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Original Article

Randomized Controlled Trial of Comparison of Absorbable Extra Long-Term (Poly Hydroxy Butyrate) Suture Versus Non-Absorbable (Polypropylene) Suture for Abdominal Wall Closure

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Abstract

Introduction: In patients undergoing midline incisions, rectus sheath can be closed with continuous or interrupted suture using absorbable or non-absorbable materials. Despite major improvements in antibiotics, better anesthesia, superior instruments, earlier diagnosis of surgical problems, and improved techniques for post-operative vigilance, post-operative complications such as incisional hernias, burst abdomen, and wound infections continue to occur, which causes significant surgical health-care problem.

Aims and Objectives: The objectives of the study were to continuous technique with non-absorbable sutures (polypropylene) – Group I and to interrupt technique with non-absorbable suture (polypropylene) – Group II.

Materials and Methods: Randomized controlled, prospective study on 271 patients with primary elective midline laparotomy in Mahatma Gandhi Memorial Hospital. Patients operated from January 2018 to June 2019 are included in this study and are followed up for a minimum period of 1 year.

Observation and Results: Group I includes 102 patients with continuous technique using non-absorbable polypropylene, Group II includes 91 patients with interrupted technique using non-absorbable polypropylene, and Group III includes 78 patients with continuous slowly absorbable polyhydroxybutyrate.

Key words: Absorbable polyhydroxybutyrate, Laparotomy, Non-absorbable polypropylene

INTRODUCTION

In patients undergoing midline incisions, rectus sheath can be closed with continuous or interrupted suture using absorbable or non-absorbable materials. Despite major improvements in antibiotics, better anesthesia, superior instruments, earlier diagnosis of surgical problems, and improved techniques for post-operative vigilance, post-operative complications such as incisional hernias, burst abdomen, and wound infections continue to occur, which causes significant surgical health-care problem.

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Decrease of the post-operative surgical complications can reduce the length of hospital stay, significant morbidity, and even mortality and financial burden to the health-care system.

In our hospital, routinely non-absorbable polypropylene is used for the closure of rectus sheath in midline laparotomy, which remains as a foreign material throughout the life after wound gains tensile strength. Several studied were conducted previously using absorbable materials for the rectus closure, with negative results. However, recently, studies in other countries showed that slowly absorbable suture materials can reduce the challenges of abdominal wall closure, which was least explored in our country.

Having good infrastructure and surgical faculty, with an enormous patient inflow, recently FDA approved slowly absorbable suture material (2010), i.e., polyhydroxybutyrate was analyzed in our hospital with all the ethical and medical factors taken into consideration.

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Aims and Objectives

The aim of study is to compare,

- Continuous technique with non-absorbable sutures (polypropylene) – Group I
- Interrupted technique with non-absorbable suture (polypropylene) – Group II
- Continuous technique with slowly absorbable sutures (polyhydroxybutyrate) – Group III, of rectus sheath closure.

Focusing mainly on incidence of incisional hernias, burst abdomen, wound infections, chronic wound pain, suture sinus, stitch granuloma, and time for rectus closure.

PATIENTS AND METHODS

Design

This was a randomized controlled, prospective study on 271 patients with primary elective midline laparotomy in our hospital.

Duration

Patients operated from January 2018 to June 2019 are included in this study and are followed up for a minimum period of 1 year.

Inclusion Criteria

The following criteria were included in the study:

1. Patients undergoing elective primary midline laparotomy,
2. Expected length of incision of at least 10 cm,
3. Informed consent about the study,
4. Age in between 18 and 70 years.
5. Life expectancy more than 1½ year.

Exclusion Criteria

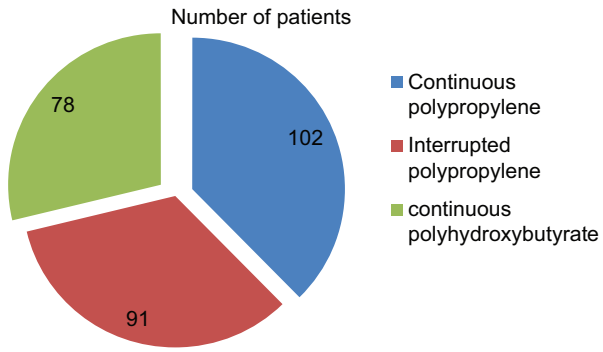
The following criteria were excluded from the study:

1. Patients requiring emergency surgery,
2. Patients undergoing immunosuppressive therapy,
3. Patients undergoing chemotherapy within 2 weeks before surgery
4. Patients undergoing radiotherapy longer than 8 weeks before surgery,
5. Patients with coagulopathy,
6. Patients with disorders that preclude study participation (dementia, and language problems).

OBSERVATION AND RESULTS

This trial was conducted on 271 randomized patients in our hospital.

1) Group I includes 102 patients with continuous technique using non-absorbable polypropylene,
2) Group II includes 91 patients with interrupted technique using non-absorbable polypropylene,
3) Group III includes 78 patients with continuous slowly absorbable polyhydroxybutyrate



Incidence of Wound Infection

In continuous non-absorbable polypropylene (Group I) – 15 patients out of 102 patients developed surgical site infection.

i.e., 15/102 × 100 = 14.70%

In interrupted non-absorbable polypropylene (Group II) – 14 patients out of 91 patients developed surgical site infection.

i.e., 14/91 × 100 = 15.38%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – 12 patients out of 78 patients developed surgical site infection.

i.e., 13/78 × 100 = 16.66%

Incidence of Incisional Hernia

In continuous non-absorbable polypropylene (Group I) – 13 patients out of 102 patients developed incisional hernia.

i.e., 13/102 × 100 =12.74%

In interrupted non-absorbable polypropylene (Group II) – 12 patients out of 91 patients developed incisional hernia.

i.e., 12/91 × 100 = 13.18%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – five patients out of 78 patients developed incisional hernia.

i.e., 05/78 × 100 =06.41%

Incidence of Burst Abdomen

In continuous non-absorbable polypropylene (Group I) – four patients out of 102 patients developed burst abdomen.

i.e., 4/102 × 100 = 3.92%

In interrupted non-absorbable polypropylene (Group II) – three patients out of 91 patients developed burst abdomen.

i.e., 03/91 × 100 = 3.29%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – three patients out of 78 patients developed burst abdomen.

i.e., 03/78 × 100 = 3.84%

Incidence of Stitch Granuloma

In continuous non-absorbable polypropylene (Group I) – five patients out of 102 patients developed stitch granuloma.

i.e., 5/102 × 100 = 4.90%

In interrupted non-absorbable polypropylene (Group II) – eight patients out of 91 patients developed stitch granuloma.

i.e., 08/91 × 100 = 8.79%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – two patients out of 78 patients developed stitch granuloma.

i.e., 02/78 × 100 = 2.56%

Incidence of Suture Sinus

In continuous non-absorbable polypropylene (Group I) – two patients out of 102 patients developed suture sinus.

i.e., 2/102 × 100 = 1.96%

In interrupted non-absorbable polypropylene (Group II) – five patients out of 91 patients developed suture sinus.

i.e., 5 / 91 × 100 = 5.49 %

In continuous slowly absorbable polyhydroxybutyrate (Group III) – one patients out of 78 patients developed suture sinus.

i.e., 1 / 78 × 100 = 1.28%

Incidence of Chronic Wound Pain

In continuous non-absorbable polypropylene (Group I) – five patients out of 102 patients developed chronic wound pain.

i.e., 5/102 × 100 = 4.90%

In interrupted non-absorbable polypropylene (Group II) – ten patients out of 91 patients developed chronic wound pain.

i.e., 10/91 × 100 = 10.9%

In continuous slowly absorbable polyhydroxybutyrate (Group III) – two patients out of 78 patients developed chronic wound pain.

i.e., 2/78 × 100 = 2.56%

Average Time for Rectus Closure

In continuous non-absorbable polypropylene (Group I), avg. time for rectus closure for 10 cm mid line incision – 9.20 min.

In interrupted non-absorbable polypropylene (Group II), avg. time for rectus closure for 10 cm mid line incision – 16.50 min.

In continuous slowly absorbable polyhydroxybutyrate (Group III), avg. time for rectus closure for 10 cm mid line incision – 9.40 min.

DISCUSSION

Wound Infection

Wound infection defined as redness, edema, culture positive secretion, or culture negative with antibiotic treatment more than 6 days (within 30 days of surgery). Incidence of surgical site infection in Group I, Group II, and Group III in this study is 14.70%, 15.38%, and 16.66%, respectively.

Comparison between Group III and Group I (Null Hypothesis I)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of surgical site infection is 16.66%.

In continuous non-absorbable polypropylene (Group I), incidence of surgical site infection is 14.70%.

P value between Group III and Group I is 0.75 (>0.05), i.e., null hypothesis I is accepted and the study shows that there is no significant difference in incidence of surgical site infection with polyhydroxybutyrate when compared with continuous polypropylene.

Comparison between Group III and Group II (Null Hypothesis II)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of surgical site infection is 16.66%.

In interrupted non-absorbable polypropylene (Group II), incidence of surgical site infection is 15.38%.

P value between Group III and Group II is 0.50 (>0.05), i.e., null hypothesis II is accepted and the study shows that there is no significant difference in incidence of surgical site infection with polyhydroxybutyrate when compared with interrupted polypropylene also.

Various previous studies from Table 1 show that the incidence of wound infections does not vary with the suture material used for fascial closure.

Wide range of variation of wound infection rates in various centers shows that incidence of wound infections is center dependent.

Most of the surgeries included in this study are clean and clean contaminated wounds, expected incidence of wound infection is <10% (clean – 1–3%, and clean contaminated 5–8%). Reaching 17%, the rate of wound infection in our hospital was much higher the antibiotic prophylaxis in today's surgical practice would lead to expect. Indeed, almost all patients received antibiotic prophylaxis and most of them suffered an opening of gastrointestinal tract during the operation.

A possible explanation for the high incidence may be due to poor hygienic condition of the patient and surroundings in our government hospital.

Limitations of the Study

Wound infections in relation to specific surgery were not analyzed in this study.

The study published in J. Am. Coll. Surg. - Aug 2011; 213(2); 236-44 – Surgical site infection and analytic morphometric assessment of body composition in patients undergoing midline laparotomy – showed that body mass index plays a role in the study, which was not taken into consideration in this study. Other important factors of wound infection such as obesity, subcutaneous fat, and collagen disorders also not analyzed in this study.

Higher incidence of wound infections in our hospital can be prevented by: (1) Careful handling of tissues, (2) meticulous dissection, hemostasis, an débridement of devitalized tissue, (3) compulsive control of all intraluminal contents, (4) preservation of blood supply of the operated organs, (5) elimination of any foreign body from the wound, (6) maintenance of strict asepsis by the operating team (e.g., no holes in gloves, avoidance of the use of contaminated instruments, and avoidance of environmental contamination, such as debris falling from overhead), (7) thorough drainage and irrigation of any pockets of purulence in the wound with warm saline, and (8) ensuring that the patient is kept in a euthermic state, well monitored, and fluid resuscitated.[1]

Incisional Hernia

Incisional hernia was defined as a fascial dehiscence after completed wound healing with or without the prolapse of abdominal organs, confirmed by abdominal ultrasound.

The incidence of incisional hernia in Group I, Group II, and Group III in this study is 12.74%, 13.18%, and 6.41%, respectively[2].

Comparison between Group III and Group I (Null hypothesis I)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of incisional hernia is 6.41%.

In continuous non-absorbable polypropylene (Group I), incidence of incisional hernia is 12.74%.

P value between Group III and Group I is 0.05, i.e., null hypothesis I is rejected and the study shows that there is significant difference in incidence of incisional hernia with polyhydroxybutyrate when compared with continuous polypropylene.

Comparison between Group III and Group II (Null hypothesis II)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of incisional hernia is 6.41%.

In interrupted non-absorbable polypropylene (Group II), incidence of incisional hernia is 13.18%.

P value between Group III and Group II is 0.05, i.e., null hypothesis II is rejected and the study shows that there is significant difference in incidence of incisional hernia with polyhydroxybutyrate when compared with interrupted polypropylene also[3,4].

In Table 2, the INLINE meta-analysis study clearly showed the decrease in incidence of incisional hernias with continuous slowly absorbable sutures, where PDS (Polydioxanone) suture was used. Having longer 50% tensile strength maintenance period of 90 days (whereas, PDS has 50% tensile strength maintenance period for 4 weeks) polyhydroxybutyrate is a positive alternative for the rectus closure.

Most important etiological factor for incisional hernia is wound infections. As there is no significant difference

Table 1: Significance of *P* value in wound infections

Comparison	*P* value	Significance
Group III and Group I	0.75	Not significant
Group III and Group II	0.50	Not significant

Table 2: Significance of *P* value in incisional hernia

Comparison	*P* value	Significance
Group III and Group I	0.05	Significant
Group III and Group II	0.05	significant

in wound infection rate and surgical technique is also randomized in this study, decrease in incidence of hernias signifies the importance of suture material. Possible explanation for the decrease in incidence of incisional hernias with polyhydroxybutyrate may be the elasticity property of material which does not interfere with respiratory abdominal movements postoperatively.

Limitations of the Study

Major limitation of this study is follow-up period of only 1 year. The study conducted by The Study Centre of the German Surgical Society – Incisional hernia rate 3 years after midline laparotomy (C. Fink, P. Baumann, M. N. Wente , P. Knebel, T. Bruckner, A. Ulrich, J. Werner, M. W. B¨uchler and M. K. Diener) signified that significant increase in incidence of hernias from 1 to 3 year follow-up period. Thus, 3 years follow-up period may be needed for further reference.

Besides surgical technique and suture material, numerous additional factors are believed to play a role in hernia formation including obesity, diabetes, and malignancy. These factors were not analyzed. Hernias in relation to specific surgery were also not analyzed in this study.

Moreover, the pathophysiology of wound healing has to be considered as a major unknown variable of hernia formation. Collagen malformation in particular was linked to hernia formation in both clinical and biochemical studies. Within this context matrix metalloproteinases, which regulate the components of the extracellular matrix, play an important role in scarring process. Likewise, Klinge *et al.* found reduced matrix metalloproteinases expression patterns in patients with incisional hernias. Moreover, smoking was related to increased collagenolysis and inappropriate repair. Genetic influences and the corresponding molecular mechanisms have to be explored in the future since various connective tissue disorders are known to be heritable or caused by genetic mutation (e.g., Homocystinuria, Marfan's, and Ehlers – Danlos syndrome).

Thus, multimodal concept of optimizing the surgical technique, the suture material, and wound healing are believed capable of reducing incisional hernia sufficiently.

Burst Abdomen

Burst abdomen defined as post-operative separation of the abdominal musculoApo neurotic layers or disruption of laparotomy wound which requires relapse operation. Incidence of burst abdomen in Group I, Group II, and Group III in this study is 3.92%, 3.29%, and 3.84%, respectively.

Comparison between Group III and Group I (Null hypothesis I)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of burst abdomen is 3.84 %.

In continuous non-absorbable polypropylene (Group I), incidence of burst abdomen is 3.92%.

P value between Group III and Group I is −0.90 (>0.05), i.e., null hypothesis I is accepted and the study shows that there is no significant difference in incidence of burst abdomen with polyhydroxybutyrate when compared with continuous polypropylene.

Comparison between Group III and Group II (Null hypothesis II)

In continuous slowly absorbable polyhydroxybutyrate (Group III), incidence of burst abdomen is 3.84 %.

In interrupted non-absorbable polypropylene (Group II), incidence of burst abdomen is 3.29%.

P value between Group III and Group II is –0.95 (>0.05), i.e., null hypothesis II is accepted and the study shows that there is no significant difference in incidence of burst abdomen with polyhydroxybutyrate when compared with interrupted polypropylene also.

The results from the previous studies from Table 3 and this study show that the incidence of burst abdomen mostly not related with suture material used.

Most important etiological factor for burst abdomen is wound infections most importantly deep space infections. Although type of suture material does not influence wound dehiscence, technical errors in fascial closure may be responsible.

Good pre-operative general condition of the patient, adequate fascial closure without tension and good post-operative care are the three main strategies which will prevent the acute wound failure. Limitation of this study is factors such as obesity, diabetes are not analyzed in this study.

Stitch Granuloma

A stitch granuloma is a small mass of clustered immune cells that may develop around the site of a surgical procedure. Suture granuloma originates when the area around a surgical incision becomes irritated or the

Table 3: Significance of *P* value in incisional burst abdomen

Comparison	*P* value	Significance
Group III and Group I	0.90	Not significant
Group III and Group II	0.95	Not significant

body's immune defenses identify medical sutures as a foreign body needing elimination. Immune cells rush to the site of the surgery and attach themselves to the medical sutures or staples. Since it is not possible to break sutures down the way an invading virus or bacteria breaks down, the body continues to send immune cells to the area where they create a large inflexible mass. The incidence of stitch granuloma in Group I, Group II, and Group III in this study is 4.9%, 8.79%, and 2.56%, respectively.

Suture Sinus

Sinus is a blind ending tract, usually lined with granulation tissue that leads from an epithelial surface into the surrounding tissue, often into an abscess cavity. The incidence of suture sinus in Group I, Group II, and Group III in this study is 1.96%, 5.49%, and 1.28%, respectively.

Chronic Wound Pain

Chronic wound pain is a condition described as unremitting, disabling, and recalcitrant pain experienced by individuals. Chronic wound pain is present for 6 months or more and occurs without any manipulation of the wound. Chronic wound pain is persistent and exists at rest. The incidence of suture sinus in Group I, Group II, and Group III in this study is 4.9%, 10.98%, and 2.56%, respectively.

Average Time for Rectus Closure

Average time for rectus closure for 10 cm mid line incision in Group I, Group II, and Group III is 9.20 min, 16.50 min, and 9.40 min, respectively.

CONCLUSIONS AND SUMMARY

No significant difference observed in incidence of wound infections in all the three groups.

However, relatively higher incidence of wound infections in noted our hospital. Further studies needed to decrease the incidence of infections in our hospital.

No significant difference was observed between the three groups with regard to burst abdomen, i.e., acute wound failure mostly depends on adequate surgical closure and post-operative care rather than suture material used.[5]

The incidence of stich granuloma is more with interrupted technique than continuous technique and is more with non-absorbable suture material.

The incidence of suture sinus is more with interrupted technique than continuous technique and is more with non-absorbable suture material.

The incidence of chronic wound pain is more with interrupted technique than continuous technique and is more with non-absorbable suture material.

The incidence of incisional hernias, suture complications such as suture sinus, stitch granuloma can be more effectively reduced with slowly absorbable continuous sutures.

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