was the rationale of the present study and the few prior prospective studies conducted elsewhere.

Episiotomy closure consists of closure of mucosa, muscle and skin. The duration for initiation of suturing and duration of suturing of mucosa and muscle layers was noted and compared, which showed no statistical significance. This supports the comparability of the skin closure parameters between the study and control groups.

The results of our study suggest that skin closure is faster when CAG is used for episiotomy. In a prospective study reported from Israel, Adoni et al compared episiotomy skin wound repair using either tissue adhesive or suture material in approximatley 100 patients in each group. The closure times for the adhesive group were faster than in the control group.[7] Mota et al and Switzer et al also reported similar conclusions regarding the superior time efficacy of adhesive glue material.[8,9]

In our study, CAG use was associated with significantly less pain during skin closure and in the first three postnatal days. Bowen et al reported comparable findings from their prospective study, in which two groups of around 30 subjects each were compared. Episiotomy skin wound was repaired using either tissue adhesive (enbucrilate) or polyglycolic acid suture. On comparison of pain scores, the adhesive glue group patients were found to have significantly less pain during the procedure, in postnatal period, and were pain- free in a shorter period of time.[10] Mota et al and Adoni et al also concluded that tissue adhesive material is less painful, both during and after the episiotomy procedure.[7,8] Visual analog scale was used to rate the pain in all these studies, including ours.

In the present study, wound healing was completed in 4 days in 89.1% in study group, which was significantly better than the control group where healing took upto 8 days in majority (73.5%). Similar results were reported by Adoni et al (3 days for wound healing) and Bowen et al (4 days).

When wound complication rates were analyzed, a randomized prospective study by Switzer involving around 22 subjects each in CAG and suture groups reported a higher complication rate in the study group. However, both Mota and the present study found similar complication rates in both the study and control groups.[8] Though ease of application, shorter time, less pain during and after the procedure with CAG are superior to conventional skin suturing, the expected outcome of superiority in wound healing and cosmesis have not been found convincingly in any study, including ours. This may be explained by the inherent differences in skin characteristics in locations other than the perineal skin, and practical difficulties in keeping this area clean and dry in the immediate postpartum period.

The use of CAG in the Indian scenario for episiotomy has hitherto not been studied. Our findings support the safe and efficacious usage of cyanoacrylate adhesive glue for episiotomy skin closure, CAG is a superior alternative to conventional suturing, with statistically better time-efficiency and pain scores. However, due to short follow up of our cases, the effect of CAG for parameters such as dyspareunia remains to be studied; and long term studies deserve merit.

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