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Comparative study of polypropylene mesh and oxidized regenerated cellulose polypropylene - polydioxanone composite mesh: An experimental study of ventral hernia repair in albino rats

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Abstract

Background

The overall incidence of incisional hernia after laparotomy is 9.9%. Currently polypropylene mesh is used most commonly for hernia repair, but this prosthetic mesh is commonly associated with adhesions formation between prosthetic mesh and abdominal viscera when it is applied intraperitoneally. Therefore we did an experimental study in albino rats with two different types of meshes; first most commonly used polypropylene mesh and another polypropylene–polydioxanone composite with oxidized regenerated cellulose (ORC) coating to compare the propensity of adhesion formation on visceral side of mesh.

Material and Method

50 rats were divided in two groups polypropylene and ORC polypropylene–polydioxanone composite mesh group with twenty five rats in each group. In all groups ventral abdominal defect was created and mesh was applied intraperitoneally, rats were sacrifice on 7 & 30 days for examining adhesion formation. Adhesion scoring were done by adhesion area score and severity score developed by Vanderbilt University, Nashville USA along with histo-pathological examination of mesh with surrounding tissue.

Result

There was statistically significantly less adhesion formation in the ORC coated polypropylene-polydioxanone composite mesh group. Combine area & severity score was 2.4 and 2.1 on seven and thirty days respectively in ORC coated polypropylene-polydioxanone composite mesh group while it was 4.8 and 4.9 in polypropylene group at the same time interval ($p=0.02$ & $p<0.01$). Similarly histo-pathological grading also confirmed that more dense adhesions formed in polypropylene group that were grade III on day thirty and grade II on day seven of mesh application in polypropylene group & grade II in on day thirty and grade I on day seven of mesh application in ORC coated polypropylene - polydioxanone composite mesh group.

Conclusion

Oxidized regenerated cellulose coated polypropylene - polydioxanone composite mesh significantly reduced adhesion formation and prevented bowel adhesion to the mesh in the early postoperative period.

Keywords: Hernia, PTFE, Proceed, Rats, Adhesions, ORC

1. Introduction

Incisional hernia is a type of ventral hernia. They are the second most common type of hernia after inguinal hernias. The overall incidence of incisional hernia after laparotomy is 9.9% [1]. Ventral hernias can cause serious morbidity, such as incarceration (in 6 to 15% of cases) and strangulation (in 2%) [2]. There is no conservative treatment option for ventral hernias cure. Surgery is the only curative therapy for abdominal hernias. Technical aspects of hernia repair continue to evolve with various primary tissue repair techniques have being developed for ventral hernia repair. Inspite of this recurrence rate of primary hernia repair ranges from 24% to 54% [3].

Hernioplasty and herniorrhaphy with prosthetic mesh is the treatment of choice for ventral hernia repair in the current era for large defects. The development of prosthetic biomaterials revolutionized surgery for the repair of abdominal wall hernias. A tension free mesh technique has drastically reduced recurrence rates for all hernias compared to tissue repairs and has made it possible to reconstruct large ventral defects that were previously irreparable.

Repair of ventral and incisional hernia is nowadays undertaken by minimal access surgery rather than the conventional open technique. The term laparoscopic inguinal herniorrhaphy can refer to any of the following three techniques totally extraperitoneal (TEP) repair, trans-abdominal preperitoneal (TAPP) repair, intraperitoneal onlay mesh (IPOM) repair.

The IPOM repair has largely fallen from favor, and currently, the most commonly performed laparoscopic techniques are the TEP and TAPP repairs [4, 5]. In IPOM technique synthetic mesh is directly applied under abdominal wall and directly in contact of the viscera. The most commonly used mesh is polypropylene, but this prosthetic mesh is commonly associated with adhesions formation between prosthetic mesh and abdominal viscera specially the bowel, which may lead to complication like strangulation, enterocutaneous fistula formation and intestinal obstruction [6, 7].

There were many mesh model proposed to minimize visceral side adhesion formation on prosthetic mesh, but there is still no consensus about which type of mesh is the best. Intra-peritoneal placement of the mesh requires a material, which have both high tissue ingrowth towards the abdominal wall side and nonadhesiveness on the other side to prevent bowel

adhesions. The peritoneum remesothelialization usually takes 5-8 days and this neoperitoneum serves as a physical barrier separating the mesh from the abdominal viscera. If adhesions can be prevented during this critical period, perhaps mesh related complications can be prevented or reduced.

Keeping this in mind we did an experimental study in albino rats with two different types of mesh, first most commonly used polypropylene mesh and another polypropylene–polydioxanone composite with oxidized regenerated cellulose (ORC) coating to compare the propensity of adhesion formation on visceral side of mesh. ORC coating prevents adhesion formation on visceral side of mesh till regeneration of neoperitoneum occurs.

Material and Method

In this study we compared polypropylene mesh and ORC coated polypropylene–polydioxanone composite mesh in terms of adhesion formation, using albino rat model. It was a two-phase prospective study using albino rats, done at animal lab of Gandhi medical college Bhopal after institutional ethical committee approval.

Fifty rats were used in this study, divided equally in both groups. Ether was used for induction as well as to maintain the anesthesia. Samples of two types of meshes had been implanted in parietal peritoneal defect, which were created surgically at ventral abdominal wall of albino rats. In ORC coated polypropylene–polydioxanone composite group mesh was implanted with the polypropylene side towards outside and oxidized regenerated cellulose layer toward inside directly facing abdominal viscera. The mesh was fixed with polypropylene 3-0 sutures. The necropsy and specimen examination were performed at 7 days and 30 days interval in each half of rats.

Assessment of degree of intra-peritoneal adhesion was done by the scale developed by adhesion scoring group of Vanderbilt University, Nashville USA and histo-pathologically. This scale incorporates adhesion area score & severity score. In Adhesion Area Score (AAS) we measured the extent of mesh coverage with adhesions. Score 0 (no adhesions), score 1(1-25%), score 2(26%50%), score 3(51%-75%), score 4(76%-100%) while in Adhesion Severity score we measure score 0 (no adhesions), score 1 (adhesions separated with minimal efforts), Score 2 (adhesions separated with moderate effort), score 3 (adhesions separated with difficulty).

For Histo-Pathological assessment we did examination of three meshes in each group along with adjoining wall, after routine tissue processing and staining with hematoxylin & eosin. Sections were microscopically studied, and incorporation of the mesh in the surrounding tissue and inflammatory reaction were assessed for each group. The grade of inflammation was assessed using a semi quantitative scoring system, the inflammation grading scale, Grade 1- Mild inflammatory reaction with giant cells, Occasional scattered lymphocytes, and plasma cells, Grade 2- Moderate reaction with giant cells and increased numbers of admixed lymphocytes, plasma cells, eosinophils, and neutrophils, Grade 3- Severe inflammatory reaction with microabscesses formation.

Result

In present study we applied polypropylene and ORC coated polypropylene–polydioxanone composite meshes in 25 rats in each groups. Twelve rats were sacrificed on 7th post operative day and thirteen rats on 30th post operative day in each group. Results of polypropylene group sacrificed on seventh day and thirty day are shown in table 1 and table 2 respectively. Similarly results of ORC coated polypropylene–polydioxanone composite meshes are shown in Table 3 and table 4 respectively.

There was significantly less adhesion formation in the ORC coated polypropylene-polydioxanone composite mesh group. Combine area & severity score was 2.4 and 2.1 on seven and thirty days respectively in ORC coated polypropylene-polydioxanone composite mesh group while it was 4.8 and 4.9 in polypropylene group at the same time interval. Analysis of adhesion score at 7^{th} day in both group by Mann-Whitney U test ($U=40$, $n1=12$, $n2=12$) were found to be significant at for two-tailed hypothesis ($p<0.05$). Adhesion score data analysis at 30^{th} day ($U=45$, $n1=13$, $n2=13$) were also found to be significant at $p=0.05$ for a two-tailed hypothesis. This means that polypropylene mesh and Polypropylene–Polydioxanone composite ORC coated mesh differ significantly in causing adhesion in the viscera. Further inspection of the results suggests that –Polydioxanone composite ORC coated mesh produces less adhesion area then polypropylene mesh.

Similarly 7^{th} day severity score data analysis by Mann-Whitney U test ($U=41$, $n1=12$, $n2=12$) have shown significant difference between two groups ($p=0.05$), while 30^{th} day severity score data analysis ($U=19$, $n1=13$, $n2=13$) results was very significant statistically at for two-tailed hypothesis ($p<0.01$). This means that polypropylene mesh and Polypropylene–Polydioxanone composite ORC coated mesh differ significantly in causing severity of adhesion to the visceral side. Further inspection of the results suggests that –Polydioxanone composite ORC coated mesh produces less sever adhesion area.

Statistical analysis of combine Adhesion and Severity score by Mann-Whitney U test at 7^{th} day data ($U=30$, $n1=13$, $n2=13$) has shown significant difference in both groups ($p=0.02$), similarly 30^{th} day data ($U=33$, $n1=13$, $n2=13$) analysis also shows significant difference for a two-trailed hypothesis ($p<0.01$). This means that polypropylene mesh and Polypropylene–Polydioxanone composite ORC coated mesh differ significantly in causing adhesion on the visceral side. Further inspection of the results suggests that –Polydioxanone composite ORC coated mesh produces less adhesion.

Histological examination finding of both groups is depicted in table 5. Using a Mann-Whitney U test to analyze Histological grading data ($U=4.5$, $n1=06$, $n2=06$), the results were found to be significant at $p=0.05$ for a two-tailed hypothesis. That also suggests that polypropylene mesh and Polypropylene–Polydioxanone composite ORC coated mesh differ significantly in causing adhesion on the visceral side. Further inspection of the results suggests that Polypropylene–Polydioxanone composite ORC coated mesh produces less adhesion.

Table 1: Polypropylene group sacrificed on 7th day

S. No.	Adhesion	Infection	Adhesion area score	Severity score	Adhesion area score + severity score
1	Present	Absent	4	2	6
2	Present	Absent	3	2	5
3	Present	Absent	3	2	5
4	Present	Absent	3	2	5
5	Present	Absent	2	2	4
6	Present	Absent	4	2	6
7	Present	Absent	3	2	5
8	Present	Absent	2	2	4
9	Present	Absent	4	2	6
10	Present	Absent	2	2	4
11	Present	Absent	2	1	3
12	Present	Absent	3	2	5
Average	Present	Absent	2.9	1.9	4.8

Table 2: Polypropylene group sacrificed on 30th day

S No	Adhesion	Infection	Adhesion area score	Severity score	Adhesion area score + severity score
1	Present	Absent	2	2	4
2	Present	Absent	2	3	5
3	Present	Absent	1	2	3
4	Present	Absent	3	3	6
5	Present	Absent	1	2	3
6	Present	Absent	3	4	7
7	Present	Absent	2	2	4
8	Present	Absent	2	4	6
9	Present	Absent	2	3	5
10	Present	Absent	4	2	6
11	Present	Absent	2	2	4
12	Present	Absent	4	3	5
13	Present	Absent	3	3	6
Average	Present	Absent	2.2	2.7	4.9

Table 3: ORC polypropylene – polydiaxanone composite mesh group sacrificed on 7th day

S. No	Adhesion	Infection	Adhesion area score	Severity score	Adhesion area score + severity score
1	Present	Absent	2	1	3
2	Present	Absent	2	2	3
3	Absent	Absent	0	0	0
4	Present	Absent	1	1	2
5	Present	Absent	2	1	3
6	Present	Absent	1	1	3
7	Present	Absent	3	2	4
8	Absent	Absent	0	0	0
9	Present	Absent	1	1	3
10	Present	Absent	2	1	3
11	Present	Absent	1	1	3
12	Present	Absent	2	1	2
Average	Present	Absent	1.4	1.0	2.4

Table 4: ORC polypropylene –polydiaxanone composite mesh group sacrificed on 30th day

S No	Presence or absence of adhesion	Infection	Adhesion area score	Severity score	Adhesion area score + severity score
1	Present	Absent	1	1	2
2	Absent	Absent	1	1	2
3	Present	Absent	1	1	2
4	Present	Absent	2	2	4
5	Absent	Absent	0	1	1
6	Present	Absent	1	1	2
7	Present	Absent	2	2	4
8	Absent	Absent	0	0	0
9	Present	Absent	1	1	2
10	Present	Absent	1	1	2
11	Present	Absent	1	1	2
12	Present	Absent	1	1	2
13	Present	Absent	1	1	2
Average	Present	Absent	1	1.1	2.1

Table 5: Histological Grading

Sr No	Mesh	Sacrificed day	Histological Grading
1	Polypropylene	7	2
2	Polypropylene	7	2
3	Polypropylene	7	2
4	ORC Polypropylene-Polydioxanone composite mesh	7	1
5	ORC Polypropylene-Polydioxanone composite mesh	7	1
6	ORC Polypropylene-Polydioxanone composite mesh	7	1
7	Polypropylene	30	3
8	Polypropylene	30	3
9	Polypropylene	30	3
10	ORC Polypropylene-Polydioxanone composite mesh	30	2
11	ORC Polypropylene-Polydioxanone composite mesh	30	2
12	ORC Polypropylene-Polydioxanone composite mesh	30	2

ADHESION WITH POLYPROPYLENE MESH

ADHESION WITH POLYPROPYLENE-PDS OXIDIZED REGENERATED CELLULOSE COMPOSITE MESH

Discussion

Prosthetic material was first introduced for abdominal ventral hernia by Burke with steel mesh in the 1940s [8]. Usher was the first to use plastic prosthetics, in 1958 [9]. These materials showed distinct advantages over steel mesh in their ease of use, pliability, and lack of disintegration with age. Monofilament polypropylene mesh (Marlex, Davol Inc, Cranston, RI), a refinement of plastic prosthetics, became available in 1962. Polypropylene mesh has since than become the most widely used prosthetic material for repair of ventral hernias [2]. Several other prosthetic materials have since been developed and used for ventral hernia repair. Some of these include multifilament polyester mesh (Mersilene, Ethicon Inc, Somerville, NJ), double-filament polypropylene mesh (Prolene, Ethicon Inc), and expanded Polytetrafluoroethylene patch (Gore-Tex, WL Gore & Associates, Phoenix, Ariz).

Laparoscopic abdominal hernia repair is one of the fastest growing minimally invasive surgical procedures performed by general surgeons. It is now established that laparoscopic repair is superior to open mesh repair in terms of less blood loss, Diminished requirement for narcotics, fewer complications such as wound or mesh infection shorter hospital stay and thus less overall hospital costs despite the increased operative costs and finally, excellent cosmetic outcome. Laparoscopic Ventral hernia repair is commonly done by intraperitoneal mesh application [6].

Usher *et al*. claimed a mechanical advantage in placing mesh in the subfascial position with direct contact with omentum or bowel [9]. In 1981, Kaufman first reported enterocutaneous fistula formation and adhesion as late complication of intraperitoneal subfascial mesh placement and advised against this technique [10]. Thereafter search for a prosthetic material which have minimal propensity toward bowel adhesion began.

Di Zerega *et al*. postulated that a barrier that separates damaged peritoneal surfaces for the entire 5–7 days of re-epithelialization (mesothelialization) would likely provide decreased adhesion formation by less inflammatory reaction, reduce fibrinolytic activity, and deprive tissues of oxygen [11]. If adhesions can be prevented during this critical period, perhaps biomaterial-related complications can be prevented or reduced. This neoperitoneum serves not only as a physical barrier separating the mesh from the abdominal viscera but potentially promotes fibrinolysis through the release of tissue plasminogen activator and inhibition of cell-cell and cell-tissue interaction through the release of hyaluronic acid.

Healing and regeneration of injured peritoneal mesothelium is unlike that of any other epithelial-like surface. It has been known since 1919 that peritoneal healing differs from that of skin, which heals gradually by epithelialization from the border. Defects in the parietal peritoneum, in contrast, heal by simultaneous epithelialization of the entire surface. Hence complete mesothelialization, developing from multiple points throughout the defect, occurs just as rapidly for large and small defects [11].

The ideal product for the prevention of adhesions would, therefore, be easy to apply, remain where placed for 7 days, produce no inflammation or foreign body reaction, not impair wound healing or mesothelial cell growth and migration, and absorb when no longer needed. Adhesion formation did not progress after day 7; any part of the prosthesis free of adhesions at 7 days remained so thereafter. The adhesion-free surfaces were found to be covered by a confluent mesothelial cell layer that appeared between days 3 and 5 and completely covered the mesh by day 7. These results indicate that an adhesion-resistant, healed, peritoneal surface can develop on polypropylene mesh within a week of implantation.

In our study both meshes were evaluated at 7 and 30 days after implantation. The reason for this dual assessment was the fact that these two time points represent different phases of wound healing. At 7 days, the inflammatory phase has just ended, and the proliferative phase has just started. According to Baptista *et al.* all adhesions have formed by this time. After 30 days, the proliferative phase has ended, and the remodeling phase has started. It is to be expected that neoperitoneum has formed and has covered the prosthetic material [12].

In our study fifty rats were experimented upon. Two type of mesh {polypropylene–polydioxanone composite with oxidized regenerated cellulose coating and plain polypropylene} applied intraperitoneally by creating ventral defect and examined after 7 and 30 days and result observed.

Oxidized regenerated cellulose absorbs in four weeks and till this time period neoperitoneum is formed on visceral aspect of mesh which control further adhesion formation. Polydioxanone component which act as an anchor between mesh and ORC also get absorbed in 6 months.

In the present study fifty rats were experimented upon. Two type of mesh Polypropylene–polydioxanone composite with ORC coating and plain polypropylene were applied intraperitoneally by creating ventral defect and examined after 7 and 30 days and result observed. Data analyzed by Mann-Whitney U test had showed that the ORC coated polypropylene-polydioxanone composite mesh is associated with statistically significant less adhesion formation on visceral aspect of mesh compare to plain polypropylene mesh on the basis of severity as well as area of adhesion ($p< 0.05$). Histological examination also confirmed above findings that higher grade adhesion formed with polypropylene mesh than oxidized regenerated cellulose coated polypropylene-polydioxanone mesh.

Richard W. Hutchinson *et al.* compared various meshes in rats and rabbit model reported mean score (adhesion area and severity score) 2.5 in ORC coated polypropylene-

polydioxanone composite mesh group and 4.5 mean score in polypropylene group at 100 days of mesh implantation. On analyzing data they had also found results statistically significant.

M. Kiudelis *et al.* of New Zealand reported statistically significant difference in adhesion formation between ORC coated polypropylene-polydioxanone composite mesh and polypropylene mesh in their study on rabbits. They reported mean degree of adhesions 9.5 in polypropylene group and 2.75 in ORC coated polypropylene-polydioxanone composite mesh group after 30 days of mesh application [13].

J. W. A. Burger, J. A. Halm *et al.* of Netherland analyzed four new meshes with polypropylene mesh and found that area covered with adhesion after 30 days in polypropylene group was 55% and in ORC coated polypropylene-polydioxanone composite mesh group 38%, but mesh incorporation is less in ORC coated polypropylene-polydioxanone composite mesh group (29%) compared to polypropylene group (35%) [14].

E. Dilege *et al.* Turkey showed that When ORC coated polypropylene-polydioxanone composite mesh was used, a significant reduction of mean percentage of adhesion formation on mesh surface 28 days, compared to the polypropylene group ($p = 0.026$) and the intra-abdominal adhesions of the rats in ORC group were significantly easier to release than in the control group ($p = 0.001$) [15].

M. van't Riet, J. W. A. Burger *et al.* proved that the parietal mesh, containing collagen coating on visceral side can also reduce adhesion formation but it is associated with statistically significant increase in incidences of infections [16].

As was confirmed in the present study, polypropylene causes a pronounced and persistent inflammatory reaction and is well incorporated in the surrounding tissue of the abdominal wall. However, because of the pronounced inflammatory reaction, polypropylene also causes a strong stimulus for the formation of adhesions. Coating of bio-absorbable membrane on visceral aspect of mesh by Oxidized regenerated cellulose (ORC) decreases adhesion formation and reduces mesh related complication.

Conclusion

Oxidized regenerated cellulose coated polypropylene-polydioxanone composite mesh significantly reduced adhesion formation and prevented bowel adhesion to the mesh in the early postoperative period. Further randomized controlled, prospective studies are needed to prove these findings in humans.

Conflict of Interest

The authors have no conflicts of interest in regards to this manuscript.

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