

Original Research Article

Pain intensity and sexual satisfaction: a comparison of cyanoacrylate adhesive glue and vicryl for episiotomy skin closure in Kano Nigeria

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ABSTRACT

Background: Episiotomy is a deliberate incision made on the perineum and posterior vaginal wall during vaginal delivery. Mothers that have a new baby are in great need for wound care and pain relief. We assessed and compared pain intensity and sexual satisfaction using cyanoacrylate adhesive glue and vicryl for episiotomy skin closure at AKTH, Kano Nigeria.

Methods: A randomised control trial was conducted among 100 women who had spontaneous vaginal delivery in the labour ward of AKTH from June to October 2019 after randomization into study group I and control group II. Cyanoacrylate and vicryl were used for skin closure following episiotomy and the patients were followed up for pain and sexual satisfaction for 14 days. Data were analysed using SPSS version 21.0 and $p < 0.05$ was set statistically significant.

Results: The mean±SD ages of the women in the study and control groups were 22.71±9.14 and 23.66±9.00 years, respectively. In group I 84% perceived no pain and 72% perceived mild pain in group II during cyanoacrylate adhesive glue procedures. At all-time intervals, pain intensity was lower in group I ($p < 0.05$). A significant difference was observed regarding sexual function between group I and group II ($p < 0.001$) but the difference was not significant in other cases.

Conclusions: Cyanoacrylate glue compared to Vicryl was found to be effective in reducing short-term pain, the need for analgesia and better sexual satisfaction following episiotomy after childbirth.

Keywords: Cyanoacrylate glue, Episiotomy, Kano, Pain intensity and sexual satisfaction

INTRODUCTION

Episiotomy is a surgical procedure made in the tissue between vaginal opening and the anus during childbirth to widen the opening of the vagina to aid difficult delivery and prevent rupture of tissues. Episiotomies are known to provide the following benefits; speed up the birth, prevent vaginal tears, protect against incontinence, protect against pelvic floor relaxation and fast healing.¹ However, there are many ways to close the vaginal opening during childbirth to secure haemostasis and restoration of anatomical structure at site of the opening without

additional suture.² Episiotomy 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.^{3,4} The advantage of an episiotomy is that it substitutes a clean cut for a ragged tear, minimizes pressure on the fetal head, and may shorten the last portion of the second stage of labour.^{3,5}

Various interventions were reported to reduce episiotomy pain and enhance the healing process which include administration of analgesics, cleanliness, topical

application by dry heat and moist heat, perineal care and complementary therapies.⁶ Most of the mothers who had undergone normal and instrumental delivery with episiotomy had complaints of pain, discomfort, wound infection and suture site and delayed healing. Mothers are in great need for relief from pain and discomfort for effective breast feeding and provision of baby care. This motivated the investigator to use cyanoacrylate glue for promoting pain relief and healing of episiotomy wound.⁷ An epidemiological study of the National Childbirth Trust in 2001 produced figures for episiotomy between 1940 and 1980 episiotomies became routine in the US and, to a lesser extent, in the United Kingdom and Australia. By 1979, episiotomies were performed in 63% of vaginal births in the US. The percentage of episiotomy was found to be 15% in England, 13% in Scotland, 10% in Wales and 22% in Northern Ireland.⁴ There was however a considerable international variation in the rate of episiotomy. According to the Royal College of Obstetricians and Gynaecologists (RCOG), it was 8% in Holland, 14% in England, 50% in the USA and 99% in Eastern Europe.⁴ In 2005 at India 23% of women report health problem in first month after delivery related to episiotomy as perineal tear, urinary incontinence, and uterine prolapse, in 2010 the overall rate of episiotomy was 40.6% in India.⁸ but in a 3 year review on the prevalence of episiotomy in a tertiary hospital in north-western Nigeria, reported a prevalence of 44.7%.⁹

A study conducted to characterize and measure perineal pain in puerperal primiparous undergoing episiotomy using the Brazilian version of the McGill questionnaire. The mean pain level was 4.2 and the intensity of perineal pain was noted to be moderate.¹⁰ Synthetic cyanoacrylate was approved by WHO in 26 August 1998, for topical skin approximation-Derma bond. Since then, the WHO has also approved 2 more cyanoacrylate tissue adhesives for topical skin approximation. In general, changes in the alkyl side chain (-R) of the cyanoacrylate adhesive will determine its properties such as the rate of degradation, rate of polymerization (with release of heat in the process), toxicity, flexibility, and the properties of the adhesive formed. The polymerized monomers are designed to slough off from the skin as the wound reepithelialises usually within 5-10 days.¹¹

This study was done to assess the comparison of cyanoacrylate adhesive glue with vicryl 2/0 for pain intensity and sexual satisfaction following episiotomy skin closure and the findings can help in identifying their benefits.

METHODS

Study area

Aminu Kano Teaching Hospital, Kano is one of the tertiary health institutions in the metropolis of Kano State, North Western Nigeria. It has about 660 beds and was established in 1988. The hospital services clients from

within Kano and the neighbouring states of Jigawa, Katsina, Kaduna, Bauchi, Kebbi, Sokoto and Zamfara States. Majority of the patients are indigenous Hausa and Fulani, although the Igbo and Yoruba ethnic groups also constitute a substantial proportion of the clients. Most of the people are traders, farmers, businessmen and civil servants. The hospital has about 5500 deliveries every year with an episiotomy rate of 41.4%.⁹

Study design

A randomized controlled clinical trial was used.

Study population

Consenting women undergoing normal vaginal delivery and had episiotomy performed in the labor ward of Aminu Kano Teaching Hospital, Kano were included and those with previous existing local infections or lesions in the perineum, HIV disease, diabetes mellitus, immunosuppressive treatment and perineal tear other than episiotomy were excluded.

Sample size determination

The minimum sample size required was calculated using the formula for randomized clinical trial.⁷ with $Z_{\alpha} = 1.96$, the probability of type II error (β) of Power set at 80%=0.84 and δ = standard deviation 1.195. After Adding 10% expected attrition, a total of 50 subjects were required in each group.

Sampling technique

Women who fulfilled the eligibility criteria and consented to participate in the study were randomized in to two groups: group 1 (study group) and group II (control group).

Fifty pieces of paper were marked group I and another 50 were marked group II. These pieces of paper were mixed thoroughly, and each placed in serially numbered 100 opaque envelopes (randomization) which were kept in a box.

Allocation was done by opening a sealed opaque envelope, thus allocating the patients in to I of II groups. The sealed envelopes were secured and placed in the labor room. The matron in the labor room who was not involved in the study opened the envelopes serially as the patients were prepared for episiotomy repair until completion of the study. Neither the surgeon nor the participants were aware of the allocation of participants to any particular group prior to opening of the envelopes.

Study period

The study was conducted from June 2019 to October 2019.

Group I (study group, cyanoacrylate adhesive glue)

This group comprised of 50 patients. The episiotomy was repaired using vicryl 2/0 on vaginal mucosa by continuous suture up to the muco-cutaneous junction at the fourchette, the muscles was sutured using two to three interrupted stitches with the same vicryl 2/0 till haemostasis was confirmed. Skin was cleaned and dried. Following this, the cyanoacrylate adhesive glue (CAG) which is colourless gel in a 10 gm tube with a separate pen was moved from its pack under aseptic precautions. The cap of the pen was removed, and tip of the glue pen touched to the upper edge of the incision. The bottom of the glue pen was pressed to release the glue. Glue was applied from the tip (upper edge) downwards to the tail (lower edge) of the episiotomy. A gentle pressure was applied on the wound edge using the right index and thumb. As the pen was for single use application, the pen with any residual glue is discarded after use. The wound was then allowed to dry. The time taken from the commencement to the completion of the episiotomy repair was noted.

Group II (control group, vicryl 2/0)

The episiotomy was repaired using the standard technique. Vicryl 2/0 was applied on vaginal mucosa by continuous suture up to the muco-cutaneous junction at the fourchette, the muscles were sutured using two to three interrupted stitches with the same vicryl 2/0 till haemostasis was confirmed. Skin was repaired using subcuticular suturing technique with vicryl 2/0. The time taken from the commencement to the completion of the episiotomy repair was noted.

Data collection method

Structured pre-tested questionnaires were administered to obtain information about the personal data and other relevant information about the study participants after taking history and physical examination of the patients enrolled in the antenatal clinic between 38 to 40 weeks. In both groups a medio lateral episiotomy were given and suturing of episiotomy was initiated as soon as the patient had delivered. Skin closure was performed with cyanoacrylate glue or continuous sub-cuticular suture as described above with primary outcome measure by self-assessment of perineal pain during and within the first three days of the procedure and secondary outcome measures by assessing the wound complications, cosmetics, time for wound healing and sexual satisfaction.

Post-operative follow-up

The postoperative period commenced immediately after the completion of the skin closure. Patient in both groups

were managed according to departmental protocol. Pain was assessed using the visual analogue score for pain on day 1 and 3 for pain intensity, patient was given a copy of the visual analogue score sheet to guide them on answering question via a telephone interview for those that couldn't come on day 3 for assessment. Wound complication, healing cosmetics were assessed on days 7 and after 2 weeks while sexual function was assessed using female sexual function index (FSFI) six weeks after the procedure during which time women normally resume coitus in our environment according to culture and tradition. Patients were followed up at two and six weeks respectively in postnatal clinic according to departmental protocol. Both the patients and their husbands telephone numbers were collected, and the cost of their transportation and the telephone calls were shouldered by the investigator. Pictures were obtained pre and post-operative respectively.

Data analysis

SPSS version 21.0 was used for the analysis after entering the data into excel sheet for checking errors and consistency. Descriptive statistics was used to determine the frequencies and percentages of the demographic variables, also frequency distribution and percentages were used to assess the pain intensity and sexual satisfaction among the study and control group.

Association between qualitative variables were assessed by Chi-square test or Fisher exact test as appropriate and associations between quantitative values were by Mann Whitney U test. Quantitative data is represented using mean \pm SD and median. P value of <0.05 was considered significant.

Ethical approval

Ethical approval for the study was obtained from Aminu Kano Teaching Hospital Health Research-Ethics Committee. The consent was obtained from all the women that participated in the study. The Helsinki declaration was respected throughout the research.

RESULTS

Socio-demographic characteristics

The mean ages (\pm standard deviation, SD) of the women were 22.71 \pm 9.14 and 23.66 \pm 9.00 years in the study and control group respectively. In the study group 84% of women were primigravida and 16% were multigravida. In the control group 82% were primigravida and 18% were multigravida but in terms of education 34% and 38% in the study and control group had secondary level of education.

Table 1: Socio-demographic characteristics.

Demographic variables		Groups			
		Study		Control	
		Frequency	Percentage	Frequency	Percentage
Age (years)	<20	11	22	7	14
	20-25	25	50	26	52
	26-30	14	28	15	35
	>30	0		2	4
	Mean±SD	22.71±9.14		23.66±9.00	
Parity	Primi	42	84	41	82
	Multi	8	16	9	18
Education	None	2	4	3	6
	informal	12	24	9	18
	Primary	13	26	12	24
	Secondary	17	34	19	38
	Tertiary	6	12	7	14

Table 2: Pain intensity.

VAS	Day 1			Day 3		
	Study group	Control group	P value	Study group	Control group	P value
1*	43	15	0.001	42	20	0.03***
2	5	34	0.083	0	29	0.82
3	2	0	0.001	6	0	0.057
4	0	1	0.024	2	1	0.001***
5**	0	0	0.001	0	0	0.001***
Mean	1.13±0.3	2.3±1.2		1.02±0.43	2.15±1.66	

*least pain **severe pain ***statistically significant.

Pain intensity

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 2) were compared. At all-time intervals, pain intensity was lower in the study group,

which was statistically significant (p<0.05). None of the patients in both the groups experienced moderate to severe pain. Yet 53% of patients in the control group experienced mild pain while none in the study group experienced even the mild pain. Similarly, no one in the study group required analgesic, while 17% of the patients in the control group required analgesic. Statistically significant correlation was found in the study group in terms of pain perception and analgesic requirement (p<0.05) as shown in Table 2.

Table 3: Mean score of sexual function.

Variables	Groups		Test results	
	Study	Control		
Sexual function	26.11±4.36	26.38±4.41	t= -0.66	P=0.509(b)
Libido	3.60 (1.20)	3.60 (1.20)	Z= -0.47	P=0.638 (a)
Sexual arousal	3.90 (1.20)	4.20 (1.50)	Z= -1.71	P=0.087(a)
Vaginal lubrication	4.80 (1.50)	5.10 (1.50)	Z= -1.87	P=0.062(a)
Orgasm	4.80 (1.60)	4.80 (1.60)	Z= -0.11	P=0.913(a)
Satisfaction	5.20 (1.20)	5.20 (1.20)	Z= -0.19	P=0.846(a)
Pain	4.00 (1.20)	4.00 (1.60)	Z= -0.22	P=0.827(a)

(a)Non-normal variables with median (interquartile range); (b)Normal variables with Mean±SD.

Sexual function

In the paired comparison of the groups, the results of Mann-Whitney U test marked a significant difference regarding sexual function between the study and control group; however, the difference was not significant in other cases. Better sexual function was observed in the subjects with calm environment during intercourse compared to the other participants ($p < 0.001$).

Sexual function had no significant difference between subjects with and without a calm environment during intercourse. Based on the findings of independent t-test, need for consultation about sexual issues was associated with low score of sexual function ($p < 0.001$). This test also revealed an association between sexual function and onset of intercourse. The results of independent t-test and Mann Whitney U demonstrated that mean score of FSFI and its components were not significantly different in the study groups (Table 3).

Dyspareunia

Data could not be collected from 3 and 8 patients of the study group and control group respectively, because they were yet to resume their sexual life by 6 weeks postpartum. There was no statistically significant difference in the rate of dyspareunia between the two groups (12.4% versus 10.7%) among those that had sexual function as shown in Table 4.

Table 4: Dyspareunia at six weeks.

Dyspareunia	Study group	Control group	P value
Yes	6 (12%)	6 (12%)	0.091
No	41 (82%)	36 (72%)	0.125

*Statistically significant

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 no effect on sexual intercourse following the procedure. In this study, CAG use was associated with significantly less pain during skin closure and in the first three postnatal days. Similarly, 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 (Dermabond) 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. Mota et al and Adoni et al also concluded that tissue adhesive material is less painful, both during and after the episiotomy procedure.^{12,13} Visual analogue scale was used to rate the pain in all these studies, including this study.

Though ease of application, shorter time, less pain during and after the procedure with CAG are superior to conventional skin suturing but the use of CAG in the Nigerian scenario for episiotomy has hitherto not been studied.¹⁴ The finding of this study supports the safe and efficacious usage of cyanoacrylate adhesive glue for episiotomy skin closure. CAG appears to be a superior alternative to conventional suturing, with statistically better time efficiency and pain scores. Participants were asked about time to sexual resumption 6 weeks postpartum. Sixty-two percent had resumed intercourse at 6 weeks. The time range of resumption ranged from 2 to 6 weeks, with a median of 8 weeks. This question on resumption was therefore a retrospective question for many respondents, and answers may have been influenced by recollection bias. On the other hand, most respondents (83%) were primiparous, and one might argue Multiparous women would be more aware than primiparous women of the time they choose to resume or attempt resumption of intercourse after a first delivery, and perhaps especially after having experienced a surgical intervention with episiotomy.

The main finding of episiotomy being the strongest predictor for postponed coital resumption in multivariate analyses is of great value whatever way this information was collected.¹⁵ For the respondents, the resumption question will be a retrospective question at any given time interval, unless participants are to be encouraged to give notice at the time, they actually resume coitus, which is unlikely to be feasible.

The questions concerning dyspareunia, could only be responded to by women who had resumed coitus. In the 6 weeks follow-up study, dyspareunia was defined as "pain during intercourse". Most of the pain experiencing women reported pain to occur during coitus, but no significant difference among different episiotomy techniques and coital pain was found. One can however argue that the pain experiencing women in this study at 6 weeks postpartum were few and that larger studies are needed to validate the findings. Few studies have addressed female sexuality after episiotomy, and even fewer in a long-term perspective of more than 6 weeks. In the Study dyspareunia was addressed both as "pain at the vaginal introitus during coitus" and as "deep penetration pain". Dyspareunia and coital difficulties were assessed 6 weeks postpartum

Despite lacking information about potential sexual problems prior to delivery, the conclusion of Episiotomy being an independent and strong predictor for postponed coital onset as well as for dyspareunia six weeks postpartum, seems justified.

There are some limitations of the study. Majority of the women (70%) are primiparous and have no prior postpartum sexual experience to make a better comparison. Some of the women (18%) have not resume coitus at the six weeks follow up period.

CONCLUSION

Pain intensity was lower in the study group and no one required analgesic but significant percentages of the patients in the control group experienced mild pain and few patients required analgesic. Cyanoacrylate glue compared to vicryl 2/0 seems to be effective in reducing short-term pain, need for analgesia and better sexual satisfaction following episiotomy repair after vaginal delivery, hence there is no need for suture removal. The study therefore, if the findings utilize will reduce waiting time for episiotomy repair and the number of follow up postpartum because cyanoacrylate glue can be applied by lower cadre health care workers.

What is already known on this topic?

Study on pain intensity and sexual satisfaction by comparing used of cyanoacrylate adhesive glue and vicryl 2/0 for episiotomy skin closure was previously studies Nigeria.

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