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Comparison of Prolene and Polydioxanone in Midline Closure

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Abstract

Objective:
To compare the frequency of post-operative wound infection with polydioxanone and prolene in midline closure in laparotomy.

Study Design:
Randomized Controlled Trial.

Setting:
Department of Surgery, KTH, Peshawar.

Duration of Study:
This study was conducted from 1st May 2021 to 1st November 2021.

Subjects and Methods:
A total of 130 patients of both gender undergoing elective laparotomy with midline abdominal incisions were included in the study. Final assessment of wound infection was done on 30th postoperative day as per operational definition from both groups and noted.

Results:
Age range in this study was 18 to 50 years with mean age of 36.569±8.03 years and mean duration of procedure was 70.430±11.29 mins in Group A and mean age of 39.446±7.79 years and mean duration of procedure was 68.646±10.81 mins in Group B. Wound infection was observed in 2 (3.1%) patients in group A as compare to 11 (16.9%) patients in group B (P= 0.009).

Conclusion:
Our study showed closure technique using Polydioxanone for closure of midline laparotomy incision is superior to prolene suture material in preventing wound infection.

Keywords: Laparotomy, Polydioxanone, Prolene, Wound Infection

Introduction

Laparotomy is the collective term for a variety of intra-abdominal surgical procedures [1]. Laparotomy is high risk surgery associated with considerable risk of morbidity and mortality. International cohort studies have demonstrated 30- day mortality rates ranging 5-19% with even higher rates in older patient groups [2, 3]. The clinical outcomes from emergency abdominal surgery appear to be inferior in comparison with outcomes from similar elective procedures [4]. The reasons for this may be multifactorial and include patient factors, underlying pathology, surgeon experience, access to diagnostic services, and timely evaluation by senior clinical decision makers [5].

The most common procedure is the midline laparotomy where an incision is made down the middle of the abdomen along the linea alba [6]. The size of the incision can be limited depending on the site of the pathology [6]. For example, an upper gastrointestinal problem may not require a lower midline incision. However, the decision can always be extended lengthways to gain more access if needed [6].

Among several factors which affect the wound closure, a careful selection of proper suture material is one of the important factors. The ideal suture material with the perspective of fast and comfortable recovery is yet to beascertained [7]. Surgeons always follow a primary wound closure because wound heals by primary intention with a minimal time period without gaping and minimal scarring. Absorbable sutures are required for a wound that heals quickly and needs temporary support [7]. Polydioxanone (PDS) a monofilament synthetic absorbable suture represents a significant advance in suturing options [8]. With its absorbability and extended wound support for up to 6 weeks, it is well suited for many types of soft tissue approximation. With the combinational property of retaining strength for considerable period and absorbability it is of significant value in laparotomy wound closure and has minimal post-operative complications [8].

In a study by Shankar KH, *et al*. has shown that frequency of post- operative wound infection was 2% with polydioxanone as compare to 16% with prolene in midline closure in laparotomy [9]. In another study by Naz S, *et al*. has shown that frequency of post-operative wound infection was 33.9% with polydioxanone as compare to 67.1% with prolene in midline closure in laparotomy [10].

Polydioxanone (PDS) and polypropylene (Prolene) are widely used suture materials. Polydioxanone is absorbed slowly over 6 months. It maintains fifty percent of their tensile for a month. Polydioxanone have 1.7 times tensile strength of prolene. No such comparative study has been done before in our general population. Therefore, I have planned to compare the frequency of post-operative wound infection with polydioxanone and prolene in midline closure in laparotomy. Result of my study will help to select the better modality in midline closure in laparotomy in our population.

Materials and methods

Study design:
Randomized Controlled Trial.

Setting:
Department of Surgery, KTH, Peshawar.

Duration of study:
This study was conducted from 1st May 2021 to 1st November 2021.

Sample size:
130 sample size was calculated with 95% Confidence Level and alpha = 5% (two-sided) with power = 80%. While using expected frequency of post-operative wound infection by 2% with polydioxanone as compare to 16% with prolene in midline closure in laparotomy [9].
65 patients was in polydioxanone group or Group A while 65 patients was in prolene group or Group B.

Sampling technique:
Non-probability consecutive sampling.

Inclusion Criteria:
- Age 18 to 50 years.
- Both gender.
- Undergoing elective laparotomy with midline abdominal incisions.
- ASA grade I and II (Annexure-II).

Exclusion Criteria:
- Already undergone operations with midline abdominal incisions.
- Patients who require closure of abdominal wall with tension sutures.
- H/o malignant ascites.

Data Collection Procedure:
Patients fulfilling the inclusion criteria from Department of Surgery, KTH, Peshawar were included in the study after permission from ethical committee. Informed consent was taken from patients. Basic demographics (Age, gender, duration of procedure) were recorded.
Randomization was performed by block randomization. 65 patients were in polydioxanone group or Group A while 65 patients were in prolene group or Group B.
Continuous single layer mass closure technique was used for closure of midline abdominal wounds. Surgery was done by a same team of surgeons. In group A patients: Midline laparotomy closure done by PDS. In group B patients: Midline laparotomy closure done by polypropylene. Prophylactic intravenous antibiotics were given to all patients to cover gram negative organisms and anaerobes at the time of induction and continued postoperatively for at least for 5 days. Intravenous analgesics also administered for same period. Wound infection was judged by wound examination till the wound heals (Daily for 7 days and then weekly for 4 weeks). Final assessment of wound infection was done on 30th postoperative day as per operational definition from both groups and noted on especially designed proforma (Annexure-I).

Data Analysis:
Data was analyzed with statistical analysis program (SPSS version 23). Frequency and percentage was computed for categorical variables like gender, ASA grade and wound infection. Mean ±SD was presented for quantitative variables like age and duration of procedure. Chi-square test was applied to compare wound infection in both groups taken $p \leq 0.05$ as significant.
Wound infection was stratified to age, gender, ASA grade and duration of procedure. Post stratification using the chi-square test for both groups, $p < 0.05$ was considered statistically significant.

Results
Age range in this study was 18 to 50 years with mean age of 36.569±8.03 years and mean duration of procedure was 70.430±11.29 mins in Group A and mean age of 39.446±7.79 years and mean duration of procedure was 68.646±10.81 mins in Group B as shown in Table-I.
Male gender was dominant in both groups as shown in Table-II.
Frequency and percentage of ASA group in both groups are shown in Table-III Wound infection was observed in 2 (3.1%) patients in group A as compare to 11 (16.9%) patients in group B (P= 0.009) as shown in Table IV. Stratification of wound infection in both groups with regard to age, gender, ASA grade and duration of procedure are shown in Table-V, VI, VII and VIII respectively.

Table 1: Mean±SD of patients according to age and duration of procedure, n=130

Demographics	Group A n=65 Mean±SD	Group B n=65 Mean±SD
Age (years)	36.569±8.03	39.446±7.79
Duration of procedure (mins)	70.430±11.29	68.646±10.81

Table 2: Frequency and percentage of gender in both groups

Gender		n=65 Group A	n=65 Group B
1	**Male**	54 (83.1%)	49 (75.4%)
2	**Female**	11 (16.9%)	16 (24.6%)
	Total	65 (100%)	65 (100%)

Table 3: Frequency and percentage of ASA group in both groups

ASA group		n=65 Group A	n=65 Group B
1	**I**	48 (73.8%)	53 (81.5%)
2	**II**	17 (26.2%)	12 (18.5%)
	Total	65 (100%)	65 (100%)

Table 4: Comparison of wound infection in both groups

Wound infection		n=65 Group A	n=65 Group B	P Value
1	**Yes**	2 (3.1%)	11 (16.9%)	
2	**No**	63 (96.9%)	54 (83.1%)	
	Total	65 (100%)	65 (100%)	0.009

Table 5: Stratification of wound infection with respect to age in both groups

For Age 18-35 years

Group	Wound infection		P value
	Yes	No	
A	2(5.9%)	32(94.1%)	0.717
B	2(8.3%)	22(91.7%)	

For Age >35 years

Group	Wound infection		P value
	Yes	No	
A	0(0%)	31(100%)	0.005
B	9(22%)	32(78%)	

Table 6: Stratification of wound infection with respect to gender in both groups

For Male

Group	Wound infection		P value
	Yes	No	
A	2(3.7%)	52(96.3%)	0.008
B	10(20.4%)	39(79.6%)	

For Female

Group	Wound infection		P value
	Yes	No	
A	0(0%)	11(100%)	
B	1(6.2%)	15(93.8%)	**0.398**

Table 7: Stratification of wound infection with respect to ASA grade in both groups

For ASA-I

Group	Wound infection		P value
	Yes	No	
A	2(4.2%)	46(95.8%)	0.023
B	10(18.9%)	43(81.1%)	

For ASA-II

Group	Wound infection		P value
	Yes	No	
A	0(0%)	17(100%)	0.226
B	1(8.3%)	11(91.7%)	

Table 8: Stratification of wound infection with respect to duration of procedure in both groups;

For ≤ 60 mins

Group	Wound infection		P value
	Yes	No	
A	0(0%)	18(100%)	0.266
B	1(6.7%)	14(93.3%)	

For > 60 mins

Group	Wound infection		P value
	Yes	No	
A	2(4.3%)	45(95.7%)	0.019
B	10(20%)	40(80%)	

Discussion

Abdominal surgeries are the most commonly done procedures. There by incision and closure (suturing) of abdominal wall is one of the commonest exercises in surgery. There are number of techniques of closure of abdominal wall with its own advantages and disadvantages [11]. Regarding the healing of abdominal wound however meticulously closed, the healing takes place en-mass, even when closures done in layered technique because of formation of dense fibrous block of tissue. This is evident from the scar of previous surgeries when it is opened. While suturing, bites should be taken at a minimum distance of 1 cm from wound edge and the interval between two sutures should be 1 cm. The material taken for suturing in the present study was four times the wound length as reported earlier [12-14]. There are many factors which delay the wound healing both systemic and local factors. In spite of improved surgical skills, the morbidity associated with abdominal wound is still high. So, surgeons give maximum importance for the wound closure and care. Systemic factors include obesity, jaundice, diabetes, malnutrition, protein deficiency, elderly patients, patients on steroids and immune-suppressants. Local factors which delay wound healing after laparotomies are wound infection, hematoma, foreign body reaction. All these impose stress on the freshly sutured abdominal wound [15-17]. In both groups, the closure of abdominal wound was done in a continuous en-mass. Polydiaxanone sutures are strong, delayed absorbable, retain their strength after implantation, are inert, cause minimal tissue reaction and technically has a better handling during the closure. The only disadvantage is their slipping quality in handling and in tying. This can be overcome by using minimum five knots as reported by others [18]. The wound complications are wound pain, wound infection, wound dehiscence, suture sinus formation, palpable knots and incisional hernia. Wound pain is the subjective feeling of pain in the postoperative wound site. Wound pain is graded according to the visual analogue scoring. Wound pain depends on the suture material. If suture material stays for a prolonged period without getting absorbed, it itself is a factor for wound pain. Because it causes irritation and causes pain. Polypropylene which is a nonabsorbable suture material is more irritant to the tissue and causes moderate wound pain. Polydiaxanone which is a delayed absorbable suture material which is less irritant to the tissue causes mild wound pain. In our study we observed wound infection (purulent discharge) among 2 patients in group A (3.1%) and among 11 patients in group B (16.9%). Also, group- B patients had a maximum infection rate even in emergency laparotomy as compared to group A.

Comparison to the earlier report our study showed that polydiaxonone sutures had a lesser incidence of wound infection [19].

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From this, it is evident that chances of wound infection in both emergency and elective operations is observed to be higher in Polypropylene (PPL) suture material compared to Polydiaxanone (PDS) and thus Polydiaxanone suture is considered preferable in emergency and elective surgery. In a prospective study conducted, wound dehiscence was noted in 7.8% patients among 30 belonging to polydiaxonone group and none of the patients had this complication among 34 patients of polypropylene group [20]. In comparison to the previous study, we observed that Polydiaxanone suture material has lesser incidence of wound dehiscence in the postoperative period when compared to polypropylene suture material [19]. In a prospective study conducted, 6 out of 141 patients developed incisional hernia in the polydioxanone group, while 5 patients developed incisional hernia in polypropylene group (P=0.981). This finding was found to be statistically insignificant as concluded in the other study as well. In a study conducted 1 patient out of 30 in the polypropylene group developed this complication, and none of the patients in the polydioxanone group developed this complication [20]. In comparison with the above study, polydioxanone had lesser incidence of suture sinus formation as observed in present study.

Conclusion

Based on the observations made in this study, it has been concluded that closure technique using Polydioxanone for closure of midline laparotomy incision is superior to prolene suture material in preventing the wound complications like post-operative wound infection.

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