Original Research Article

Efficacy of Octyl-Cyanoacrylate Dermabond Adhesive Glue versus Polyglactin 3/0 Suture for Closure of Caesarean Section Skin Incision - A Prospective Randomised Controlled Trial

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Abstract

This was a prospective randomised controlled trial conducted at a tertiary hospital on 82 women who underwent caesarean section aiming to assess the efficacy of octyl-cyanoacrylate tissue adhesive glue versus polyglactin 3/0 suture for the closure of caesarean sections skin incision. The study group consisted of 41 women who underwent skin closure using octyl-cyanoacrylate tissue adhesive glue, whereas 41 women in the control group had subcuticular skin closure using polyglactin 3/0 sutures. The choice of anaesthesia, prophylactic antibiotic, operative technique, and immediate post-operative oral analgesia was standardised between the two groups. Time taken for skin closure, pain score at day 2 and 14, the total analgesia dose needed and duration (day two onwards), and any adverse events were recorded. The time required for skin closure was significantly less in the study group, with a mean difference of 97.7 seconds (170.8 seconds vs 268.5 seconds, $p<0.001$). Pain scores on day 2 were similar between the two groups (4.0 vs 5.0, $p=0.09$), whereas pain score on day 14 was significantly lower in the study group (2.0 vs 4.0, $p<0.001$). The median duration (day two onward) of oral analgesia use was four days in the study group and six days in the control group. The difference was statistically significant ($p=<0.001$). The median amount of additional analgesia required was a third less in the tissue adhesive group than in the control group. On day 14, surgical site infection was similar in both groups. In conclusion, octyl-cyanoacrylate tissue adhesive glue may safely close a caesarean section skin incision. It was associated with faster application, lesser pain score, and lesser need for analgesia without additional adverse events compared to the conventional suturing method.

Keywords: Caesarean section; polyglactin 3/0; skin closure; subcuticular, tissue adhesive glue

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Introduction

A simple, efficient, quick, and cost-effective way of wound closure while keeping wound cosmesis and patient satisfaction is always the wish of a surgeon (1,2). This has always been a challenge. Closure of wounds was reported as early as 1100 BC when abdominal incisions on mummies were closed using leather ligatures (3). Ancient catgut was the suture of choice previously, but it had the greatest tissue reaction. Newer inventions in wound closure have resulted in fewer tissue reactions, namely synthetic sutures, adhesive tapes, staples, and, in the recent past, cyanoacrylate tissue adhesives.

Given the increasing number of caesarean sections performed, there has been increasing attention to improve and optimise surgical techniques and outcomes (1,4). Nowadays, the majority of caesarean sections are done using transverse suprapubic (Pfannenstiel) incision. A transverse incision has the advantages of having better strength, better healing outcomes, and potentially lesser infection rate than vertical midline incisions (4-6). Poor healing or non-

healing of caesarean section wounds may be perceived as a serious complication as women nowadays tend to concentrate on the cosmetic aspects of the scar (7).

Skin closure after a caesarean section is commonly performed using synthetic absorbable undyed sutures sized 3/0, and polyglactin 910 is one of them. It is the second synthetic absorbable suture introduced after polyglycolic acid. It is a braided, absorbable suture and has similar in many of its characteristics to polyglycolic acid. It retains 50-65% of its tensile strength at two weeks. It elicits a minimal inflammatory reaction with complete absorption by hydrolysis.

Cyanoacrylates were initially synthesised by a German chemist in 1949 (8). Wound closure with cyanoacrylate was then reported 10 years later (9). N-butyl-cyanoacrylates were the initial form of cyanoacrylates used in wound closure, which was only limited to small, low-tension lacerations and incisions. Over the years, with the advancement of technology, a stronger and more flexible 8-carbon 2-octyl cyanoacrylate (Dermabond) was developed in 1998. This marked a significant achievement in the field of wound closure. The reported breaking strength was four times greater than N-butyl-2-cyanoacrylate and may be indicated for various wound types (10). It has consistently been demonstrated to be comparable with other standard wound closure devices and has obtained approval from the FDA (11,12). It is associated with lower patient discomfort than conventional suturing materials (13). There were numerous reports of its use in the repair of traumatic lacerations in children and adults, offering reliable wound closure and acceptable cosmetic results (14,15). This topical cyanoacrylate adhesive polymerises into a thin protective film over the wound edges when in contact with skin moisture. Cyanoacrylate tissue adhesive is a low-viscosity liquid monomer that polymerises on contact with tissue surfaces in an exothermic reaction, creating a strong yet flexible film that bridges the wounds and holds the opposed wound edges together (16). It has microbial-resistant barrier properties and is water-resistant to permit showering. It typically sloughs off with keratinised epithelium within ten days, corresponding to the usual time for wound healing. The safety aspects of 2-cyanoacrylates include minor allergies, with no toxicity or carcinogenicity reported despite their use for many years (17).

Murrmann et al. (2010) compared cyanoacrylate to conventional skin closure techniques among women undergoing hysterectomy or caesarean. The hysterectomy cohort showed a non-statistically significant difference between cyanoacrylate versus sutures or staples in their study. In contrast, the caesarean cohort showed a significantly lower infection rate and cost than sutures or staples. They concluded that cyanoacrylate had comparable or lower infection rates and hospital costs than sutures or staples (18).

The CORONIS Trial (International Study of Caesarean Section Surgical Techniques) was completed in October 2007, and a later large randomised control trial, the CAESAR Study (Caesarean Section Surgical Techniques), published in June 2010, failed to address any of the caesarean skin closure technique despite evaluating various operative surgical methods. On the other hand, the product manufacturer recommended its use in caesarean section and total abdominal hysterectomy with at least bursting strength equivalent to a 4.0 suture (19).

Despite its popularity in other surgical fields, obstetricians still do not commonly use adhesive glue worldwide. The fundamental reason might be due to differences in patient groups, type of operation, and the relative scarcity of information regarding the use of tissue adhesive compared to other more established techniques, making this study none but important. This study assessed the efficacy and safety of skin closure using 2-octyl cyanoacrylate tissue adhesive against polyglactin 3/0 suture in caesarean section skin closure.

Materials and Methods

This prospective randomised controlled trial was conducted at Universiti Kebangsaan Malaysia Medical Center (UKMMC) between 1st June 2012 and 31st March 2013. The local research ethics committee approved the study with the code project FF-231-2012. We invited all pregnant mothers who needed a caesarean section and fulfilled the inclusion criteria to participate in this study. All of them were counselled before the procedure, and informed consent was obtained. The inclusion criteria were Malaysian pregnant mothers aged above 18 years going for an elective caesarean section. The exclusion criteria were pre-pregnancy body mass index (BMI) of above 30 kg/m^2, previous abdominal surgery, active cutaneous infection on incision site, pre-existing diabetes, history of drug allergy or allergy to cyanoacrylates, and estimated blood loss of above 1L. Sample sizes, 35 subjects in each arm, were calculated according to a study by Ranaboldo et al. (1992) (20) and Pichitronnachai et al. (2008)(21).

Women who fulfilled the inclusion criteria and consented were included. Demographic data, including age, body mass index, ethnicity, educational

level, parity, haemoglobin level, and type of caesarean section, were documented. They were randomised into two groups, tissue adhesive glue or polyglactin suture group, using a computer-generated 'research randomiser'. The study protocol was summarised in Fig. 1. Spinal anaesthesia – 0.5% heavy bupivacaine 1.8-2.0 ml with 25.0 mcg fentanyl with 0.15 mg morphine was the standardised regime used. The operative field was prepared by dry shaving the site with a disposable razor in the antenatal ward. The abdomen was cleaned with povidone-iodine and draped in the usual manner. Prophylactic antibiotic in the form of intravenous ampicillin/sulbactam 1.5 g stat was given at induction. The same surgeon performed the caesarean sections in this study. Surgical incisions compatible with the standard practice were made according to the lines of minimal tissue tension along the Langer's line. The uterus was closed in two layers without closing the peritoneum. The subcutaneous layer was closed continuously 1 cm apart using polyglactin 3/0 with the knot buried. Skin closure was performed according to the randomisation. Adequate haemostasis was ensured before skin closure. The wound was cleaned with normal saline, dried using surgical gauze, and covered with surgical dressing.

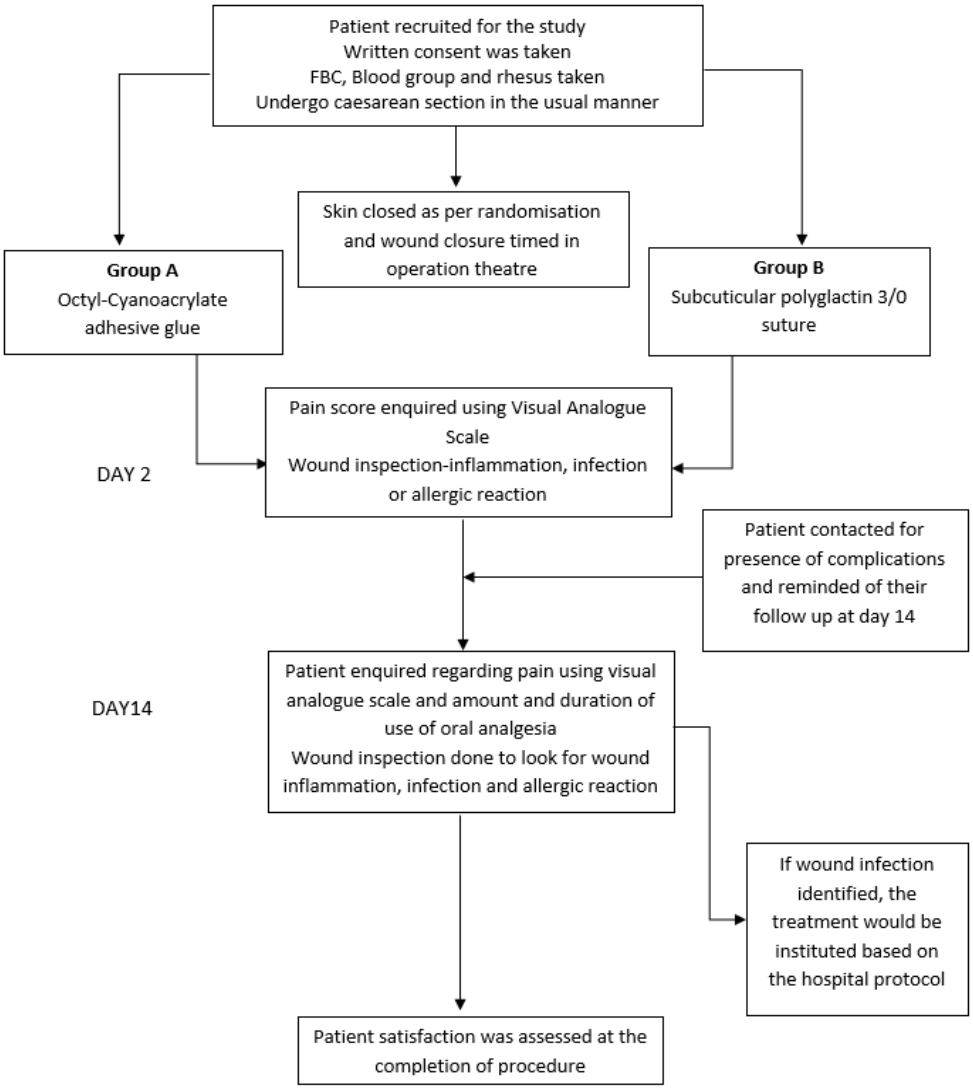

FIGURE 1: Flow chart of methodology

In the tissue adhesive glue group, the wound edges were closely approximated using atraumatic tissue forceps. The adhesive glue was supplied in a glass vial within a plastic container. It was gently crushed, and the glue will be expressed through the tip of the applicator, allowing immediate application onto the approximated skin incision. An independent nursing staff monitored the time needed for the skin incision closure using a stopwatch. Care was taken to avoid introducing the glue between the wound edges as it may impede later healing. The first layer of glue was applied above the closely approximated skin incision. This first layer was allowed to polymerise for 60 seconds before applying the second and third layers. The interval between second and third layers was 25-30 seconds. A sterile dressing was then applied. Similarly, a polyglactin suture size 3/0 curve 3/8 cutting needle was used to close the skin incision in the subcuticular. The duration needed for skin closure was monitored, from the start of the first layer of glue application until the end of the third layer of glue application for the study group and from the first bite of skin suturing until the end of knotting and cutting off the suture for the control group.

After the immediate completion of the caesarean section, a paracetamol suppository of 500 mg was given rectally as per standard protocol. Both groups were given a standardised prescription of oral celecoxib 200 mg twice daily for the first two days, starting 6 hours post-operatively until discharge. Women were kept in the ward for a total duration of 2 days post-operatively unless they had other indications for further stay. The patient's temperature was documented as febrile or afebrile using a 37.5°C cut-off value. The wound inspection was done on day 2 to look for any inflammation, wound gaping, wound discharge, and allergic reaction (indicated by itching). Before being discharged, the pain was assessed using the visual analogue scale (VAS) consisting of a 10 cm horizontal line with the endpoints labelled 0 for "pain-free" and 10 for "worst possible pain". Upon discharge, oral celecoxib 200 mg was prescribed for pain control when needed, with a maximum of twice daily 12 hours apart (20 tablets given), and these instructions were written on the discharge notes and explained to the patient. A diary was provided to record the amount of analgesia used. Women in both groups were educated on pain relief, good nutrition, good wound care practices and methods of identifying infection.

The primary investigator contacted the patients on day 7 to enquire about the presence of wound complications and were reminded of clinic visits on 14. Upon clinic visit, the primary investigator assessed their pain score using the visual analogue scale, the usage of oral analgesia (amount and duration of analgesia used), the presence of any allergic reaction, and if any evidence of infection, including serous/pus discharge from the wound. Healing was considered adequate if wound margins were completely opposed, and there was no dehiscence. If there was any evidence of wound dehiscence or breakdown, appropriate treatment per protocol was given. Women who voluntarily withdrew or were not compliant with subsequent follow-up at any time during the study period were reviewed as per hospital protocol.

All data were analysed using the statistical package SPSS version 20. The test was considered significant if p-value <0.05. Comparison between the groups for baseline characteristics was done using the Mann-Whitney test for continuous non-parametric data. In contrast, categorical data were calculated using Fisher's exact test or Pearson chi-square, depending on the fulfilment of the assumption. The difference in time for wound closure (seconds) between the two groups was analysed using the independent t-test. Differences in pain scores between the two groups on day two and day 14 were made using the Whitney Test. The total additional analgesic dose and duration of analgesic use were analysed using the Mann-Whitney Test. Analysis of adverse events, allergic reactions and patient satisfaction were presented descriptively.

Results

A total of 82 women who underwent caesarean section via a Pfannenstiel incision were included. Forty-one women were allocated randomly to each group: the adhesive glue (intervention) group or the polyglactin suture (control) group. Two women in the control group were lost to follow-up. They were considered dropouts and were not included in the analysis. A total of 80 women attended their scheduled visit and completed follow-up as required.

The baseline characteristics were similar between the two groups. Malays formed the majority in both groups, followed by Chinese and Indians, reflecting Malaysia's demographic distribution of races. More than half of our study subjects had tertiary-level education, and the others had completed secondary school. The intervention group had significantly more primiparous women (Table 1).

The haemoglobin levels in the control group were lower compared to the adhesive glue group. Though it was statistically significant, the accounted difference of 0.7 g/dL might not be clinically significant. The

TABLE 1: Demographic data

	Adhesive glue (intervention) n= 41	Polyglactin suture (control) n= 39	p- value
	Median (IQR)	**Median (IQR)**	
Age (years)	28 (6)	28 (5)	0.570
BMI (kg/m^2)	22.03 (4.49)	23.20 (4.75)	0.130
	n (%)	**n (%)**	
Ethnicity			
• Malay	25 (61.0)	27 (69.2)	0.780
• Chinese	13 (31.7)	8 (20.5)	
• Indian	1 (2.4)	1(2.6)	
• Others	2 (4.9)	3 (7.7)	
Education Level	18 (43.9)	15 (38.5)	0.620
• Secondary	23 (56.1)	24 (61.5)	
• Tertiary			
Gravida			
• Primiparous	33 (80.5)	23 (59.0)	**0.036***
• Multigravida	8 (19.5)	16 (41.0)	

Median was used in quantitative data as it was not normally distributed; Chi-square was used in categorical data
***Significant value p <0.05**

TABLE 2: Clinical characteristics and surgical details

	Adhesive glue (intervention) n=41 (%) Median (IQR)	Polyglactin suture (control) n=39(%) Median (IQR)	p- value
Haemoglobin (g/dL)	11.60 (1.65)	10.90 (1.70)	**0.042***
Preop. gestation (weeks), n (%)			
• Less than 37	5 (12.2)	2 (5.1)	0.649
• 37 to 39+6	25 (61.0)	25 (64.1)	
• More than 40	11 (26.8)	12 (30.8)	
Type of caesarean, n (%)			
• Emergency	33 (80.5)	35(89.7)	0.25
• Elective	8 (19.5)	4(10.3)	

Median was used in quantitative data as it was not normally distributed; Chi-square was used in categorical data
*Significant value p <0.05

majority of women were beyond 37 weeks' gestation (Table 2). Fig. 2 showed the indications for caesarean sections. The majority of the mothers underwent caesarean sections for fetal distress (32.5%), followed by poor labour progress (23.8%) and fetal malpresentation (20%). Big babies contributed to 6.3% of the indications, while 17.5% of caesarean sections were done for failed induction of labour.

The time was measured in seconds rounded to the nearest 10 seconds. The mean time spent for skin closure using adhesive glue was 170.7 seconds, 97.7 seconds shorter than skin closure using subcuticular polyglactin 3/0 suture, which needed 268.5 seconds, which was statistically significant (Table 3).

Postoperative median pain scores on day 2 were 4.0 and 5.0 for women in the adhesive glue and polyglactin suture groups, respectively, which was not statistically significant. In contrast, the pain score on day 14 was significantly lower in the adhesive glue group than in the polyglactin suture group (2.0 vs 4.0; p=0.001) (Table 4).

As for analgesic dose (excluding the 1st two days postoperatively), the duration of analgesia needed and total analgesia requirement after day two were significantly lesser in the adhesive glue group than in the polyglactin suture group (Table 4). It was worth mentioning that seven women from the adhesive glue group did not require any analgesia after day 2.

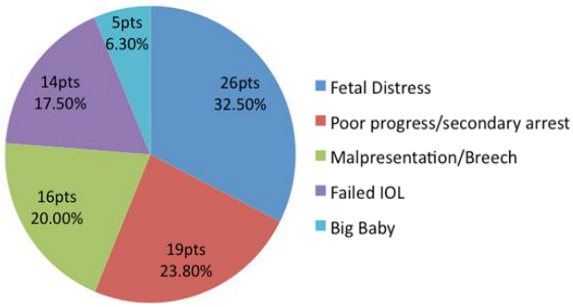

FIGURE 2: The indications for caesarean section

TABLE 3: Total skin closure time

	Adhesive glue (intervention) Mean ± SD	Polyglactin suture (control) Mean ± SD	F stat	p- value	95%CI
Time of closure in seconds	170.73 ± 16.49	268.46 ± 23.34	0.801 (78)	**<0.001***	-106.69, -88.77

*Significant value p <0.05

TABLE 4: Comparison of Outcomes

	Adhesive glue (intervention) Median (IQR)	**Polyglactin suture (control) Median (IQR)**	**p- value**
VAS pain score • Day 2 • Day 14	4.0 (1) 2.0 (1)	5.0 (1) 4.0 (1)	0.09 **0.001***
Duration of analgesia use (days)	4 (2)	6 (1)	**<0.001***
Total amount of oral celecoxib (mg)	1600 (600)	2400 (400)	**<0.001***
Wound infection, n (%)	2 (4.9)	3 (7.7)	0.67
Satisfied with skin closure method, n (%)	41 (100.0)	32 (82.1)	0.005

Median was used in quantitative data as it was not normally distributed; Chi-square was used in categorical data
*Significant value p <0.05

The incidence of wound breakdown was 4.9% and 7.7% in the adhesive glue group and polyglactin suture group, respectively. No febrile episode was detected in either group during the follow-up duration. All women with wound breakdown were given prophylactic oral antibiotics. Swab culture and sensitivity did not grow any organism. Upon further history, it was found that despite advising against medicated oil or cream, one patient from the adhesive glue group had applied medicated oil, which might have contributed to the failure of the skin adhesive.

A simple question was asked to assess the patient satisfaction with whether they would like to use the same skin closure method in future surgery. The alternative skin closure technique in this study was also explained. All women (100%) with adhesive glue skin closure, including the two women with wound breakdown, were satisfied and wished to use the same method in the future, in contrast to 82.1% who wished to repeat the subcuticular suturing method, which was statistically significant. Interestingly, all three women with wound breakdown in this group wanted to switch over to adhesive glue in the future.

Discussion

Wound closure aims to achieve haemostasis, avoid wound infection, and provide cosmetically acceptable scars (22). Through this study, we aimed to ascertain the safety and efficacy of 2-octyl cyanoacrylate tissue adhesive glue in the closure of Pfannenstiel caesarean scar compared to conventional skin closure. It must be reiterated that this was a pilot study comparing 2-octyl cyanoacrylate tissue adhesive glue and polyglactin suture 3/0 in caesarean section in our local population of Malaysia. A literature review has revealed the need for more data on its use in caesarean skin incision closure. Most studies concentrated on plastic and paediatric surgery populations (15,23). Quinn et al. (1977) compared 2-octyl cyanoacrylate tissue adhesive glue with monofilament sutures for facial, selected trunk, and extremity lacerations. They reported its use was faster and less painful, added with cosmetically equivalent closure with suture (13). A clinical trial by Dey et al. (2000) on women undergoing transverse skin incisions for gynaecologic surgery demonstrated that the skin closure time needed was significantly shorter when using 2-octyl cyanoacrylate tissue adhesive glue (24). Formal cost-effective analysis suggested that adhesive glue was more cost-effective than sutures or staples (25,26), with the additional benefit of minimising the possibility of needle prick injury.

Our result was comparable to others (27-31), where the pain score was significantly lower in the tissue adhesive glue group on day 14. The need for oral analgesia after day two post-operative was also less in the tissue adhesive group. The lowered intake of oral analgesia lessens the potential side effects of analgesia with the added advantage of reducing the medical cost. Suture material in the skin may cause longer tissue reactivity as its standard complete absorption ranges from 60-90 days, whereas 2-octyl cyanoacrylate tissue adhesive glue sloughs off between day 5-10 post application.

It was a common finding amongst studies that using tissue adhesive glue in extended incision closure was considerably faster (13, 31-33). Maw et al. (1997) found an approximately 10-fold longer mean closure time for sutures versus tissue adhesive glue in head and neck procedures (32). However, it is yet to be confirmed in women undergoing caesarean section. From this study, we found that the use of tissue adhesive glue was significantly faster than that of the subcuticular suture. The time needed was at least one-

third shorter than subcuticular suturing, though the clinical benefit of this reduced intraoperative time in reducing surgical site infections remained unclear.

The observed surgical site infection (SSI) rate post caesarean section has been reported to be between 2.9% and 17.9%, depending upon various risk factors, including age, body mass index (BMI), amount of blood loss, method of wound closure, and emergency setting (34). A more appropriate term, surgical site infection (SSI), is defined according to CDC criteria: the presence of purulent discharge from a surgical site; isolation of organisms from an aseptically obtained fluid or tissue culture from the superficial incision; the surgeon's diagnosis of infection, a surgical site that requires reopening (35). Compared with the subcuticular polyglactin group, the wound infection rate in the tissue adhesive group was similar. However, it is thought that the tissue adhesive glue might have the beneficial effect of a microbial barrier and water resistance that might be associated with lesser SSI. Our sample size was probably inadequate to demonstrate the difference.

There was a lack of data on patient satisfaction regarding wound closure using tissue adhesive glue. Patients' satisfaction is often influenced by pain, ease of ambulation, wound infection, and, most importantly, the wound appearance. We demonstrated 100% patient satisfaction in the tissue adhesive group. However, evaluating patient satisfaction within 14 days may not be the most appropriate indicator of the final wound appearance, as completing incisional remodelling takes about 12 months.

Conclusion

In conclusion, 2-octyl cyanoacrylate tissue adhesive glue meets many criteria for ideal wound closure in caesarean sections. It is efficacious, with a relatively easy learning curve, faster application, less pain, a low infection rate, and higher patient satisfaction. Some drawbacks of this study include the failure to study formal cost benefits and cosmetic appearance.

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