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A Prospective Comparative Open Label Study to Evaluate Wound Outcome in Laparotomy Patients using Polydiaxonone Vs Polypropylene for Abdominal Fascia Closure

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1. Introduction

Laparotomy through midline abdominal incision is commonly used technique because it is easy, fast and provides good exposure to all four quadrants. Prevention of complication is important to reduce postoperative morbidity, mortality and decrease hospital stay. Wound healing following abdominal fascia closure is a dynamic and complex process with changing wound health status of the individual and changing wound environment. There were several factors which affect the wound closure, appropriate selection of proper suture material depends upon its characteristics like strength, durability, ease of handling and resistance to infection. there is no established technique generally considered as safe and best for abdominal fascia closure after laparotomy. In primary wound closure the wound heals by primary intension with a minimal duration of period without gaping and minimal scarring. Absorbable suture were required for a wound that heals quickly and gives temporary support. Polydiaxanone (PDS) a monofilament synthetic absorbable suture having its absorbability and extended wound support for up to 6 months and suited for many types of soft tissue approximation. The combinational property of absorbability and retaining strength for considerable period helps in laparotomy fascia closure. Non absorbable sutures are required where longer wound support is needed. Polypropylene is a synthetic nonabsorbable suture material and has a property of non adherent to tissue and less tissue reaction.

Aim

To compare the effectiveness of delayed - absorbable (Polydioxanone; PDS) versus non - absorbable (Polypropylene; Prolene,) for abdominal fascial closure in patients undergoing midline laparotomy.

Objectives

- To compare for wound pain between 2 groups.
- To compare for Wound discharge between 2 groups.
- To compare for incidence of wound dehiscence between 2 groups
- To compare for Suture sinus formation between 2 groups.
- To compare for Palpable knots between 2 groups.
- To compare for incidence of incisional hernia.

2. Methods

A prospective comparative study of 100 patients admitted in the department of surgery sir t hospital Bhavnagar who undergo laparotomy operations with midline abdominal incisions were included in the study, divided into two groups.

Group A patients with Polydiaxone closure and Group B with polypropylene in laprotomy will be observe up to the time of discharge by every day follow up and weekly (4weeks) and monthly follow up.

Prophylactic intravenous antibiotics were given to all patients to cover gram positive, 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 will be judged by wound examination till the wound heals (Daily up to discharge and then weekly for 4 weeks) and monthly once.

Duration of hospital stay, local wound complication, post operative pain using VAS pain score, were the parameters that were studied to compare about the efficacy of suture material.

3. Result

Table 1: Age distribution

			Allocated to group A/B:		Total
			Group A	Group B	
Age	15 - 30 years	Count	10	12	22
		% within Age recorded	45.5%	54.5%	100.0%
		% within Allocated to group A/B:	20.0%	24.0%	22.0%
		% of Total	10.0%	12.0%	22.0%
	31 - 45 years	Count	18	17	35
		% within Age recorded	51.4%	48.6%	100.0%
		% within Allocated to group A/B:	36.0%	34.0%	35.0%
		% of Total	18.0%	17.0%	35.0%
	46 - 60 years	Count	16	14	30
		% within Age recorded	53.3%	46.7%	100.0%
		% within Allocated to group A/B:	32.0%	28.0%	30.0%
		% of Total	16.0%	14.0%	30.0%
	Above 60 years	Count	6	7	13
		% within Age recorded	46.2%	53.8%	100.0%
		% within Allocated to group A/B:	12.0%	14.0%	13.0%
		% of Total	6.0%	7.0%	13.0%
Total		Count	50	50	100
		% within Age recorded	50.0%	50.0%	100.0%
		% within Allocated to group A/B:	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

In our present study of total 100 patients, mean age was 44.11 years and SD of 15.584. In group A mean age was 44.48 and SD of 14.54 and in Group B mean age was 43.74 and SD of 16.70

While in study done by Samina Naz, the mean age was 31.81 years with SD of 14.37 in Group A and the mean age was 33.99 years with SD of 14.86 in Group B

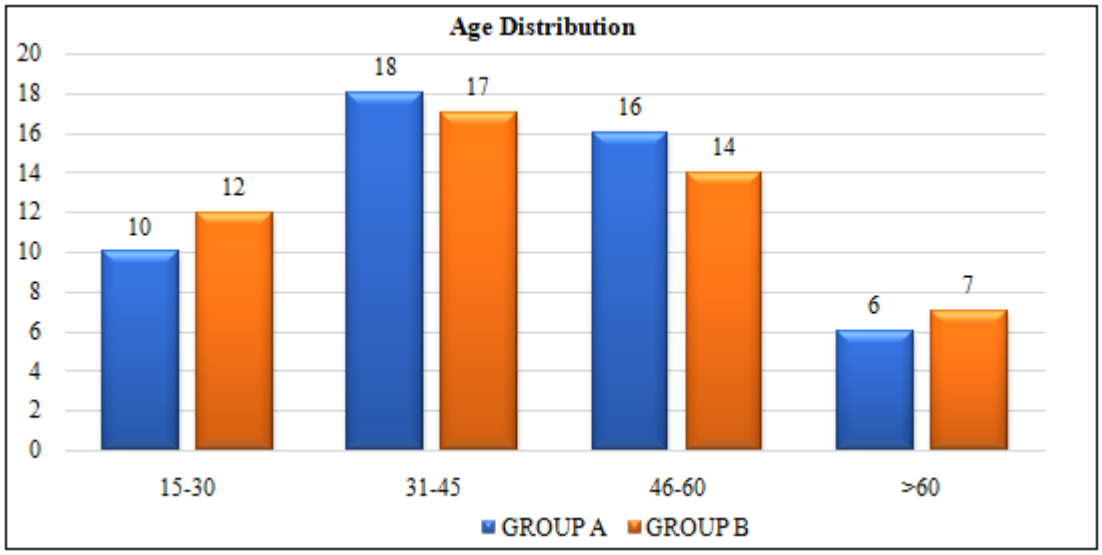


Table 2: Total duration of hospital stay (Days):

Hospital Stay	Group A	Group B
Mean	13.48	13.80
Standard Deviation	4.45	4.77

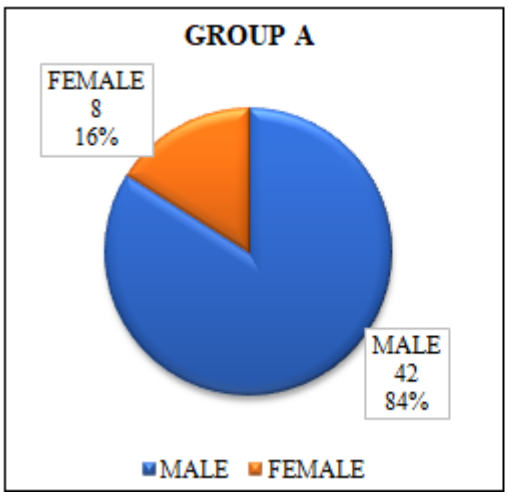
In this study, mean hospital stay was 13.48 and SD was 4.45 in Group A and mean hospital stay was 13.8 and SD was4.77 in Group B.

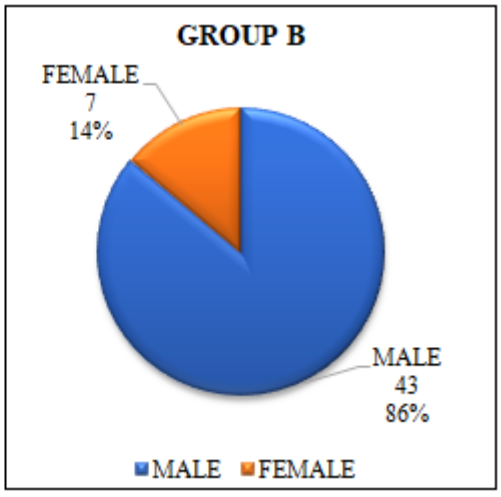
While in study carried out by Samina Naz et al [59], mean hospital stay in Group A was 11.8 and of SD 5.33 and mean hospital stay in Group B was 9.2 and of SD 1.81.

Table 3: Sex distribution

			Allocated to group A/B:		
			Group A	Group B	Total
SEX	**Male**	Count	42	43	85
		% within SEX	49.4%	50.6%	100.0%
		% within Allocated to group A/B:	84.0%	86.0%	85.0%
		% of Total	42.0%	43.0%	85.0%
	Female	Count	8	7	15
		% within SEX	53.3%	46.7%	100.0%

		% within Allocated to group A/B:	16.0%	14.0%	15.0%
		% of Total	8.0%	7.0%	15.0%
Total		Count	50	50	100
		% within SEX	50.0%	50.0%	100.0%
		% within Allocated to group A/B:	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%





In Group A 84% male patients and 16% female patients and in Group B 86% are male patients and 14 % are female patients. While in study done by Samina Naz et al [59] in Group A 54.2% are male patients and 45.8% are female patients and in Group B 53.2% are male patients and 46.8% female patients.

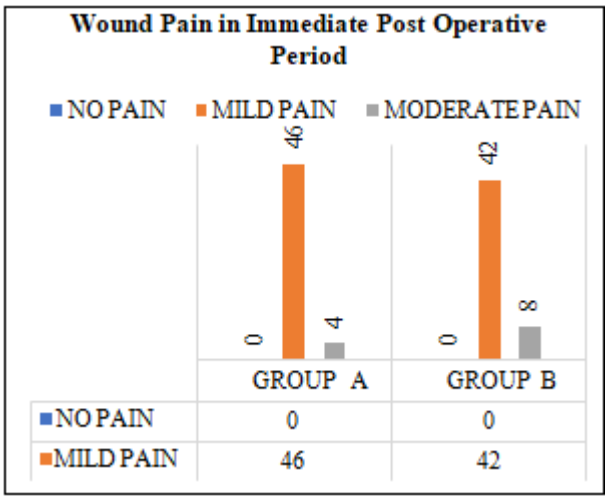
Table 4: Type of Surgery

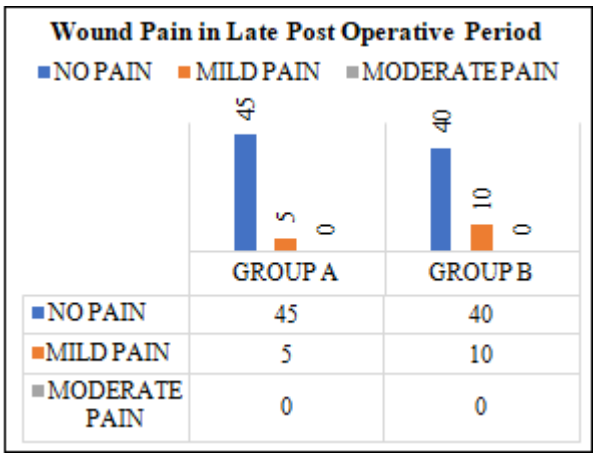
			Allocated to group A/B:		Total
			Group A	Group B	
Type of Surgery	Clean contaminated	Count	7	6	13
		% within TYPE OF SURGERY	53.80%	46.20%	100.00%
		% within Allocated to group A/B:	14.00%	12.00%	13.00%
		% of Total	7.00%	6.00%	13.00%
	Contaminated	Count	35	34	69
		% within TYPE OF SURGERY	50.70%	49.30%	100.00%
		% within Allocated to group A/B:	70.00%	68.00%	69.00%
		% of Total	35.00%	34.00%	69.00%
	Dirty	Count	8	10	18
		% within TYPE OF SURGERY	44.40%	55.60%	100.00%
		% within Allocated to group A/B:	16.00%	20.00%	18.00%
		% of Total	8.00%	10.00%	18.00%
Total		Count	50	50	100
		% within TYPE OF SURGERY	50.00%	50.00%	100.00%
		% within Allocated to group A/B:	100.00%	100.00%	100.00%
		% of Total	50.00%	50.00%	100.00%

In our study in Group A 14% clean contaminated, 70% contaminated and 8 % dirty type of surgery performed and in Group B 12% clean contaminated, 68% contaminated and 10 % dirty type of surgery performed While in AEP Cameron study [60], in Group A 79% clean contaminated, 6.29%contaminated and 13.98% dirty type of surgery performed and in Group B 77.30% clean contaminated, 9.21% and 13.47% dirty type of surgery performed

VAS Score and Postoperative Pain

VAS Score	Group A		Group B	
	Mean	SD	Mean	SD
POD 1	2.28	0.60	2.46	0.76
POD 2	2.06	0.58	2.22	0.91
POD 3	1.98	0.42	2.06	0.65
POD 4	1.8	0.42	1.88	0.55
POD 5	1.5	0.50	1.78	0.46
POD6	1.32	0.47	1.7	0.50
POD 7	1.08	0.75	1.78	0.46
2ND WEEK	0.1	0.30	0.22	0.46
3rd WEEK	0.062	0.24	0.16	0.37





In our study we observed that in Group A 46 (out of 50) (92%) patients had mild pain and 4 (out of 50) (8%) patient had moderate pain in immediate post operative period and in Group B 42 (out of 50) (84%) had mild pain and 8 (out of 50) (16%) had moderate pain in immediate postoperative period.

In Group A 45 (out of 50) (90%) patients had no pain and 5 (out of 50) (10%) patients had mild pain in late postoperative period and in Group B 40 (out of 50) (80%) patients had no pain and 10 (out of 50) (20%) had mild pain in late postoperative period.

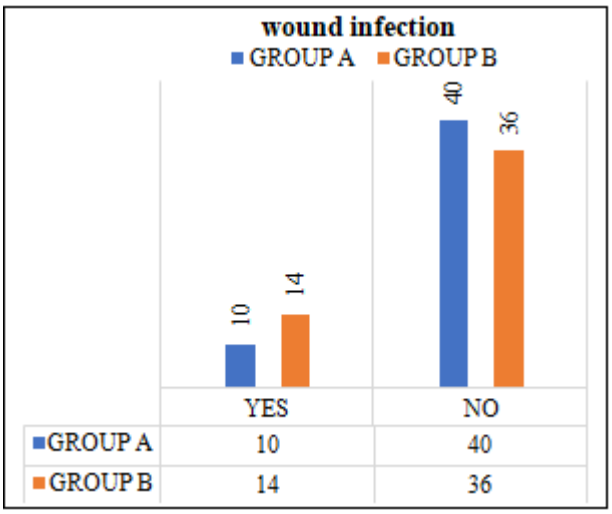
While in study Kiran Shankar H study [61] in Group A 96% patients had mild pain and 4% patient had moderate pain in immediate post operative period and in Group B 100% patients had moderate pain in immediate postoperative period.

In Group A 100% patients had no pain in late postoperative period and in Group B 100% had mild pain in late postoperative period.

Wound Infection

			Allocated to group A/B:		Total
			Group A	Group B	
Wound infection developed: Y/N	Yes	Count	10	14	24
		% within Wound infection developed: Y/N	41.7%	58.3%	100.0%
		% within Allocated to group A/B:	20.0%	28.0%	24.0%
		% of Total	10.0%	14.0%	24.0%
	No	Count	40	36	76
		% within Wound infection developed: Y/N	52.6%	47.4%	100.0%
		% within Allocated to group A/B:	80.0%	72.0%	76.0%
		% of Total	40.0%	36.0%	76.0%
Total		Count	50	50	100
		% within Wound infection developed: Y/N	50.0%	50.0%	100.0%
		% within Allocated to group A/B:	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

Chi square – 0.877; p - value – 0.349



In this study we observed wound infection among 10 (out of 50) in Group A (20%) and among 14 (out of 50) in group B (28%).

While in study done by Samina Naz et al [59], wound infection in group A is 33.9% and in group B is 67.1%

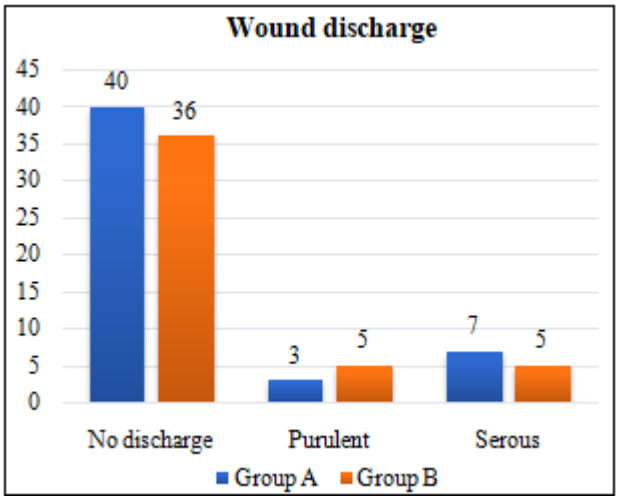
Wound Discharge

			Allocated to group A/B:		Total
			Group A	Group B	
Type of discharge	No discharge	Count	40	36	76
		% within type of discharge	52.6%	47.4%	100.0%
		% within Allocated to group A/B:	80.0%	72.0%	76.0%
		% of Total	40.0%	36.0%	76.0%
	Purulent	Count	3	5	8
		% within type of discharge	37.5%	62.5%	100.0%
		% within Allocated to group A/B:	6.0%	10.0%	8.0%
		% of Total	3.0%	5.0%	8.0%
	Serous	Count	7	9	16
		% within type of discharge	43.8%	56.3%	100.0%
		% within Allocated to group A/B:	14.0%	18.0%	16.0%
		% of Total	7.0%	9.0%	16.0%
Total		Count	50	50	100
		% within type of discharge	50.0%	50.0%	100.0%
		% within Allocated to group A/B:	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

Fisher's exact test – 0.961; p - value – 0.619

In our study we observed purulent discharge among 3 patients (out of 50) (6%) and serous discharge among 7 patients (out of 50) (14%) in Group A and purulent discharge among 5 patients (out of 50) 18% and serous discharge among 9 patients (out of 50) (18%).

While in study done by Kiran Shankar H [61], purulent discharge in 2% and serous discharge in 15% patients in Group A and purulent discharge in 16% and serous discharge in 13% patients in Group B.



Wound Dehiscence

			Allocated to group A/B:		Total
			Group A	Group B	
Wound dehiscence: Y/N	Yes	Count	4	8	12
		% within Wound dehiscence: Y/N	33.3%	66.7%	100.0%
		% within Allocated to group A/B:	8.0%	16.0%	12.0%
		% of Total	4.0%	8.0%	12.0%
	No	Count	46	42	88
		% within Wound dehiscence: Y/N	52.3%	47.7%	100.0%
		% within Allocated to group A/B:	92.0%	84.0%	88.0%
		% of Total	46.0%	42.0%	88.0%
Total		Count	50	50	100
		% within Wound dehiscence: Y/N	50.0%	50.0%	100.0%
		% within Allocated to group A/B:	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

Fisher's exact test – 1.515; p - value – 0.218

In our study the incidence of wound dehiscence was 8% in group A and incidence of wound dehiscence was 16% in Group B. While in Kiran Shankar H study [61], the incidence of wound dehiscence was 0% in Group A and 4% in Group B.

Palpable Knots

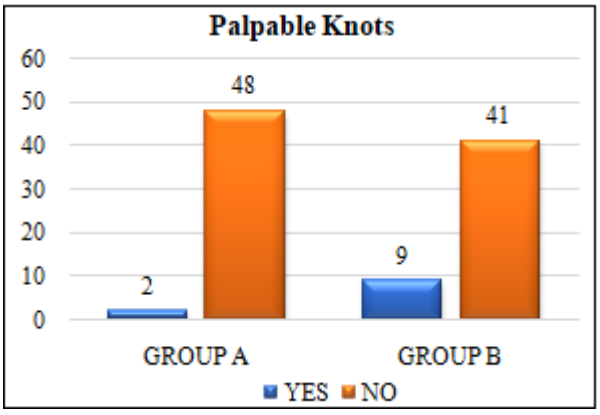
			Allocated to group A/B:		Total
			Group A	Group B	
Palpable knots: Y/N	Yes	Count	2	9	11
		% within Palpable knots: Y/N	18.2%	81.8%	100.0%
		% within Allocated to group A/B:	4.0%	18.0%	11.0%
		% of Total	2.0%	9.0%	11.0%
	No	Count	48	41	89
		% within Palpable knots: Y/N	53.9%	46.1%	100.0%
		% within Allocated to group A/B:	96.0%	82.0%	89.0%
		% of Total	48.0%	41.0%	89.0%
Total		Count	50	50	100
		% within Palpable knots: Y/N	50.0%	50.0%	100.0%
		% within Allocated to group A/B:	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

Fisher's exact test – 5.005; p - value – 0.025

In our study we observed that the incidence of palpable knots in Group A is 4% and incidence of palpable knots in Group B is 18%.

While in Kiran Shankar H study [61], the incidence of palpable knots in Group A is 0% and incidence of palpable knots in Group B is 23%.

Incidence of palpable knots is significantly more in polypropylene with p value 0.025.



Suture Sinus

			Allocated to group A/B:		Total
			Group A	Group B	
Suture sinus: Y/N	Yes	Count	2	5	7
		% within Suture sinus: Y/N	28.6%	71.4%	100.0%
		% within Allocated to group A/B:	4.0%	10.0%	7.0%
		% of Total	2.0%	5.0%	7.0%
	No	Count	48	45	93
		% within Suture sinus: Y/N	51.6%	48.4%	100.0%
		% within Allocated to group A/B:	96.0%	90.0%	93.0%
		% of Total	48.0%	45.0%	93.0%
Total		Count	50	50	100
		% within Suture sinus: Y/N	50.0%	50.0%	100.0%
		% within Allocated to group A/B:	100.0%	100.0%	100.0%
		% of Total	50.0%	50.0%	100.0%

Fisher's exact test – 1.382; p - value – 0.240

In our study we observed that the incidence of suture sinus in Group A is 4% and incidence of suture sinus in Group B is 10%.

While in Kiran Shankar H study [61], the incidence of suture sinus in Group A is 2% and incidence of suture sinus in Group B is 9%.

No cases of incisional hernia were reported in this study

4. Discussion

Laparotomy is a most commonly done procedure. There are various techniques of closure of abdominal wall which has its own advantages and disadvantages. The healing of abdominal wound takes place en - mass because of formation of dense fibrous block of tissue. Suture material plays a very important role and its selection helps in reducing wound complications.

In both groups, the closure of abdominal wound was done in a continuous en - mass method. Polydioxanone sutures are strong, delayed absorbable, cause minimal tissue reaction causes mild pain. Polypropylene which is a non - absorbable suture material needs 5 - 7 knots for adequate strength and these knots may cause pain and also does not absorb as compared to polydioxanone and elicits tissue reaction against foreign body which causes pain.

In immediate postoperative period, 92% patient had mild pain and 8% had moderate pain in polydioxanone group and 16% patient had moderate pain and 84% had mild pain in Polypropylene groupin present study. And in late post operative period 10% patient had only mild pain in polydioxanone group and 20% patient had mild pain inPolypropylene group in present study. While compared with Kiran Shankar H study [61] in Group A 96% patients had mild pain and 4% patient had moderate pain in immediate post operative period and in Group B 100% patients had moderate pain in immediate postoperative period. In Group A 100% patients had no pain in late postoperative period and in Group B 100% had mild pain in late postoperative period.

The pain demonstrated on visual analogue scale shows that high incidence of mild and moderate pain in polypropylene group as compared to Polydioxanone group.

In our study we observed wound infection among 10 (out of 50) in Group A Polydioxanone group (20%) and among 14 (out of 50) in group B Polypropylene group (28%). While in study done by Samina Naz et al [59], wound infection in group A is 33.9% and in group B is 67.1%.

Wound infection in both emergency and elective operations is observed to be higher in polypropylene suture material compared to polydioxanone suture material.

In our study the incidence of wound dehiscence was 8% in group A with Polydioxanone and incidence of wound dehiscence was 16% in Group B with polypropylene. While in Kiran Shankar H study [61], the incidence of wound dehiscence was 0% in Group A and 4% in Group B.

As compared with the above study we observed that polydioxanone suture material has lesser incidence of wound dehiscence in post operative period when compared to polypropylene suture.

In our study we observed that the incidence of palpable knots in Group A is 4% and incidence of palpable knots in Group B is 18%. While in Kiran Shankar H study [61], the incidence of palpable knots in Group A is 0% and incidence of palpable knots in Group B is 23%.

Polypropylene suture material which is non absorbable has tendency to stay permanently even after the wound is healed completely. so this property leads to formation of palpable knots in the region where the knots are secured.

The incidence of suture sinus in Group A is 4% and incidence of suture sinus in Group B is 10%. While in Kiran Shankar H study [61], the incidence of suture sinus in Group A is 2% and incidence of suture sinus in Group B is 9%.

In comparison with the above study groups Polydioxanone had lesser incidence of suture sinus formation.

There is no cases of incisional hernia reported in present study.

While in Kiran Shankar H study [61], 2% incidence of incisional hernia was reported in polypropylene group.

5. Conclusion

Based on the observations made in this study, it has been concluded that the continuous mass closure technique using no: 1 polydioxanone for closure of midline laparotomy incision is superior to no: 1 polypropylene suture material.

The overall morbidity from abdominal fascia closure was considerably reduced in Polydioxanone group. There is a reduction in wound complications like wound infection, wound pain, suture sinus formation and palpable knots in Polydioxanone group compared to Polypropylene.

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