

Original article**A RANDOMIZED CONTROLLED STUDY OF PORT SITE CLOSURE USING 2-OCTYL CYANOACRYLATE VERSUS CONVENTIONAL SUTURING, POST LAPAROSCOPIC CHOLECYSTECTOMY**

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Abstract**Background:**

Wound closure techniques have evolved over a period of time. Several different materials have been used to close the surgical wounds, each with its own set of advantages and shortcomings. We conducted the study to assess the outcome of 2-octyl cyanoacrylate application versus the conventional suturing of port sites, following laparoscopic cholecystectomy.

Material and methods:

This randomized study was conducted in post-graduate department of surgery in a tertiary care teaching hospital in North India. 100 patients were enrolled in the study design and divided into two groups, A and B having 50 patients each. The 10 mm port sites in group A were approximated with 2-octyl cyanoacrylate whereas in group B 10mm port sites were closed with 3/0 polyamide sutures. Both the groups had similar demographic features. Our assessment criteria included time taken for closure, wound related morbidity & patient satisfaction based on cosmetic appearance of the wound.

Results:

Time taken for closure of port sites in group A was significantly less in comparison to the group B (143.4 ± 17.26 versus 227.1 ± 13.25 seconds). Patients in group A complained of less pain than those of group B; 18% versus 46% at one week and 8% versus 18% at 2 weeks respectively. At 2 months follow up, patient satisfaction regarding cosmetic appearance based on visual analogue score was significantly more in group A (32%) in comparison to group B (10%).

Conclusion:

10 mm port site closure using 2-octylcyanoacrylate is an effective approach and is significantly better in terms of time consumed, wound morbidity and patient satisfaction when compared to port site closure using 3/0 polyamide sutures, following laparoscopic cholecystectomy.

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Introduction

Proper wound closure is one of the most important aspects of successful wound care. The ideal wound closure material ensures rapid and easy application, less pain and tissue desiccation with minimal chances of infection and scarring apart from being inexpensive.¹ Different materials find a mention in the suturing history be it the plant fibers, tendons or the woven horse hair to begin with and cotton, silk and linen towards the later part.²

With the evolution of advancing technology, arrays of synthetic polymeric threads, skin adhesives, surgical staples and tapes have supplemented the armamentarium of wound closure techniques. The wound adhesive 2-octyl cyanoacrylate is approved by the US Food and Drug Administration (FDA) for closure of incised skin (US Food and Drug Administration. Accessed: February 10, 2011).The cyanoacrylates

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were first synthesized in 1949 by Airdis.³ Coover HN et al described their adhesive properties and suggested their possible use as surgical adhesives.⁴

The cyanoacrylate tissue adhesives are liquid monomers that polymerize on contact with fluid or basic medium, thereby forming a strong bond when applied to moist skin.[5] However, their use has been restricted to small, low-tension lacerations and incisions. The development and introduction of the stronger and more flexible octyl-cyanoacrylate (OCT) in 1998 has been a major advance in the wound closure field and has been used widely. Along with increased flexibility, it has four times the breaking strength of the older type cyanoacrylate.

We conducted the study to evaluate the efficacy of 2-octyl cyanoacrylate tissue adhesive versus the 3-0 polyamide suture for the approximation of 10 mm port sites following laparoscopic cholecystectomy and to compare various parameters which included time taken for closure, wound morbidity and cosmetic appearance.

MATERIAL AND METHODS:

The prospective randomized study was carried out in the postgraduate Department of General Surgery in a teaching tertiary care hospital in North India for a period of one year after it was approved by the Institutional Ethical Committee.

100 patients admitted for elective laparoscopic cholecystectomy were divided into two groups of 50 each using computer randomization. Exclusion criteria included Immunocompromised patients including diabetes, allergy to skin adhesives, history of corticosteroid therapy, intraoperative enlargement of port sites for gall bladder removal.

Method of collection of data:

The selected patients were evaluated with detailed history, clinical examination and routine investigations and prepared for elective laparoscopic cholecystectomy. Preoperative shaving of the part was done at the same time on previous evening. Injection cefoperazone 1gm was given intravenously to all the patients at the time of induction. After the completion of surgery, port sites were assessed for hemostasis and contamination if any and 10mm port sites were closed either with suture or 2-octyl cyanoacrylate in respective groups.

Group A: Patients underwent port site wound closure with 2-octyl cyanoacrylate after approximation of subcutaneous tissue with 3/0 poliglecaprone.

Group B: Patients underwent port site wound closure with 3/0 polyamide, using mattress sutures.

Technique of closure with skin adhesive:

- 1) Applicator was held away from the patient with the tip pointing upwards.

- 2) The bulb was squeezed to crush the ampoule inside and pressure was released.
- 3) Bulb was squeezed again to moisten the internal filter with adhesive.
- 4) Wound edges were approximated using forceps.
- 5) The wound adhesive was applied in single continuous layer maintaining steady bulb pressure.
- 6) A second coat was applied after 30 seconds.
- 7) Port site was left untouched for about 3 minutes for full polymerization.
- 8) A dry dressing was applied only after complete polymerization of skin adhesive. Patients were instructed to take care of the wound and not to remove the polymerized film at the wound site for the next 7 days.

Outcome variables:

Both the groups were assessed in terms of time taken in seconds for the closure of 10mm ports. Evaluation of the wound was done postoperatively in both groups at one week and two weeks in terms of pain, erythema, discharge, infection and wound dehiscence. Wound was assigned 1 or 0 points each in the presence or absence of the above-mentioned complications.

Assessment of patient satisfaction based on cosmetic appearance of the healed wound was done at end of 2 months. Patients were asked to score the cosmetic appearance ranging from 1-10. Patients were graded as un-satisfied (score 1-4), satisfied (score 5-7) and highly satisfied (score 8-10) based on the score given. The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were summarized as Mean ± SD and categorical variables were expressed as frequencies and percentages. Graphically the data was presented by bar diagrams. Student's independent t-test was employed to analyze the statistical differences in parametric data. Chi-square or Fisher's exact test, whichever appropriate, was applied for categorical data. A P-value of less than 0.05 was considered statistically significant.

RESULTS:

The data obtained was analyzed and final results and interpretations were presented in terms of demographic variables, time taken, the condition of wound and patient satisfaction vis a vis cosmetic appearance of the wound. Most of the patients belonged to age group of 45 years to 59 years (34% in group A and 32% in group B) [Table 1]. Female preponderance was there with 72% of patients in group A and 66% in group B [Table 1]. Both the differences were statically insignificant. In the

present study the mean time taken for closure of port sites in group A was significantly less in comparison to the group B (143.4 ± 17.26 versus 227.1 ± 13.25 seconds: $P < 0.001$, [Table 2].

Assessment of the wound variables at one week is depicted in table 3. Patients in group A complained of less pain than those of group B which was found to be statically significant (18% versus 46%, $p=0.003$). However, discharge, erythema and dehiscence were comparable in group A and B ($p>0.050$). Wound condition at two weeks is depicted in table 3. Pain was present in 8% patients in group A compared to 18% in group B. Discharge, erythema and dehiscence were comparable in both the groups. At 2 months follow up, patient satisfaction regarding cosmetic appearance based on visual analogue score was significantly more in group A (32%) in comparison to group B (10%). Again the difference is statistically significant ($p=0.015$, Table 4).

Table 1. Age and gender distribution of study patients among two groups

Age and Gender distribution among two study groups			
1.	Age (Years)	Group A(n=50) N(%)	Group B(n=50) N(%)
<30	11(22)	7(14)	
40-44	14(28)	15(30)	
45-59	17(34)	16(32)	
≥60	8(16)	12(24)	
Mean±SD	45.3±15.37	47.5±16.67	
P-value	0.490		
1. Gender			
Male	14(28)	17(34)	
Female	36(72)	33(66)	
P-value	0.517		

Table 2. Mean Surgical Time for Wound Closure

	Time (seconds) Mean±SD	Range	P-value
Group A(n=50)	143±17.26	113-168	
Group B(n=50)	227.1±13.25	209-251	<0.001*

Table3.Wound condition at one and two weeks among two groups

Wound condition at one week	Group A N(%)	Group B N(%)	P-value	Wound condition at two weeks	Group A N(%)	Group B N(%)	P-value
Pain	Present 9(18)	23(46)	0.003*	Pain	Present 4(8)	9(18)	0.234
	Absent 41(82)	27(54)			Absent 46(92)	41(82)	
Discharge	Present 2(4)	5(10)	0.436	Discharge	Present 0(0)	1(2)	1.000
	Absent 48(96)	45(90)			Absent 50(100)	49(98)	
Erythema	Present 0(0)	2(4)	0.495	Erythema	Present 0(0)	0(0)	-
	Absent 50(100)	48(96)			Absent 50(100)	50(100)	
Dehiscence	Present 1(2)	3(6)	0.617	Dehiscence	Present 0(0)	2(4)	0.495
	Absent 49(98)	47(94)			Absent 50(100)	48(96)	

*Statistically Significant Difference (P -value<0.05)

Table 4: Comparison based on patient satisfaction regarding cosmetic appearance among two groups

Patient Satisfaction	Group A N(%)	Group B N(%)	P-value
Unsatisfied	5(10)	11(22)	0.015*
Satisfied	29(58)	34(68)	
Highly Satisfied	16(32)	5(10)	
Total	50(100)	50(100)	

*Statistically Significant Difference (P -value<0.05)

DISCUSSION:

The method of closing laparoscopic wounds has evolved over time, from sutures to skin staplers and adhesive tapes, and more recently skin adhesive glues. With so many methods available for skin closure and each method having its own advantages and disadvantages, it becomes imperative to know which method is best suited in a particular setting.

Approximation of the skin incision using adhesive glues is potentially least invasive method and appears most feasible. However, the advantage if any needs to be established in terms of clinical parameters. Hence our study was undertaken to compare 2-octyl cyanoacrylate application with conventional suturing of 10 mm port sites during laparoscopic cholecystectomy. The parameters for comparison included time taken for closure, wound condition and cosmetic outcome on follow up.

100 patients admitted for elective laparoscopic cholecystectomy were divided into two groups of 50 each using computer randomization. Exclusion criteria included immunocompromised patients, diabetes mellitus, allergy to skin adhesives, history of corticosteroid therapy, intraoperative enlargement of port sites and or port sites contamination.

Time for 10 mm port closure in group A was 143.40 ± 17.26 seconds compared to 227.10 ± 13.28 seconds in group B which was statistically significant ($p<0.001$). Similar observations have been documented in various studies. One of the earliest studies conducted by Quinn J. et al, in 1997 reported similar results.⁶ Consistent reports were published by Haider Jan et al and Sajid M Set al.^{7, 8} However, a Cochrane review incorporating many trials found the sutures significantly faster to use when compared to the glue.⁹ Plausible explanation for the contrary results rests on the facts the glue application is a skill just like suturing and has a learning curve.⁵ Also working in the surgical field without too many instruments, sutures and needles probably makes it easier, safer and more convenient.¹⁰ Also one doesn't have to bother about the risk of needle stick injury.

In our study, at one week follow up, there was

statistically significant difference in pain in both the groups. 18% of patients in group A had mild pain or discomfort at wound site compared to 46% of patients in group B ($p=0.003$). At 2 weeks follow up the difference still persisted however it was not statistically significant. Although there was lower rate of dehiscence, erythema and discharge seen in wounds closed with 2-octylcyanoacrylate as compared to sutures but the difference was not statistically significant. Similar observations were made by Chen K et al where in the incidence of patients with complications including erythema, tenderness and drainage was lower with 2-octylcyanoacrylate than with sutures. Also, ports closed with 2-octyl cyanoacrylate had lower margin separation ($P<0.05$).¹¹ It was concluded that laparoscopic ports closed with 2-octylcyanoacrylate had fewer early complications when compared with conventional suturing. In contrast the study done by Singer AJ et al revealed comparable infection and wound dehiscence rates at one week, however fewer of the 2-octyl cyanoacrylate wounds were erythematous (18% vs 36%, $P<.001$).¹²

The report published by Clement TH Chan et al and an update by Dragu A et al incorporating many trials revealed decreased rates of dehiscence and even faster closure time with conventional suturing compared to 2-octyl cyanoacrylate.^{5,13} The plausible explanation for the divergent reports lies in the training and the expertise in the particular method of skin approximation. Glue application is an art and needs to be taught well to the residents. Closure of the wounds that are not dry enough or harboring underlying collection is bound to give way. Similarly, wrong suture selection and or improper suturing technique are not going to fare well. Meticulous application of glue seals off the tissue immediately while as epithelization after suturing takes approximately 48 hours. Moreover, sutures can also at times act as a conduit for microorganisms thereby exposing the patients to possible risk of wound complications.¹⁴

In a multicenter randomized clinical trial Singer AJ et al compared eight hundred and fourteen patients with nine hundred and twenty-four patients at a follow up of three months and found no statistical difference vis a vis the cosmetic appearance of the wound.¹² Once the scar settles down the outcome becomes comparable. However, the ethnic descent of the patient influences the appearance of the post-operative scar.⁵ In a study conducted by Quinn J. et al, there was no significant difference in cosmesis based on visual analogue score ($p=0.65$). Where as in our study 10 mm port closure using 2-octyl cyanoacrylate required significantly less time, with

less post-operative pain, less wound related complications and hence achieved a better cosmetic outcome as compared to closure with 3-0 polyamide suture. In group A, 32% of patients were highly satisfied compared to 10% in group B regarding cosmetic appearance of the wound which was statistically significant ($p=0.015$). Similar observations were made in a study by Toriumi DM et al, where the results of the visual analogue scale ratings at one year stood at 21.7 ± 16.3 for the 49 patients treated with 2-octyl cyanoacrylate and 29.2 ± 17.7 for the 51 control patients treated with sutures.¹⁵ There was superior cosmetic outcome and the difference was statistically significant ($p, 0.03$). Additionally, patient satisfaction was very high in the group treated with 2-octyl cyanoacrylate.

Conclusions

10 mm port site closure using 2-octylcyanoacrylate is an effective approach and is significantly better in terms of time consumed, wound morbidity and patient satisfaction when compared to port site closure using 3/0 polyamide sutures, following laparoscopic cholecystectomy.

We believe that increased patient satisfaction post 2-octyl cyanoacrylate application is multifactorial. Glue seals off the wound immediately and there is no need for frequent dressings and removal of sutures or staples. Patient is spared frequent visits to the hospital which reflects positively on the state of mind of the patient. Also, post-operative discomfort at port site and the hatch marks left by the sutures has a bearing on cosmetic appearance and patient satisfaction. Pertinent to mention here that all factors put together improve the quality of life of the patient.

Hence, we strongly recommend the application of 2-octyl cyanoacrylate for closure of 10mm port sites as it saves time, causes less pain and morbidity and ensures better cosmetic appearance and has a positive bearing on quality of life.

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