Original Research Article

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Comparison of conventional suturing and tissue adhesive (2-octyl cyanoacrylate) for port site skin closure in laparoscopic surgeries

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ABSTRACT

Background: Today there are numerous methods available for closure of wounds like tissue adhesives, staplers, adhesive tapes and obviously the age old conventional suturing, all of which have their own pros and cons. The aim was to study the complications and results of use of 2-octyl cyanoacrylate on wound healing and compare them without those of conventional suturing.

Methods: Study comprised of 100 patients undergoing clean or clean contaminated elective laparoscopic surgery. After randomization 50 patients had their port site skin incision closed using 2-octyl cyanoacrylate. In the rest the port site skin incision was sutured using 3-0 polyamide. The scar was assessed using the stony brook scar evaluation scale. **Results:** The average Stony Brooke scar evaluation scale score was 4.2±1.03 (95% CI: 3.90 - 4.49) in the 2-octyl cyanoacrylate group and 3.12±1.04 (95% CI: 2.82-3.41) in the suturing group. The score was significantly higher in the 2-Octyl Cyanoacrylate group (p value≤ 0.001). 4 of 50 (8%) patients from the tissue adhesive group developed

respectively(p value - 0.65). None of the patients showed any hypersensitivity to the product. **Conclusions:** 2-octyl cyanoacrylate is a safe and effective method for closure of skin incisions without any toxicity to the product. There is no difference in early complications such as breaking of film, wound dehiscence and wound infection when compared with conventional suturing. According to the Stony Brooke scar evaluation scale

breaking of adhesive film. 8% and 4% developed wound infection from the suturing and 2-octyl cyanoacrylate group

laparoscopic port sites closed using 2-octyl cyanoacrylate have better short term cosmetic appearance.

Keywords: Laparoscopy, Skin closure, 2-Octyl cyanoacrylate

INTRODUCTION

Ideal method for wound closure has always been a debateable topic. Today there are numerous methods available for closure of wounds like tissue adhesives, staplers, adhesive tapes and obviously the age old conventional suturing, all of which have their own pros and cons. Every patient would want a method that would heal a wound with minimal scar. However the final decision to use a particular method rests on the surgeon. The surgeon must evaluate each case individually and

choose closure material which will maximize the opportunity of healing and minimize the likelihood of infection.

The proper closure material will allow the surgeon to approximate the tissue with little trauma. Every surgery leaves behind a scar that may have functional, cosmetic or psychological consequences. Principle of wound closure should be to achieve precise wound approximation, have easy handling and working properties and have low infection rates. 1,2

In today's age minimally invasive surgeries are commonly performed. The advancement of laparoscopic surgeries has led to minimal post-operative scarring apart from decreasing the overall morbidity and hospital stay. Sutures are the classical and conventional technique for the purpose of wound closure. They require passage of a foreign material through tissues, if tied tightly or left for too long it may leave permanent suture marks and if removed early will result in dehiscence. Added to these setbacks, is an additional requirement of a dressing to protect the wound and suture as well. The ever-striving search for an alternative procedure and material lead to the discovery and development of tissue adhesives.

Cyanoacrylate is the generic name of the family of strong fast acting adhesives with industrial, medical and household uses. 3.4 Tissue adhesive were invented in 1949 and tried clinically for the first time in 1959. This procedure allows for normal wound healing and is accomplished without the need of local anaesthesia or entry of foreign material. The tissue adhesives, have been used in general surgery in the procedures related to abdomen, eyes, kidney, liver and vascular surgeries. This study aimed at evaluating the results of use of 2-octyl cyanoacrylate for port site skin closure in planned elective surgeries, comparing them with results of suturing.

METHODS

Study conducted a prospective consecutive 6 month interventional study including patients undergoing clean and clean contaminated elective laparoscopic surgeries at a tertiary care center. The study was initiated after obtaining the approval of The Institutional Ethics Committee as per Ethical Guidelines for Biomedical Research on human subjects, Indian Council of Medical Research, New Delhi, 2006. Written informed consent was taken from everyone willing to participate. The exclusion criteria included patients, with family history of keloids, on corticosteroid therapy, on anticoagulation therapy, any immune-compromised states, patients who required a conversion to open procedure or those who required a repeat surgery before the scar assessment. Patients were randomly divided pre operatively into 2 groups. The randomization was done using the randomization.com software that randomized each subject to a single treatment by using the method of randomly permuted blocks.

At the end of surgery the sheath and subcutaneous tissue at all the port sites were closed using no 1 polygalactin suture. Perioperatively each patient was given a single dose of injection cefotaxime 1gm, at the time of induction of anesthesia. The skin incisions at port sites in one group were sutured using no. 3-0 polyamide suture whereas; the other group was closed using 2-octyl cyanoacrylate. Polyamide was chosen as a comparator as it commonly used for skin closures. It is tough, possessing high tensile strength, as well as elasticity and luster. It is chemically

inert not reacting to alkali and acids. Being monofilament doesn't pose a risk to harbor micro-organisms.

Procedure

- In the comparator group after suturing the fascia with no 1 polygalactin, 3-0 polyamide suture was taken and the skin sutured with simple knotting technique
- 2-octyl cyanoacrylate is available in a sterile pre filled applicator, consisting of a breakable glass ampoule inside a plastic applicator. The ampoules contain 0.5 ml of adhesive. After the removal of all ports, hemostasis was confirmed. Port sites were cleaned and dried. The adhesive applicator was taken and ampoule in it crushed. Skin edges at the port site were held approximated with a forceps. Using the applicator a single layer of adhesive was applied and allowed to dry
- Post operatively all patients received 3 doses of Cefotaxime 1 gm 12 hours apart
- Prior to discharge a wound check was done to look for any wound infection, discharge or breaking of the tissue adhesive film. The presence of wound infection was decided by subjective clinical assessment by the presence or erythema, edema or wound discharge. Scar assessment was done after 1 month.

Table 1: Stony brook scar evaluation scale.

	Scar category	Points	
Width	>2 mm	0	
	≤ 2 mm	1	
Height	Elevated/depressed in relation to surrounding skin	0	
	Flat	1	
Color	Darker than surrounding skin	0	
	Same color or lighter than surrounding skin	1	
Hatch marks/Suture marks	Present	0	
	Absent	1	
Overall appearance	Poor	0	
	Good	1	

The scars of the patients were assessed using the Stony Brooke scar evaluation scale. This particular scale was selected as it was a subjective method of assessment with no devices required. More the score on the scale better is the cosmetic appearance of scar. Also this scale was developed for short term assessment of wounds 1. The reliability of this scale has been shown by Singer in his study 2. The data was compiled and statistically analyzed.

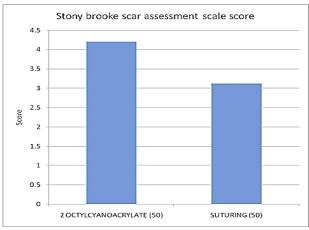
RESULTS

100 patients were enrolled into the study. 50 patients underwent closure of their laparoscopic port sites with 2-octyl cyanoacrylate of which 4 (8%) patients developed breaking of the tissue adhesive film. 8% of patients from the suturing group and 4% from the 2-octyl Cyanoacrylate group developed port site wound infection. The estimated relative risk for developing wound infection was 0.65 (CI 95%). None of our patients from either group developed hypersensitivity to 2-octyl Cyanoacrylate or polyamide sutures. The scar width, scar

height and scar colour was comparable between the 2 groups (p value - 1.00) (Table 1). For obvious reasons there were no hatch marks in the 2-octyl cyanoacrylate group. The Stony Brooke scar evaluation scale score showed the average score of 4.2±1.03 (95% CI, 3.90-4.49) in the 2-octyl cyanoacrylate group. The average score in the suturing group was 3.12±1.04 (95% CI: 2.82-3.41). The Stony Brooke scar assessment scale score was significantly higher in the 2-octyl cyanoacrylate as compared to the suturing group (p-value <0.001) (Figure 1).

Table 2: S	Scar evaluation with p-value.
rvlate (50)	Suturing (50)

Parameter	2 octyl cyanoacrylate (50)	Suturing (50)	p-value	Relative risk	CI of relative risk
Scar width	>2 mm: 11	>2 mm: 12	1.00	0.94	0.58-1.52
	<2 mm: 39	<2 mm: 38			
Scar height	Elevated with respect to surrounding: 8 Flat: 42	Elevated with respect to surrounding: 9 Flat: 41	1.00	0.93	0.53-1.608
Skin color	Darker than surrounding:10	Darker than surrounding:8	0.8	1.13	0.71-1.82
	Same color or lighter than the surrounding: 40	Same color or lighter than the surrounding: 42			
Hatch marks	Present: 0	Present: 50	< 0.001	-	-
	Absent: 50	Absent: 0			
Overall	Poor: 11	Poor: 16	0.36	0.76	0.46-1.26
appearance	Good: 39	Good: 34			



*p<0.0001 using Mann Whitney test as compared to the suturing group

Figure 1: Comparison of the SBSES scores.

DISCUSSION

The wound adhesive 2-octyl cyanoacrylate is approved by the US Food and Drug administration for closure of incised skin.³ Apart from using it for skin closure, various studies have been conducted showing the versatile use of 2-octyl cyanoacrylatye like reinforcing a colorectal anastamosis or a pacreaticojejunostomy, or repairing a clitoral laceration. This study consisted of clean and clean contaminated laprascopic surgeries which mainly comprised of laparoscopic cholecystectomies, laparoscopic appendicectomies, laparoscopic hernia repairs and diagnostic laparoscopy.

4 of 50 patients in 2-octyl cyanoacrylate group experienced breaking of the tissue adhesive film, 3 of which ultimately developed wound gape and required secondary suturing. Sebesta et al, found that 2 of 30 patients i.e. 6.6% who had their laparoscopic trocar wounds closed with 2-octyl cyanoacrylate developed subcuticular seroma with skin separation. Singer AJ and colleagues repaired traumatic lacerations using 2-octyl cyanoacrylate, on follow up they found that, only 1 wound was infected and only 2 wounds (out of 63 patients), required enclosure due to dehiscence. None of our patient experienced any hypersensitivity to the new technique of wound closure establishing the safety of the product. However studies across the globe have reported few cases of contact dermatitis related to cyanoacrylate.9 Adrian Dragu reported a case of foreign body reaction after 3 weeks in a 39-year-old female patient after usage of 2-octyl cyanoacrylate treating a superficial wound of the right wrist. ¹⁰ Sebesta and colleagues showed that there was no difference was noted in complication rates between tissue adhesive and suture group. ⁷ Similar findings were seen in our study.

8 percent of subjects in the suturing group developed wound infection compared to just 4 percent in the tissue adhesive group. These findings correlate with the finding of Maartense et al. that 2-octyl Cyanoacrylate was associated with fewer wound infections than were sutures. 11 Souza et al, found that routine use of topical adhesive for wound closure decreased the infection rates when used as an add-on measure to conventional sutures. with a significant reduction in infection rates for cardiovascular surgery patients. 12 Recently a comparative study conducted by Ando M et al, wound closure with staples was compared with 2-octyl cyanoacrylate. 8 out of 294 patients in the metal-staple group compared with none of 315 patients in the 2-octyl cyanoacrylate group acquired surgical site infections (SSIs) (p < 0.01). The study revealed that wound closure using 2-octylcyanoacrylate was associated with a lower rate infection.¹³ However, on the contrary, a recent Cochrane review concluded that there were no differences in the rates of wound infections or wound dehiscence between high viscosity octyl cyanoacrylate adhesives and sutures. 14

On assessment of the scar we found out there was no significant difference between the two groups with respect to the scar height, scar width or color of the scar (p value =1.00). After a 3 month follow up none of our patient developed a keloid or a hypertrophic scar. When compared with 2-octyl cyanoacrylate, for obvious reasons all the port sites closed by conventional suturing had hatch marks present at the end of one month (p value-<0.001). On subjective assessment of the scar there was no significant (p value- 0.36) difference between the two groups.

This study lacked the estimation of time duration of closure and cost of wound closure. The first prospective randomized trial in laparoscopic port site closure was done by Maartense et al, they found that closure of laparoscopic trocar wounds with 2-octyl cyanoacrylate reduces the operating room time. Sebesta in his study found that the skin closure with octyl cyanoacrylate is cheaper and faster by 9 minutes per case. Matin S et al found out that in laparoscopic surgeries involving 4 or more port sites the time required for closure was significantly less (median 2.5 minutes versus 6 minutes, p < 0.001) when compared to conventional suturing. Is

Studies comparing conventional suturing with tissue adhesive for closure wound incisions in other surgeries have had varied results. In 1997, a randomized control trial comparing octyl cyanoacrylate and sutures in the management of lacerations found no difference in the cosmetic outcome and there was no difference in the percentage of early or late optimal wound evaluation

scores. Tissue adhesive was found to be a less painful method of closure. This study showed that 2-octyl cyanoacrylate was fast and painless method of closure. Toriumi compared sutures with 2-octyl cyanoacrylate for closure of incision in facial surgeries, results of wound evaluation at 90 days determined by the modified Hollander scale revealed equivalent cosmetic results in both groups.¹⁷ A randomized controlled trial by Zempsky et al, achieved similar cosmetic results tissue glue in facial lacerations in children. 18 Singer AJ et al conducted a prospective, randomized, controlled trial of tissue adhesive versus standard suturing for laceration repair. There were 63 patients randomized to the tissue adhesive group and 61 patients with standard suturing technique. They concluded that the long term cosmetic appearance was similar in both the groups.⁸ On the contrary, Bernard L et al, compared tissue adhesive and conventional suturing for lacerations and surgical wounds found that the cosmetic outcome of cutaneous excisional surgery wounds closed with standard suturing was found to be superior to that of wounds closed with octyl cyanoacrylate.19

In this study the average Stony Brooke scar evaluation scale score in the 2-octyl cyanoacrylate group was $4.2\pm1.03~(95\%~CI:~3.907-4.49)$. In the suturing group the average score was $3.12\pm1.04~(95\%~CI:~2.82-3.41)$. On comparing the two methods of port site skin closure there was statistical significance (p value ≤ 0.001) showing that 2-octyl cyanoacrylate was a better method when subjective parameters of scar were compared. A metananlysis based on four clinical trials encomassing 404 patients showed that there is insufficient evidence that port-site wound closure technique by tissue adhesives is superior to traditional suture closure technique in terms of wound infection, wound dehiscence, and patient satisfaction. 20

Finally the Cochrane review in which eight RCTs (630 patients) on comparison of tissue adhesives and sutures were included no statistically significant difference was found for dehiscence, infection or cosmetic appearance. However a statistically significant difference was found for surgeons' assessment of cosmetic appearance with mean difference 13 (95% CI 5 to 21), the higher mean rating for the tissue adhesive group.²¹

In 2010 this was updated in which an additional six trials resulting in a total of fourteen RCTs (1152 patients). 10 trials showed that sutures were significantly better than tissue adhesives for minimizing dehiscence. On the contrary to previous studies, sutures were also found to be significantly faster to use. There was no significant difference between sutures and tissue adhesives for in terms of infection, patient and operator satisfaction and cost. One of the trials had compared tissue adhesives with a variety of methods of wound closure and found that both patients and clinicians were significantly more satisfied with the alternative closure methods than the adhesives.

CONCLUSION

From this study it can be concluded that the use of 2-octyl cyanoacrylate has an advantage of cosmetically better scar when compared to conventional suturing. However, there are no differences in the early complications between the tissue adhesive and suturing. 2-octyl cyanoacrylate is a safe and effective method for closure of skin incisions without any short term side effect related to the product. There is no difference in early complications such as breaking of film, wound dehiscence and wound infection when compared with conventional suturing. According to the Stony Brooke scar evaluation scale laparoscopic port sites closed using 2-octyl cyanoacrylate have better short term cosmetic appearance.

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institutional ethics committee

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