Intra Peritoneal Polypropylene Mesh and Newer Meshes in Ventral Hernia Repair: What EBM Says?

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Abstract Incisional hernias and other ventral hernias are common surgical problems. It is estimated that incisional hernia complicates about 2 % to 10 % of laparotomies. Ventral and incisional hernia repairs are among the common surgeries done by a general surgeon. It is proven beyond any doubt that suture repair of these hernias should not be done as recurrence rates are unacceptably high, some series reporting as high as 54 % on long-term follow-up. A prosthetic mesh should always be used in ventral hernia repair (VHR). Now, the polypropylene mesh (PPM) has become the prosthetic mesh of choice in the repair of hernias, including inguinal hernia. However, with the advent of laparoscopic repair where the mesh is placed intraperitoneally, concerns regarding safety of PPM are raised. Newer meshes are introduced, claiming lesser complication rate. Many types of newer meshes are available now. Newer meshes are invariably costlier than PPM by 15–20 times. Is this extra cost worth? We looked in to available literature for an answer.

Keywords Ventral hernia repair · Incisional hernia repair · Intraperitoneal mesh · Laparoscopic hernia repair · Open hernia repair · Polypropylene mesh (PPM) · Newer meshes · PTFE mesh · ePTFE mesh · Composite mesh · PCO mesh

Abbreviations

VHR Ventral hernia repair

PPM Polypropylene mesh

Errors using inadequate data are much less than those using no data at all.—Charles Babbage (1792–1871)

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Introduction

VHR is one of the commonest operations performed by general surgeons. It is now proved beyond doubt that primary repair using suture repair techniques should not be used, as they are fallowed, on long term follow up, by unacceptably high recurrence rate, as high as 31 %–54 % [1, 2]. To overcome this high recurrence rate, a prosthetic mesh repair should be used, which decreases the recurrence rate to less than 10 % [1]. Initially steel mesh was used. But it led to problems such as infection, sinus formation, mesh cracking, fragmentation etc. In 1963, Usher introduced PPM in the repair. It has been used in open surgery successfully without much of dilemma and is the choice of many surgeons now. However, the mesh is placed in a variety of ways. Techniques of mesh placement include on-lay, in-lay and sandwich. In the on-lay technique, the mesh is placed over the external oblique fascia. In the in-lay technique, the mesh is placed either intraperitoneally or in preperitoneal plane. In the sandwich technique, one mesh is placed on-lay and one is placed in-lay. Laparoscopic methods are also very popular now and use a mesh placed intraperitoneally. A few surgeons do laparoscopic repair by raising a flap of the peritoneum, placing the mesh and closing the peritoneum over the mesh, i.e. separate the mesh and viscera by the peritoneum [3]. Spreading or even stitching/tacking omentum to the mesh to separate it from the viscera is also advocated. However, these techniques may not be always possible as the adequate peritoneum/omentum may not be always available, especially in recurrent hernia cases, because of scarring. Many rents may appear in the peritoneum during dissection. Also, it is technically demanding and all laparoscopic surgeons may not be able to do it. Most of the surgeons place the mesh intraperitoneally, anchoring the mesh with 4–6 transfascial sutures and tackers on the margins of the mesh in between the sutures to close the gap between the mesh and the abdominal wall, so as to prevent herniation.

If there is a layer of muscle, fascia or peritoneum between the mesh and the viscera, there is no problem. However, if the mesh is in direct contact with intestines, then the question of safety arises. Concerns regarding intraperitoneal PPM are adhesions (with consequent intestinal obstruction), intestinal fistulization, sinus formation and infection. These complications may require surgery to relieve obstruction, removal of the mesh to treat infection or fistula and sometimes even intestinal resection. Mesh removal may be followed by recurrence of hernia. Hence, the newer meshes were introduced, with its attendant high cost. We have a number of newer meshes like PTFE, composite mesh, PCO (polyester coated with antiadhesive collagen layer) etc. When we ask surgeons for their choice of mesh, some of them say that they have been using PPM for a long period without any problem". Other are equally sure in telling that PPM should never be used intraperitoneally for the fear of adhesions and fistulization. Most of these decisions are based on anecdotal case reports and undocumented personal experiences. It is desirable to have more scientific data on which we base our choice. We looked into literature for the evidence to accept or reject PPM. This is of great importance as newer meshes are 15–20 times costlier than PPM. If PPM can be accepted for intraperitoneal placement, a large number of Indian patients can be benefited by laparoscopic repair, which they cannot afford presently because of high cost of newer meshes.

Materials and Methods

We searched for electronic data on the Internet by Google search, Google scholar, Medline, Pubmed, Cochrane library, etc. for as much of information as possible. We also searched websites like www.who.int/hinari/en/, www.inasp.info/file/68/about-inasp.html, www.nlm.nih.gov/pubs/factsheets/medline, www.nlm.nih.gov/pubs/factsheets/pubmed, www.Intute.ac.uk, www.tripdatabase.com/, etc. The articles which did not provide necessary information we wanted (on incidence of complications of the intraperitoneal mesh) or meet necessary criteria (intraperitoneal PPM or newer mesh) were discarded. We got a heterogeneous data, some in support of and some against the use of PPM intraperitoneally. It was difficult to compare the data as demographics, protocols, methods, techniques and meshes used were different in different studies. We could not find a prospective controlled randomized double blind study comparing intraperitoneal placement of PPM with newer meshes. So, we concentrated on the data on complications of intraperitoneally placed PPM and newer meshes by both open and laparoscopic techniques in the reported literature. Recurrence is not much of controversy. Arguments against the use of intraperitoneal PPM are because of incidence of

complications like enterocutaneous fistula, bowel adhesions with consequent intestinal obstruction, chronic infection, sinus formation, erosion of the mesh into the viscera, etc. Based on these data, we drew our conclusions.

Results

Reports: In Support of PPM

Plastic surgeons have used PPM in open surgical reconstruction of complex abdominal wall defects without many complications. According to Mathes et al. [4], for hernias with stable skin coverage, intraperitoneal placement of the Prolene (PPM) mesh is preferred, and has not been associated with visceral complications or failure of hernia repair. There are many other reports from plastic surgeons using PPM intraperitoneally [5].

Vrijland et al. [6] published a report in 2000, a retrospective study of 16-year period involving 136 patients where intraperitoneal PPM was placed. The median follow-up was 34 months. They found 6 % wound infection and sinus formation in only 2 (1.5 %) patients. There were no cases of fistulization. None of them needed mesh removal. There was no case of persistent infection; all cases settled with antibiotics. They concluded entero cutaneous fistula is very rare, regardless of omental coverage or peritoneal closure.

Alkhoury et al. [7] reported results of laparoscopic VHR are comparable in the PPM and newer mesh, but PPM at a significantly lesser cost. Their study included 141 patients who had undergone laparoscopic VHR with PPM, of which 123 patients were available for follow-up. The median follow-up period was 40 months. Partial transient small bowel obstruction occurred in 2.4 % of patients, which settled with conservative management and did not require surgery. Wound infection occurred in 3.2 % patients, port site hernia in 1.6 %, seroma in 0.7 % and recurrence in 4.8 % of patients.

On the other hand, even a composite mesh can have complications. In a retrospective study of 95 cases (over a period of 4.5 years) of intraperitoneal composite mesh repair of incisional hernia repair, one patient had fistulization and eight patients had infection. All the eight patients needed mesh removal and fistulization needed bowel resection. Over all, 10 patients had recurrence (including eight cases following mesh removal) [1].

Reports: Against PPM

Many of the reports against PPM are based on experimental studies in animal models. Ginty et al. [8] conducted experiments in eight pigs by placing three types of meshes and compared adhesion formation and fibrous ingrowth at

28 days. They found adhesions and adhesion peel strength are least with the PCO (polyester with antiadhesive collagen layer) mesh, less with PTFE compared to PPM. PCO facilitates fibrous ingrowth better. In 2009, Nathalie [9] reported an experimental study in albino rats comparing the PPM with the ePTFE mesh, which were placed intraperitoneally. They also had a control arm with no mesh placed. All animals killed at 21 days and studied for adhesions, degree of adhesions, percentage of the mesh compromised by adhesions and strength needed to rupture these adhesions. Both the groups showed similar results with respect to the factors studied, but after excluding adhesions at the edges, ePTFE fared better with respect to adhesions. Another experimental study by Novotny [10] in rabbits compared the intraperitoneally placed knitted PTFE mesh with PPM. They found fewer adhesions but more shrinkage in the PTFE group. However, it remains debatable whether these experimental results can be extrapolated to human beings and significant in the clinical settings. The study period is typically short. So, without further clinical studies PPM cannot be rejected on these grounds only.

In 2007, Halm et al. [11] published a report in the *World Journal of Surgery* on data of 39 patients who had intraperitoneal PPM and required relaparotomy at a later date. Complications were seen in 76 % [12] of patients and eight patients needed small bowel resection. The other complications recorded were surgical site infection and enterocutaneous fistula. They advised against intraperitoneal PPM placement as they were associated with complications. This study considered only patients with complications and did not mention the number of the original intraperitoneal PPM repair needed in laparotomy. It includes only patients who needed laparotomy at a later date. Hence, we haven't included these cases in the statistics for comparison. Millikan et al. [13] reported results of 102 incisional hernia repairs using the bilayered mesh (ePTFE and PPM). Except for two cases of wound infection, there were no mesh-related complications or recurrences on the median follow-up of

28 months. However, there was no comparison group for PPM.

Basoglu et al. [14], in their article on PPM repair of incisional hernia, reported recurrence rate of 5.4 %, chronic infection and sinus formation 3.4 % and small bowel obstruction 2.5 %. There were no cases of enterocutaneous fistula. However, the cases were mixture of preperitoneal placement (12 patients) and intraperitoneal placement (42 patients). The proportion of these complications at which they occurred between these groups was not clear in the article, hence not included in our study.

Rosen [15] reported experience with the use of intraperitoneal placement of a newer mesh, i.e. the polyester-based mesh with a collagen hydrogel antiadhesive barrier, both by open and laparoscopic techniques. Out of 109 repairs, they reported four cases of infection (three in open surgery group and one in the laparoscopy group) and one case of intestinal obstruction. Partial excision of the mesh had to be done in one case for infection. They concluded that the polyester mesh they described has an acceptable rate of complications. In 2010, Wassenaar et al. [16] have reported results of subsequent abdominal surgery after PTFE dual mesh repair of laparoscopic ventral incisional hernia repair (LVIHR). Out of 695 repairs, 72 required a subsequent abdominal surgery. Seven cases were done in the early period for peritonitis and out these, six cases required mesh removal. Sixty five cases required surgery later than 1 month. Out of these, 83 % had adhesions to the implant – 65 % to the omentum and 18 % to the bowel. However, adhesiolysis was easy and no enterotomies occurred. Authors concluded: “(1) no relaparoscopies had to be converted, (2) no inadvertent enterotomies were made during adhesiolysis and (3) subsequent abdominal operations have practically been devoid of peri- and postoperative complications, indicating that subsequent abdominal operations can be safely performed after the previous LVIHR with the dual mesh”. This study was excluded for statistics as exact long-term follow-up results of all patients were not available for analysis in the study.

Table 1 Studies on PPM

	Year	N	Infection	Fistulization	Sinus formation	Adhesions	Recurrence	Seroma
Vrijland et al.[6]	2000	136	8	0	2	0		
Alkhoury et al.[7]	2011	123	4	0	0	2	6	1
Scripcariu et al.[21]	2004	107	0	1	5	0	5	0
Bingener et al.[19]	2004	20	0	0	0	1	0	0
Kua et al.[20]	2002	25	0	0	0	1	3	0
Jitea et al.[22]	2008	21	0	0	0	0	0	3
Chowbey et al. [17]	2000	202	0	0	0	0	2	36
Yavuz et al.[18]	2005	85	0	0	0	3	5	0
		719	12	1	7	7	21	40

Table 2 Studies on newer meshes

	Year	N	Infection	Fistulization	Sinus formation	Adhesions	Recurrence	Seroma
Millikan et al. [13]	2003	102	2	0	0	0	0	0
Rosen et al. [15]	2009	109	4	0	0	1	0	0
Cobb et al. [1]	2003	95	8	1	0	0	10	0
DeMaria et al.[23]	2000	21	1	1	0	0	1	0
Tollens et al.[24]	2011	176	3	0	0	3	12	7
Iversen et al.[25]	2010	152	5	0	0	0	4	
Aura et al.[26]	2002	86	0	0	12	0	6	
Eid et al.[27]	2003	78	0	0	0	0	4	3
Martorana et al.[28]	2007	52	0	0	0	0	3	0
Heniford et al. [29]	2003	850	6	0	0	0	35	21
Verbo et al. [30]	2007	41	0	0	0	0	1	2
		1762	29	2	12	4	76	33

There are several articles both in support of and against the use of PPM and superiority of newer meshes over PPM without prospective randomized controlled trials. We have observed that older articles (before 2005) are more likely to be in favor of PPM and newer articles (after 2005) are in favor of the newer meshes, with a few exceptions. This raises a question whether there is a bias or influence of the newer mesh manufacturers on the studies. Table 1 shows studies on PPM and Table 2 shows studies on newer meshes. The net results of these tables are shown in Table 3 with statistical significance.

Discussion

It can be seen from Table 3 that there is no statistically significant difference in the incidence of complications between PPM and newer mesh groups, except in adhesions and seroma formation. So, it can be safely stated that adhesions and seroma are the only complications to be considered while selecting the mesh. The fear of other complications of PPM mentioned in the literature is exaggerated. They occur rarely with PPM as well as the newer mesh. A high incidence of seroma in the PPM group is

because of one study by Chowbey [17], which has contributed to 36 seroma in 40 cases. The author has not given any reason for this high reported incidence of seroma. Barring this one study, none of the other studies showed a high incidence of seroma. So, ultimately only factor to be considered is adhesion formation with consequent risk of intestinal obstruction. In the PPM group, out of seven adhesions, three occurred in Yavuz et al. [18] series and two cases in the Fuad Alkhoury series. But none of them required surgery. One case occurred in Bingener et al. [19] study. But this was detected by ultrasound examination and was not of any clinical significance. Patients didn't present with clinical intestinal obstruction. Only one case in the Kua et al. [20] series required relaparoscopy to release the adhesions. So out of 719 cases of PPM, only one case required surgery for complication of adhesion. Based on these evidences in the literature, we conclude that there is no evidence in the published literature to reject PPM for intraperitoneal placement in VHR.

There is also a greater tendency of the ePTFE mesh for shrinkage. This and the cost should be kept in mind while choosing the mesh.

According to findings and conclusions of Eriksen et al. [12] in their review article: "There is a tendency toward greater

Table 3 Comparison of results of PPM and Newer meshes

	N	Infection	Fistulization	Sinus formation	Adhesions	Recurrence	Seroma
PPM	719	12	1	7	7	21	40
Newer Mesh	1762	29	2	12	4	76	33
Statistical Test Used		Chi Sq. test	Fisher's Exact Test	Chi Sq. test	Fisher's Exact Test	Chi Sq. test	Chi Sq. test
P value		0.967	1	0.452	0.018	0.117	<0.0001
Significance		NS	NS	NS	Significant	NS	Significant

shrinkage in ePTFE-based meshes, but no differences seem to exist between different mesh materials in other relevant outcome parameters from clinical series. In conclusion, the literature cannot give general recommendations for the choice of the mesh based on randomized controlled trials. The final choice of the mesh for LVHR will, therefore, typically be based on surgeons' preference and cost while we await further data from randomized controlled clinical trials".

If we go by criteria of levels of evidence (http://www.mh.org.au/royal_melbourne_hospital/levels-of-evidence/w1/i1017827/), these do not even meet the first level of evidence criteria.

However, ours is a metaanalysis and we are aware of the limitations. The surgeries are done at different centers, different periods of time and by different surgeons. The follow-up period also varies. Methods to assess complications are different. We feel it is worth conducting a prospective controlled randomized double blind study comparing intraperitoneal placement of PPM with the newer mesh to confirm our results and conclusions.

Conclusions

Complications of intraperitoneal PPM (adhesions, infection, intestinal fistulization, sinus formation, seroma and recurrence) can occur with the newer mesh also. There is no statistically significant difference in the incidence of these complications between these meshes. We do not have even the first level of evidence in the literature to reject intraperitoneal PPM in VHR. However, this is only a literature review and needs confirmation by prospective controlled randomized double blind study comparing intraperitoneal placement of PPM with the newer mesh. Till then, the choice of the mesh depends on the surgeon's preference and cost of the mesh rather than EBM.

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