An ideal suture for midline abdominal closure?

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Abstract

Background Within the last decade the customary trend of using non absorbable sutures has changed, with numerous studies and meta-analyses advocating the use of slowly absorbable sutures, claiming comparable wound strength with significantly lower incidence of wound complications. It was the objective of this randomized clinical trial to compare two universally accepted suture materials, the non-absorbable Nylon and the slowly absorbable Polydioxanone for midline abdominal closure in the Indian context.

Method 64 patients undergoing midline laparotomy were allocated, using block randomization, to mass closure of the abdominal wall with continuous polyamide (34 patients) or continuous polydioxanone (30 patients).

Results There was an alarmingly higher incidence of wound dehiscence in the PDS group requiring secondary suturing (Nylon 0; PDS 5). Mid-way through the trial, an interim analysis was performed which revealed an unacceptably high incidence of wound dehiscence in the PDS group. This necessitated a premature curtailment of the study. There was, however, a statistically significantly higher incidence of scar pain in the Nylon group (Nylon 9; PDS 1).

Conclusion There is a need for a study with larger series, and PDS as a choice of suture for midline wound closure cannot be recommended.

Keywords Midline abdominal closure · Polyamide · polydioxanone

Introduction

The midline laparotomy incision is extremely standardized and easy to perform, yet there has been considerable variation in the method of the repair of this incision. The ideal suture should prevent incisional hernia and wound dehiscence, without increasing wound infection, wound pain or the formation of suture sinus [1].

Within the last decade the customary trend of using nonabsorbable sutures has changed, with numerous studies and meta-analyses advocating the use of slowly absorbable sutures, claiming comparable wound strength with significantly lower incidence of wound complications [2–6].

Polydioxanone is a synthetic monofilament absorbable suture, which is relatively inert in tissues and retains its strength for longer (nearly 60% percent at 4 weeks) than other absorbable materials. This extension of wound support provided by polydioxanone is highly significant, providing substantially increased support beyond the required 4-week period in which the abdominal fascia commences remodeling by cross-linking of collagen fibers [7].

Although some studies have been performed in the western scenario, no study has been conducted so far on the Indian subject. The Indian patient differs from his/her counterpart in developed countries in terms of nutritional status and associated morbidity patterns [8]. It was the objective

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of the present study to compare two universally accepted suture materials, the non-absorbable Nylon and the slowly absorbable Polydioxanone for midline abdominal closure in the Indian context.

Patients and methods

This randomized prospective comparative study was conducted in the Department of Surgery, Christian Medical College and Hospital, Ludhiana, extending over a proposed period of two years, from 1st October 2004 to September 30th 2006. Adult patients undergoing a laparotomy through a midline incision in the Department of Surgery were recruited into this study. Informed consent was obtained from each patient and the study was approved by the Research & Ethics Committee of Christian Medical College & Hospital, Ludhiana.

Using block randomization, patients were allocated at surgery to abdominal fascial closure with Ethilon (Polyamide) or PDS II (Polydioxanone) (Ethicon Inc., (Loop) no. 1, round bodied half-circle needle, 50 mm needle length, 150 cm suture length).

The overall operative, antibiotic and management policies were standardized. The abdominal fascia was sutured by the continuous mass-closure technique including all the layers of the abdominal wall excluding skin. Wide bites, at least 1 cm from the wound edges were taken, with a distance of 1 cm between suture bites. The practice of delayed primary closure was implemented for contaminated wounds at the discretion of the operating surgeon⁹.

All patients were followed up daily for the first 7 days, then on the 14th and 21st postoperative days, and thereafter

on the 3rd and 6th months. Wound complications were observed or enquired for at this time.

The abdominal surgical wound was defined as clean when the alimentary or genitourinary tract was not entered. It was defined as clean-contaminated when the alimentary tract was entered without significant spillage, or a non-infected genitourinary or biliary tract was entered. It was defined as contaminated when there was gross spillage from the alimentary tract, or an infected genitourinary or biliary tract was entered [10]. Wound infection was defined as frank pus discharge from the wound or if wound fluid culture was positive. Dehiscence was recorded when evisceration occurred. Direct enquiry was made as to the persistence of wound pain or suture awareness at follow up. Any reported pain was recorded as moderate or, if the patient took analgesics, graded as severe. Incisional hernia was reported when a protruding swelling and a fascial defect was palpable in the wound. Suture sinus was reported when a sinus was present in the suture tract.

Any complication, if identified, was followed up. Additional information on diagnoses, operative procedure, postoperative complications and antibiotic therapy was recorded prospectively.

Patients were stratified according to factors independent of suture material including age (≥ 60 years, < 60 years), gender, type of surgery (elective, emergency), degree of contamination (clean, clean-contaminated, contaminated), surgeon (consultant, registrar), incision (supra-umbilical, or extended on either side of umbilicus), and presence of a stoma (Table 1).

Patient-related factors including anemia, jaundice, pulmonary complications, hypoproteinemia, sepsis, uremia,

Table 1 Factors independent of suture material

Subgroup allocation	Nylon (n=34)	PDS (n=30)	Total (n=64)		Chi-square	p value
	No.	No.	No.	%		
≥ 60 YRS	4	6	10	15.6	.820	.365
< 60 YRS	30	24	54	84.4		
Male	26	20	46	71.9	.758	.384
Female	8	10	18	28.1		
Elective	13	13	26	40.6	.172	.679
Emergency	21	17	38	59.4		
Clean	17	11	28	43.7	1.241	.538
Clean-contaminated	8	11	19	29.7		
Contaminated	9	8	17	26.6		
Consultant	28	26	54	84.4	.225	.635
Registrar	6	4	10	15.6		
Supra-umbilical	3	7	10	15.6	2.545	.111
Both	31	23	54	84.4		
Stoma present	5	6	11	17.2	.314	.575
Stoma absent	29	24	53	82.8		

There were no statistically significant differences between factors ($p > 0.05$)

malignancy, hypertension, and diabetes mellitus, were also recorded.

Statistical analysis

Analyses were conducted using Statistical Package for the Social Sciences (SPSS, Chicago, Illinois, USA) software (Version 12). Statistical homogeneity was assessed by Pearson chi-square (χ^2) tests of heterogeneity. $P \leq 0.05$ was considered to be statistically significant.

Results

A total of 64 patients were recruited into the study, 34 in the Nylon group and 30 in the PDS group. The two groups were well matched according to age, gender, type of surgery, degree of contamination, surgeon, incision, presence of a stoma, and patient-related factors.

There was a statistically significantly higher incidence of wound dehiscence in the PDS group ($p=0.013$), with 5 patients in the PDS group ($n=30$) experiencing wound dehiscence requiring secondary suturing, and no cases of wound dehiscence in the Nylon group. The overall incidence of wound dehiscence in this study was high ($n=5$, 7.8%).

An analysis was performed after one year of the commencement of the study. The unacceptable incidence of wound dehiscence in this study necessitated an early discontinuation of the study.

The incidence of wound infection did not show a statistically significant difference between suture groups ($p=0.821$). The incidence of scar pain was significantly higher in the Nylon group ($p=0.011$). 9 patients in the Nylon group ($n=34$) experienced scar pain (at 3 months), while there was only 1 such patient in the PDS group.

There were no reported cases of incisional hernias in this study. The incidence of suture sinus demonstrated no statistically significant difference between suture groups ($p>0.344$).

No significant difference in incidence of wound complications was reported when patients were stratified according to factors independent of suture material such as age, gender, type of surgery, degree of contamination, surgeon, and presence of a stoma ($p>0.05$). Furthermore, no patient-related factors (anemia, jaundice, pulmonary complications, hypoproteinemia, sepsis, uremia, malignancy, hypertension, and diabetes mellitus) statistically significantly influenced wound complications. ($p>0.05$)

Discussion

Abdominal fascial closure has remained a procedure that often reflects a surgeon's personal preference with a

reliance on tradition and anecdotal experience despite advances in surgical technique and material. Numerous randomized controlled trials of abdominal fascial closure have failed to determine the ideal suture material with finality [11–13]. Certain meta-analyses [1, 14] recommend the use of non absorbable sutures, where as others [4, 5] advocate slowly absorbable suture material for abdominal fascial closure. These results from previously performed studies have often been conflicting. Furthermore, a study performed on the Indian patient need not offer concurring results as those conducted on their counterparts in developed countries because of the greater prevalence of malnutrition, anemia, and hypoproteinemia as well as dissimilar co-morbidity patterns [8]. No such study has been carried out till date in the Indian setting.

Mid-way through the trial, an interim analysis was performed which revealed a significantly high incidence of wound dehiscence in the PDS group. This necessitated a premature curtailment of the study.

There was a very high incidence of wound dehiscence ($n=5$) in the PDS group, which has not been reported in any previously performed study [6, 11–13, 15]. Individual patient profile was recorded for the 5 patients with wound dehiscence (Table 2). Furthermore, abdominal closure methodology was standardized for all patients and all participating surgeons re-confirmed proper closure technique post-operatively, leaving little room for surgical error. All 5 cases of wound dehiscence in the PDS group occurred in the first 7 post-operative days and a broken suture was found on secondary suturing, though a standard suture from a reputed company was used.

Various studies [3, 6] have demonstrated a significantly lower incidence of wound infection as well as suture sinus in the PDS group. However in this study, the incidence of these complications were not statistically significantly different between suture groups.

The short follow up period (6 months) may be a possible reason for the absence of incisional hernias in this study since $>5\%$ of incisional hernias have been reported to occur after 6–12 months [16].

There was significantly less scar pain experienced in the PDS group, possibly because PDS being an absorbable suture caused less foreign body tissue reaction [17]. Similar findings were reported by another study [6].

The present study demonstrated a statistically significantly higher incidence of scar pain in the Nylon group; however, there was a significantly higher incidence of wound dehiscence requiring secondary suturing in the PDS group (Table 3).

There is a strong selection bias in the study because only those patients who surgeons thought would have a relatively more favorable outcome were recruited for randomization. This, along with substantial patient consent denial and premature curtailment of this study produced a small sample size, with results theoretically inferior to larger studies.

Table 2 Individual patient profile (wound dehiscence)

Factor	Patient no. 2	Patient no. 3	Patient no. 16	Patient no. 19	Patient no. 22
Age	35	44	58	38	75
Gender	Male	Male	Male	Male	Female
Type of surgery	Emergency	Emergency	Elective	Emergency	Emergency
Degree of contamination	Contaminated	Contaminated	Clean	Contaminated	Clean
Surgeon	Consultant	Registrar	Consultant	Registrar	Consultant
Incision	Extended	Extended	Extended	Extended	Extended
Stoma	Yes (loop ileostomy)	Yes (Loop Ileostomy)	No	No	No
Wound infection	Yes (E. Coli)	No	No	Yes (E. Coli)	No
Anemia (Hb<10)	Yes (Hb 8)	No (Hb 11)	Yes (Hb 9)	No (Hb 12)	No (Hb 11)
Jaundice (Bil >3)	No (Bil 2)	No (Bil 1)	Yes (Bil 6)	No (Bil<1)	No (Bil 1)
Pulmonary disease	Yes (Pneumonia)	Yes (pneumonia)	No	No	No
Hypoproteinemia (Alb<3)	Yes (Alb 2.5)	No (Alb 4.1)	Yes (Alb 2)	No (Alb 4.3)	No (Alb 4.0)
Sepsis	Yes	No	No	No	No
Uremia (Cr>1.7)	No	No	No	No	No
Malignancy	No	No	Yes (Ca head of pancreas)	No	No
Hypertension	No	Yes	No	No	Yes
Diabetes	No	No	No	No	No

Table 3 Wound complications

Complications	Nylon (n=34)	PDS (n=30)	Total (n=64)		Chi-square	p value
	No.	No.	No.	%		
Wound dehiscence	0	5	5	7.8	6.147	0.013
Wound infection	4	3	7	10.9	0.051	0.821
Incisional hernia	0	0	0	0		
Suture sinus	1	0	1	1.6	0.896	0.344
Scar pain	9	1	10	15.6	6.472	0.011

There was a statistically significantly higher incidence of wound dehiscence in the PDS group ($p=0.013$).

There was a statistically significantly higher incidence of scar pain in the Nylon group ($p=0.011$).

However, inspite of this selection bias, an unexpected and alarmingly high incidence of wound dehiscence was observed. Our attempts to account for this complication have only been able to highlight the suture material (polydioxanone) as a risk factor for wound dehiscence. The probability of faulty suture material, faulty technique and patient factors have all been taken into account, but no evidence in favor or against these factors have turned up (Table 2). All the sutures used were from the same batch.

Conclusion

In conclusion, there is a need for a study with larger series, and PDS as a choice of suture for midline wound closure

cannot be recommended. The towering rate of wound dehiscence in the study as well as the compelling evidence favoring nylon has not yet been reported in literature. Despite its theoretical flaws this study emphatically induces the surgeon to take note of the apparent shortcomings in the effectiveness of slowly absorbable sutures for midline abdominal closure.

Conflict of interest The authors do not have any disclosable interest.

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