Prospective Study of Comparison of Outcomes with Use of Polyglactin with Polypropylene Mesh Vs Polypropylene Mesh in Inguinal Hernioplasty

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ABSTRACT

BACKGROUND
Hernioplasties are common surgeries done in general surgical practice in the groin area, and one in four men are expected to have undergone surgery for hernia during his lifetime. The prevalence rate of surgeries for hernia repair is expected to be 200/10000 and nearly 8% of all surgeries in the groin region occur in women¹. Groin hernia repairs have evolved from tension repairs to tension free repairs using appropriate mesh to reinforce the posterior wall of the inguinal canal. It is strongly recommended by the European Hernia guidelines for an open inguinal hernia that a synthetic non absorbable mesh or a composite mesh with non-absorbable component must be used.² Though most of the meshes used are optimal in the treatment of hernias, the present trend is towards use of light weight meshes to decrease the rate of complications associated with repair.

METHODS
In this prospective study we present 50 cases who underwent Lichtenstein open inguinal hernioplasty using different meshes- polypropylene mesh and polyglactin with polypropylene mesh (light weight mesh). We have studied their outcomes with regard to pain, seroma, foreign body sensation and patient satisfaction.

RESULTS
Polyglactin with polypropylene mesh was found to be superior to polypropylene mesh with regard to pain and seroma.

CONCLUSIONS
Lighter mixed mesh materials like polyglactin with polypropylene mesh had better acceptance among patients in the immediate post-operative phase of the surgery; but mesh type and material did not affect the late post-operative period.

KEY WORDS
Inguinal Hernia, Polyglactin, Polypropylene, Mesh
BACKGROUND

Initially, external management with bandages, trusses were used to treat inguinal hernias which were primarily used by a French surgeon Gud de Chaulic and taken up by Ambroise Pare. Subsequent forms of plugs were used to block the internal ring. In the year 1884 Bassini performed a surgical intervention without using prosthesis. This was documented as 'Bassini repair' with the mortality and recurrence rate with 2.6% and 3.1% in 227 patients with 98% follow-up in 4.5 years. With the widening of this procedure, a variety of types of wire and suture were used in reinforcing the abdominal wall. Later, early forms of mesh consisting of stainless steel, which was too stiff were created and implanted then nylon that disintegrated too quickly was formed and then the polypropylene. The EU trialist collaboration reviewed 58 randomized controlled trials, which then proposed that use of mesh is superior to other techniques. They noted the less recurrences and post-operative pain. The European hernia guidelines strongly recommend for using the synthetic non absorbable or composite mesh with non-absorbable component for the open inguinal hernias. It was in the year 1998 Vypro mesh was first introduced which was very light and the dominance of it over the meshes which were heavy was greatly acknowledged. These have pores which are larger in size of about 3mm-5mm with a diminutive surface area, which diminished the provocative response and hence was found to be with superior elasticity.

We wanted to compare outcomes of polypropylene versus polyglactin with polypropylene mesh (Light Weight mesh) in inguinal hernioplasty.

METHODS

This is a prospective study conducted in the department of general surgery, Sri Ramachandra Medical College. The study was carried out after procuring approval from the ethical committee, 50 participants were taken into two groups of 25 each. The study participants were chosen by randomized technique and were categorized into two groups, group 1: Included patients who had polypropylene mesh for inguinal hernioplasty and group 2: Had participants who were given polyglactin with polypropylene mesh which is light weighted.

Polypropylene Mesh

It is made up of knitted polypropylene monofilament which is resistant to degradation by tissue enzymes and retains strength indefinitely. Polypropylene is known to have bidirectional elastic property.

Inclusion Criteria

Patients with clinical diagnosis of adult uncomplicated inguinal hernia within age group of 20-55 yrs. Both indirect and direct inguinal hernias were included. Only open inguinal hernioplasty is taken into account for this study.

Exclusion Criteria

Patients with recurrent hernias/complicated hernias, who have undergone laparoscopic hernia repair, with h/o immunosuppression were excluded.

Materials used in the study

- a) 6 x 11 cm Polypropylene Mesh (Non absorbable material).
- b) 6 x 11 cm Polyglactin with Polypropylene Mesh (contains both absorbable and non-absorbable material).
- c) 2-0 Prolene for anchoring the mesh.
- d) 2-0 Ethilon for skin closure.

Statistically Analysis

The data was collected, and significance of complications was statistically analysed using Pearson Chi square test.

RESULTS

In this prospective study of 50 patients, who were diagnosed to have adult inguinal hernia? Patients were divided into 2 groups. 25 were operated with polypropylene mesh in group 1 and 25 patients were operated with polyglactin with polypropylene mesh in group 2.

Sex

There was a male predominance in the study with male patients accounting for 98% of the study material. Only one female patient was accounted in the entire study.

Age

The study group had 5 patients from group 1 and 8 from group 2 who were between 20 and 30 years of age. For the age group of 31-50 years, there were 14 patients in group 1 and 11 patients in group 2. For patients with age more than 51 years, 6 patients each were there in both groups.

Types of Hernia

In the entire study 60% of the study group were diagnosed to have indirect hernia and 40% of the study group were diagnosed to have direct hernia. In group 1, 16 patients (64%) of the study group were diagnosed to have indirect hernia and 9 patients (36%) of the study group were diagnosed to have direct hernia. In group 2, 14 patients (56%) of the study group were diagnosed to have indirect hernia and 11 patients (44%) of the study group were diagnosed to have direct hernia.
Assessment of Complications

Pain
In the immediate post-operative period (24-48 hrs), pain was measured in both the study groups by using visual analog scale. Patients with pain score 4 or more as per the visual analog scale were taken as significant in the study. Immediate post-operative pain was more than 4 according to visual analog scale in group 1 in 10 patients, compared to 4 patients in group 2. Statistical analysis for pain comparison between the mesh types had a P value of 0.059, which did not have a positive correlation.

Seroma
Seroma was observed in 4 patients (16%) in group 1 postoperatively, whereas in group 2 none of the patients developed seroma. Statistical analysis for seroma formation between the two mesh types showed a positive P value of 0.37, which showed a positive correlation.

Foreign Body Sensation
Foreign body sensation was complained postoperatively by 3 patients in group 1, whereas in group 2 none of the patients had complaints of foreign body sensation. Statistical analysis for foreign body sensation between the mesh types showed that P value of 0.074, which did not have a positive correlation.

Follow Up- Satisfaction
Postoperatively on follow up at 1 week and 6 months, patients were asked whether they were satisfied with the surgery or not. 5 patients in group 1 were unsatisfied with the surgery in terms of immediate post-operative pain, seroma and foreign body sensation on follow up, whereas in group 2 all the patients were satisfied with the surgery. Statistical analysis for patient satisfaction between the mesh types showed that there was a significant P value of 0.18, which showed a positive correlation. In this study, none of the complications like wound infection/dehiscence, mesh rejection, chronic groin pain, recurrence of hernia were encountered. In comparative value evaluation, p values obtained by chi square test examined values <0.5 or insignificant. Hence the statistical data could suggest superiority of polyglactin with polypropylene mesh over polypropylene mesh in areas of pain, seroma, etc.

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of Cases</th>
<th>Result</th>
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<tbody>
<tr>
<td>Goldenberg A et al; 2005</td>
<td>14 rabbits</td>
<td>Vypro had better fibrosis Both meshes had similar Adhesions</td>
</tr>
<tr>
<td>Puccio F et al; 2005</td>
<td>45</td>
<td>Both mesh were similar for pain and discomfort</td>
</tr>
<tr>
<td>Peeters E et al; 2010</td>
<td>59</td>
<td>59 High incidence of poor sperm motility in Prolene vs Vypro</td>
</tr>
<tr>
<td>Hannu paajanen et al; 2013</td>
<td>312</td>
<td>Results and complications seemed to be similar</td>
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Studies of Interest that Compared Polypropylene Mesh and Polyglactin with Polypropylene Mesh

DISCUSSION

Lichtenstein open inguinal hernioplasty is a tension free hernia repair with use of mesh. The Lichtenstein hernioplasty repair depends on inflammatory foreign body reaction for reinforcement of the posterior wall. The inflammatory reaction due to the mesh leads to neovascularisation and connective tissue/fat ingrowth leading to fibrosis and entrapment of the surrounding structures. Polyglactin with polypropylene mesh (Light Weight mesh) which consists of both absorbable and non-absorbable material and polypropylene mesh which consists of only nonabsorbable material are used in this study. There lie a myriad of complications representing this response of mesh like, pain-immediate and chronic, nerve entrapment, seroma formation, mesh rejection, wound infection, along with hernia recurrence.

Though hernia recurrence and chronic groin pain rates equalled in most of the studies which were done to prove the efficacy of the meshes, immediate complications like seroma formation, improved abdominal movement, and decreased foreign body feeling were less observed in light weight meshes like polyglactin with polypropylene mesh versus the pure polypropylene mesh. In this study, we sought to find a better mesh for the open inguinal hernioplasty and compared polyglactin with polypropylene mesh and polypropylene mesh. The study group was divided into two groups based on randomization by lot method. 25 patients were assigned to group 1 in which polypropylene mesh was used. 25 patients were taken into group 2 in which polyglactin and polypropylene mesh was used. Lichtenstein open inguinal hernioplasty was performed in both the groups and the respective meshes were used. The patients were subjected to one week and six months follow ups. The presence of immediate post-operative pain, seroma formation, wound infection/dehiscence, mesh rejection, chronic groin pain, foreign body sensation, recurrence of hernia & patient satisfaction after surgery were assessed. There was a male preponderance in the study, with the male patients accounting for 98%. Most of the patients belonged to the third-fifth decade. In group 1, 64% of the study group were diagnosed to have indirect hernia and 36% of the patients were diagnosed to have direct hernia. In group 2, 56% of the study group were diagnosed to have indirect hernia and 44% of the patients were diagnosed to have direct hernia.

Immediate Post-Operative Pain
Pain was assessed in the immediate post-operative period (24-48 hrs.) using visual analogue scale. Pain score of more than 4 was considered positive. A pain score of 4 or more was present in 40% of the patients in group 1 whereas only 16% of the patients in group 2. Polyglactin with polypropylene mesh was found to be superior than polypropylene mesh in terms of immediate postoperative pain. Similar results were obtained by Bringman S et al in their study in 590 patients (68) and Gao et al in their study in 2027 patients. Pain in both the immediate and delayed post-operative period was mainly due to irritation of the inguinal nerves by suture/mesh; inflammatory reaction against the mesh or simply scar tissue. Statistical analysis was done for pain comparison between the two mesh types showed a p value of 0.059 which did not show a positive correlation. Puccio F et al in their study in 45 patients found that there was no statistically significant difference between the groups in terms of overall early and late complications.
Seroma
Seroma formation was observed in 16% of the patients with polypropylene mesh whereas none of the patients with polyglactin with polypropylene mesh had seroma formation. Statistical analysis done for comparison of seroma formation between two mesh types showed a p value of 0.037 suggesting a positive correlation. Hence polyglactin with polypropylene mesh is superior than polypropylene mesh in terms of seroma formation.

Foreign Body Sensation
Foreign body sensation was observed in 12% of the patients with polypropylene mesh whereas none of the patients with polyglactin with polypropylene mesh had foreign body sensation. Polyglactin with polypropylene mesh is superior to polypropylene mesh in terms of foreign body sensation. Gao M et al in their study of 2027 patients found that foreign body sensation was significantly lower in patients with polyglactin and polypropylene mesh.

Wound Infection
The groin appears to be a protected area, as wound infection after inguinal herniorrhaphy occurs in less than 5% patients. Cobb. W.S. et al found that diminishing the solidity of polypropylene instigate less foreign-body response resulting in improved abdominal wall compliance with less reduction or declination of the mesh allowing for enhanced tissue incorporation.

Statistical analysis done for comparison of foreign body sensation between two mesh types showed a p value of 0.074 which did not show a positive correlation.

Patient Satisfaction
After 6 months follow up of patients, 20% patients with polypropylene mesh were unsatisfied due to the presence of either pain, seroma formation or foreign body sensation. Whereas in patients with polyglactin with polypropylene mesh there was 100% patient satisfaction post operatively. Statistical analysis done for patient satisfaction between both the mesh types showed a significant p value of 0.018. In this study, none of the complications like wound infection/dehiscence, mesh rejection, chronic groin pain, recurrence of hernia were encountered.

CONCLUSIONS
Lighter and mixed mesh materials like polyglactin with polypropylene mesh had better acceptance among the patients in the immediate post-operative phase of the surgery, but mesh type and material did not affect the late post-operative period. Hernia recurrence and chronic groin pain, wound infection/dehiscence, and mesh rejection, were not encountered in any mesh group. There was a definite liking towards the use of polyglactin with polypropylene by the surgeon and patient as it made the surgery less painful and less eventful in terms of pain, seroma formation and foreign body reaction compared to polypropylene mesh. Ultimately a good mesh is one which has negligible foreign body reaction and no pathologic fibrosis.


