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Comparison of Use of 2-Octyl Cyanoacrylate Tissue Adhesive and Standard Skin Sutures In Closure of Abdominal Incisions – A Prospective Randomized Controlled Study.

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Abstract
BACKGROUND: *Octylcyanoacrylate is a liquid adhesive being used for the closure of lacerations and surgical incisions. The purpose of this study was to evaluate the efficacy of 2-octylcyanoacrylate tissue adhesive (OCA) as a wound closure material in comparison to standard skin sutures (SWC) in closure of abdominal incisions.*
MATERIALS AND METHODS: *This was a randomized prospective study of 200 patients, Group 1(n=100, incisions closed by SWC) & Group 2 (n=100, incisions closed using OCA). Wounds were evaluated for time of closure and wound complications (pain, inflammation, dehiscence, infection, haematoma) and cosmesis (wound closure/wound seal). The scar and the surface texture were evaluated only after a minimum follow up of one month post operatively.*
RESULTS: *Groups were similar in baseline characteristics.Wound closure with OCA was faster than with SWC (166 versus 318 seconds; P=0.000). Infection rates were more in suture group (6% versus 2.0%; P = 0.79) and fewer OCA wounds were erythematous (6% vs. 2%, P= 0.150). There were no significant differences in wound dehiscence rates and hematoma. Wound closure with OCA was less painful than SWC (Mean pain using visual analogue scale score 2.1 ± 1.3 versus 2.6 ± 1.6; P=0.017) and had better cosmetic scores (Mean score using cosmetic visual analogue scale scores 68.9 ± 12.66 versus 6.9 ± 10.7;P=0.236).*
CONCLUSION: *Wound closure with OCA is a faster and less painful method. It also results in less postoperative complications (infection, inflammation & hematoma). Dehiscence rates are similar with cosmetic results slightly better than suturing.*
Key Words: *Wound closure; 2-Octylcyanoacrylate; Tissue Adhesive; Suture; Cosmesis; Complication.*

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I. Introduction

Precise approximation of skin incisions and lacerations with different wound closure techniques is critical to a favorable esthetic and functional surgical result. Suturing remains a time-tested and most common method of wound closure. The ever-striving search for an alternative procedure and material has led to the discovery and development of tissue adhesives. Tissue adhesives were invented in 1949 by Ardis [1] and tried clinically for the first time in 1959 when Coover [2]discovered their inherent adhesive properties.

N-butyl-2-cyanoacrylate, has been used safely throughout countries other than the United States [3,4]. More recently, a new tissue adhesive designed to address the limitations of the butyl-2-cyanoacrylate group, 2-octyl cyanoacrylate (Dermabond;Ethicon Inc., Norwood, Mass), has been approved by the US-FDA.Alongwith increased flexibility, 2-octyl cyanoacrylate has 4 times the breaking strength of *N*-buytl-2-cyanoacrylate [5].Majority of studies looking at cyanoacrylate use in wound repair indicate that this technique takes only 30-60% of the time required for repair using suture closure [6-9].The purpose of this study was to evaluate the efficacy of 2-octylcyanoacrylate tissue adhesive (OCA) as a wound closure material in comparison to standard skin sutures (SWC) in closure of abdominal incisions.

II. Materials and Methods

The study was conducted in Department of Surgery of Government Medical College hospital in Srinagar for a period of two years.Ours was a prospective, randomized in vivo study on patients attending the department of surgery, Government medical college Srinagar for various surgical procedures. A total of 200 patients were randomly allocated in two groups, Group 1 (Closed with SWC) and Group 2 (Closed with OCA)

using a computer generated random number table. Attention was paid to the fact that the patients in two groups had similar length of the abdominal wound. Detailed clinical histories along with routine necessary investigations for each surgical procedure were carried out. The selected patients were then informed about the nature of surgery and method of closure of the surgical wound, its advantage and complication. A formal consent was obtained from the patients for the study.

Wounds were evaluated for time of closure at the time of surgery. On 1st post-operative day, discharge and on 1st follow up; wounds were evaluated for wound complications (pain, inflammation, dehiscence, infection, and hematoma) and cosmesis. Pain was evaluated by visual analogue scale score (VAS) and cosmesis by visual cosmesis scale score (CVAS). The scar and the surface texture were evaluated only after a minimum follow up of one month post operatively.

The Inclusion criteria included:

- The patients in good general health with no significant systemic abnormalities.
- Only clean incisions.
- Maximal length of incision = 10 cm.

The Exclusion Criteria were:

- Patients who were medically/immunologically compromised.
- Patients with a known history of contact dermatitis towards formaldehyde.
- Patients with Vascular diseases /collagen diseases and clotting disorders.
- Patients with a history of keloid formation and hypertrophic scars.
- Patients with contaminated and dirty wounds.

In Group 1 the incisions were closed with silk by simple interrupted suturing technique making sure that theskin edges were in close approximation to each other during the closure. Following the completion of suturing, an antiseptic medicated cream/ betadine was applied followed by a protective dressing for the first forty eight to seventy two hours. The sutures were removed usually after an interval of 8 days.

In Group 2 skin edges were approximated and maintained in this position either with skin hooks, Adson forceps or manually with fingers. The applicator was removed from the packaging, holding the tip pointing upward. Pressure was applied at the midpoint of the ampoule, crushing the inner glass tube. The applicator then was inverted and gently squeezed so as to express the liquid adhesive through the applicator tip along the edges of the incision, all the time taking care that the adhesive did not flow between the skin edges. Three repeated applications with an interval of 15 seconds were done, maintaining the skin approximation all along till the polymerization was complete.

The data thus collected was compiled and analyzed using SPSS version 21 for Mac (IBM Corporation, 2012). Qualitative variables were expressed as proportions in percentages. The association between variables was calculated for 95% confidence intervals by using "Chi square test". "Unpaired t – test" was used to compare the means. A P-value < 0.05 was taken as significant. For quantitative data, mean and standard deviation was calculated. An approval for this study was obtained from the Institutional Ethical Committee.

III. Results

Both the groups were comparable as regards the baseline variables and every effort was made to minimize the confounding factors [Table 1]. Most common diagnosis was symptomatic cholelithiasis (42% in both the groups) followed by Inguinal hernia (17% in SWC & 15% in OCA) and resolved appendicular lump (17% in SWC & 14% in OCA). The mean time of closure for OCA was almost half the time taken for SWC (166 versus 318 seconds; P = 0.000; Table 2).

Most of the patients experienced moderate amount of pain on 1st postoperative day (72% in SWC& 71% in OCA; P = 0.224). On discharge majority of patients experienced no pain in both the groups (71% in SWC& 74% in OCA; P = 0.465). On follow up again majority of patients experienced no pain in both the groups (73% in SWC& 90% in OCA; P =0.002). Overall, the mean VAS scoreswere 2.6 $\pm$ 1.6 in SWC and 2.1 $\pm$ 1.3 in OCA (P = 0.017; Fig 1). There was no statistically significant deifferences in the number or pattern of complications between the two groups (Table 3). The surface texture was smooth in 98% patients in OCA as compared to 91% in SWC (P = 0.030). Patients with OCA closure were discharged earlier as compared to SWC (2.5 $\pm$ 0.5 versus 3.7 $\pm$ 1.2 days; P = 0.000). The mean CVAS score in SWC was 66.9 $\pm$ 10.7 mm and that in OCA was 68.9 $\pm$ 12.6 mm (P = 0.236).

IV. Discussion

The principle of wound closure should be to achieve precise wound approximation, low infection rates and better cosmetics.The traditional and the gold standard method of wound closure against which all the methods need to be compared continues to be sutures. Inherent disadvantages of sutures include risk of needle stick injury, need of anaesthesia and risk of infections. To circumvent these, many alternative methods of wound closure have been developed that include skin staplers, wound closure strips and tissue adhesives [5-7]. The past fifty years have witnessed development and refinement of tissue adhesive, that represents a new era in wound closure. After their discovery by Ardis [1] in 1949, the tissue adhesives were used during the Vietnam War, in the 1960s, to glue the chest and abdominal wounds of soldiers, who were then transferred to surgical units [3].

Use of cyanoacrylate adhesives offers several advantages over other methods of wound closure and tissue fixation. Favorable features of cyanoacrylates include their ability to rapidly form a flexible bond, act as an occlusive protective dressing, decrease inflammation, and reduce follow-up care and medical costs[3-9]. Adhesives provide a needle-free method of wound closure, an important consideration in the light of the risks presented by blood-borne viruses. In addition, adhesives do not require local anesthetics. Cost-effectiveness studies of wound closure have compared suture and cyanoacrylate techniques and have demonstrated an actual cost reduction with use of the adhesive.Cost reduction is most reflected in reduced physician and ancillary services, decreased equipment needs, and fewer required follow-up visits [9].

One of the more alluring features of cyanoacrylates is their ease of application. This was reflected amply in our study as the time to closure was almost half in the OCA group as compared to SWC group. The major causes of postoperative pain are the stretching of the wound during surgery and the length of the fascial incision [10]. As expected use of sutures increases the postoperative pain, as the needle pricks lead to nociceptive sensations. Our study demonstrated that postoperative pain scores were significantly less in the OCA group. Local anaesthetic infiltration is helpful in decreasing the postoperative pain [10] but was not done in our study. Unlike sutures and staples, tissue adhesives do not leave any hatch marks. For these reasons, closure with a topical skin adhesive tends to result in a better cosmetic outcome. Our study reported a statistically significant smooth texture of the wound in the OCA group. Though cosmesis was marginally better in the OCA group, it did not reach statistical significance.

The strength of our study is that it is a randomized controlled trial and included a variety of surgical procedures. One of the criticisms of our study is that it was not a double-blinded study. However, the postoperative pain assessment was somewhat blinded as all scoring was performed by the attending nurse who was unaware of the ongoing study. Our study may also be criticized on the plea that incisions more than 10 cm were excluded, but this was done, as we were apprehensive about the efficacy of tissue adhesives for longer wounds.

V. Conclusion

We conclude that wound closure with OCA is a faster and less painful method. It results in less postoperative complications likeinfection, inflammation & hematoma and consequently lesser hospital stay. Dehiscence rates are similar and cosmetic results slightly better than suturing.

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Table 1: Baseline Parameters of the patients

PARAMETER	SWC (n =100)	OCA (n=100)	P Value
Mean Age (Years)	31.23 ± 2.12	36.51 ± 2.43	0.675
Male: Female	61:39	61:39	1.000
Rural: Urban	1.76:1	1.81:1	0.994
Mean BMI (kg/m^2)	21.28± 2.61	21.51 ± 2.23	0.863
Average Built	73	75	0.817

Table 2: Time of closure of the surgical incision sites

Treatment Received	SWC	OCA	P value
Diagnostic Laparoscopy	320 ± 14	170 ±28	0.333
Laparoscopic Cholecystectomy	333 ±48	172 ±26	0.000
Open Cholecystectomy	388 ±28	195 ±63	0.000
Laparoscopic Appendectomy	300 ±07	170 ± 14	0.333
Open Appendectomy	312 ±30	192 ±13	0.000
Open Hernia Repair	380 ±69	204 ±64	0.000
Herniotomy	164 ±57	93 ± 19	0.000
SU/EP Hernia Repair	310	125 ±92	0.667
Laparoscopic Hydatid Cystectomy	380	210	1.000
Open Hydatid Cystectomy	405 ±7	380	0.667
Elective Splenectomy	450	220	1.000
Herniotomy	247 ±65	108 ±52	0.036
Total	**318 ±92 (105-460)**	**166 ± 59 (55-300)**	**0.000**

Table 3: Complications in the two groups

PARAMETER		SWC		OCA		P value
		n	%	N	%	
1st POD* Wound infection	*Yes*	1	1.0	0	0.0	0.317
1st POD Inflammation	*Yes*	1	1.0	0	0.0	0.317
1st POD Dehiscence	*No*	100	100.0	100	100.0	1.000
1st POD Hematoma	*Yes*	2	2.0	1	1.0	0.561
DC** Wound infection	*Yes*	6	6.0	2	2.0	0.150
DC Inflammation	*Yes*	6	6.0	2	1.0	0.150
DC Dehiscence	*Yes*	3	3.0	2	2.0	0.651
DC Hematoma	*Yes*	2	2.0	1	1.0	0.561
FU*** Wound infection	*Yes*	4	4.0	1	1.0	0.175
FU Inflammation	*Yes*	2	2.0	0	0.0	0.156
FU Dehiscence	*Yes*	3	3.0	3	3.0	1.000
FU Hematoma	*No*	100	100.0	100	100.0	1.000
Overall wound infection	*Yes*	6	6.0	2	2.0	0.790

*Postoperative Day; **Discharge; ***Follow-up

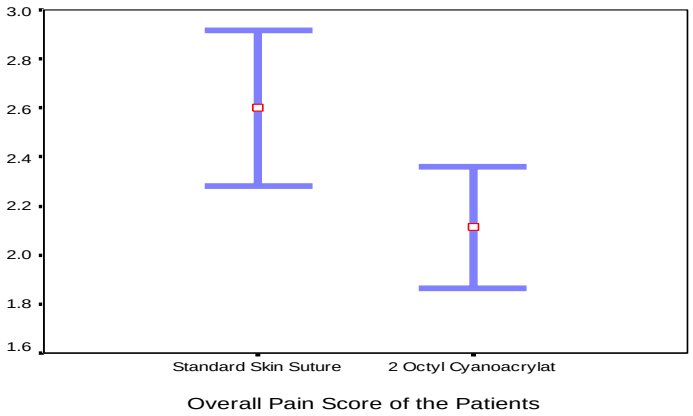

Figure 1: Mean overall Pain scores (VAS)

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