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Research Article

A PROSPECTIVE COMPARATIVE STUDY OF LIGHTWEIGHT AND HEAVYWEIGHT POLYPROPYLENE MESHES IN 50 CASES OF UNILATERAL INGUINAL HERNIA. ULTRAPRO Vs PROLENE

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A B S T R A C T

Purpose: The purpose of this study was to study the advantages of lightweight mesh and compare them to heavyweight standard polypropylene mesh before their induction into the standard hernia repair protocol of the department of surgery in our institute. **Methods:** Fifty males who were diagnosed with inguinal hernia were prospectively enrolled in the study after approval of the institutional ethics committee and operated on between October 2010 and August 2012. These patients were allocated alternately to two groups: Group A- Light weight poly-propylene mesh (ULTRAPRO) Group B- Standard heavy weight polypropylene mesh (PROLENE) Data were expressed in percentages and the two groups were compared using the Chi square test and the Fischer's exact test. A P-value of 0.05 or less was considered statistically significant. **Results:** There was a statistically significant reduction in pain, analgesic requirement and mesh consciousness at day 30 and 90 in lightweight mesh group as compared to the heavyweight mesh group. There was no difference in pain impeding activity, no wound infection and no recurrence in either group. **Conclusion:** Hence a lightweight mesh has proven to be superior to the heavy weight mesh in terms of reduction in pain at rest, decreased analgesic requirement, and reduced mesh consciousness. Neither group has had a recurrence so far.

INTRODUCTION

Inguinal hernia repair is one of the most commonly performed surgeries in the world. Traditionally, inguinal hernias were treated primarily with a suture based repair. Bassini repair, (suturing the conjoint tendon to the reflected part of the inguinal ligament) was the standard surgery performed. These provide excellent results in patients with good abdominal muscle tone. In patients that lacked tone reinforcement was needed. It came first in the form of a polyethylene and then polypropylene mesh used by Usher in 1958. It was hypothesized that the use of a mesh would reinforce the abdominal wall, with the formation of scar tissue. The added benefit was it was that it was tension free. Tension impedes tissue microcirculation, decreases local tissue oxygenation and interferes with hydroxylation of proline and lysine. [1] As more surgeons began noticing the benefits of tension free repair, the more it was popularized. Lichtenstien Hernia Institute was the first to successfully publish these results. [2] Unfortunately, the fibrotic reaction from the mesh could also lead to pain and stiffness. The polypropylene mesh imparted a tensile strength, which was ten times more than the maximal abdominal pressure, which was unnecessary. This led to the development of lightweight mesh in 1998. These meshes have large pores (normally 3–5mm) and a small surface area. They cause a reduced inflammatory reaction, have greater elasticity and flexibility, shrink less and are associated with less pain. [3] However, placing a mesh has its complications - infection, foreign body sensation, foreign body reaction, recurrence due to improper fixation of the mesh at the edges, mesh degradation, loss of tensile strength, intra-operative nerve damage and entrapment associated pain of nerves within the mesh framework. [3] With this study our search for the best option among meshes continues.

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MATERIALS AND METHODS

Our study was approved by the Institutional Ethics Committee (IEC), Seth G.S Medical College and King Edward Memorial Hospital (KEM), Mumbai in September 2010.

50 male patients with inguinal hernia were enrolled for the study and operated on between October 2010 and August 2012. Each patient was allocated alternately to one of the two groups mentioned below:

Group A- Lightweight polypropylene mesh (ULTRAPRO)
Group B- Standard heavy weight polypropylene mesh (PROLENE)

Our inclusion criteria were

1. Patients who voluntarily agreed to consent after being informed in writing of the procedure and the mesh.

2. All patients above the age of 12 with inguinal hernia.
3. Open inguinal hernia repair. (Direct sac or indirect sac or both components together)

The exclusion criteria were

1. Patients who refused consent.
2. Recurrent hernia
3. Bilateral hernias
4. Complicated hernias including irreducible, obstructed or strangulated hernias.
5. Patients < /= 12 years of age.

The patient and caregivers were provided with a patient information sheet. All patients underwent a Lichtenstein meshplasty.

Group A: 25 patients operated using the lightweight mesh (ULTRAPRO)

Group B: 25 patients operated using the standard heavy weight mesh (PROLENE)

All procedures were performed under spinal anesthesia. A standard groin incision was taken. It was placed 1.25 cm above and parallel to the inguinal ligament, over medial two-thirds of the groin. The inguinal canal was opened in layers. Space was created by blunt dissection after opening the external oblique aponeurosis. The limits of this blunt dissection went up to the pubic tubercle medially, the conjoint tendon superiorly, beyond the deep inguinal ring laterally, and up to the upturned part of the inguinal ligament inferiorly. The cord was hooked and sac was dissected. Indirect sac was excised and direct sac was inverted. The mesh (light weight or heavy weight as per the groups) was placed with the first stitch (with polypropylene 2-0) taken over the pubic tubercle. Subsequently the mesh was fixed such that it overlapped the upturned part of the inguinal ligament by 3 mm, using interrupted stitches along its length. The mesh was then cut transversely (a method commonly referred to as 'fish-tailing) so as to accommodate the cord structures entering the inguinal canal through the deep inguinal ring. Interrupted sutured were placed to fix the mesh over the conjoint tendon and two stitches were taken to fix the mesh to the rectus sheath medially. The incision was then closed in layers, external oblique aponeurosis with 2-0 polypropylene in a continuous fashion, subcutaneous layer with 3-0 poliglicaprone in an interrupted manner and skin was sutured with 3-0 poliglycaprone with subcuticular stitches.
Patients were followed up during the immediate postoperative period, and at 15, 30, 90 days post-operatively. Follow up for recurrence was done for up to 5 years after enrollment.

Statistical analysis

Statistical analyses were performed using SPSS version 19.0. Relevant calculations were obtained for qualitative and quantitative variables. Data were expressed in percentages and the two groups were compared using the Chi square test and the Fischer's exact test. A P-value of 0.05 was considered statistically significant.

RESULTS

The parameters studies after enrolling patients were,

Pain at rest

POD 30 - In group A, 24% of patients suffered from pain at rest, while in group B 56% patients had pain at rest.. At POD 90 - Only 4% of patients in group A and 32% in group B had pain at rest. The difference in pain at rest at the 30th (P=0.021) and 90th (P=0.023) postoperative day between group A and group B was statistically significant. The data is depicted in Table I.

Table I		Light weight mesh (A)		Heavy weight mesh (B)	
		Count	Column n %	Count	Column n %
Pain at rest 30 days	Yes	6	24.00%	14	56.00%
	No	19	76.00%	11	44.00%
	Total	25	100.00%	25	100.00%
Pain at rest 90 days	Yes	1	4.00%	8	32.00%
	No	24	96.00%	17	68.00%
	Total	25	100.00%	25	100.00%

Day 30 P=0.021 (significant)
Day 90 P=0.023 (significant)

Pain impeding activity

POD 15 - Only 16% of the patients of group A had pain, which impeded activity while those who experienced it in group B constituted 64%. The difference was statistically significant (P=0.001). This is depicted in Table IV. There was no significant difference between the two groups on day 30 and 90.

Analgesia requirement

POD 30 - In group A, 24% of patients required analgesics, and in group B, 64% required analgesics at 30th postoperative day, which was statistically significant (P=0.004).

POD 90 - Only 8% patients in group A and 40% patients of group B had analgesic requirement, with the difference being statistically significant (p=0.008). The data is depicted in Table II.

Table II		Light weight mesh		Heavy weight mesh	
		Count	Column n %	Count	Column n %
Pain impeding activity 15 days	Yes	4	16.00%	16	64.00%
	No	21	84.00%	9	36.00%
	Total	25	100.00%	25	100.00%

Day 15 P=0.001 (Significant)

Mesh consciousness at the 30th and 90th postoperative day,
POD30 - There was a statistically significant difference in mesh consciousness (P=0.005) and at POD90 (P=0.001) between the two groups. Patients of group A had lesser mesh consciousness as compared to those in heavyweight meshes group. The data is depicted in table III.

Table III		Light weight mesh(A)		Heavy weight mesh(B)	
		Count	Column n %	Count	Column n %
Analgesics requirement 30 days	Yes	6	24.00%	16	64.00%
	No	19	76.00%	9	36.00%
	Total	25	100.00%	25	100.00%
Analgesics requirement 90 days	Yes	2	8.00%	10	40.00%
	No	23	92.00%	15	60.00%
	Total	25	100.00%	25	100.00%

Wound discharge

The incidence of wound discharge was 12% for group A, 8% for group B. This was not statistically significant (P=1.000).

There was no wound infection or seroma formation in any of the patients in either group.

None of the patients had a recurrence after five years of follow-up.

		Light weight mesh(A)		Heavy weight mesh(B)	
Table IV		Count	Column n %	Count	Column n %
Mesh like sensation at 30 days	Yes	1	4.00%	9	36.00%
	No	24	96.00%	16	64.00%
	Total	25	100.00%	25	100.00%
Mesh like sensation 90 days	Yes	2	8.00%	13	52.00%
	No	23	92.00%	12	48.00%
	Total	25	100.00%	25	100.00%

Day 30 P=0.005 (significant)
Day 90 P=0.001 (significant)

DISCUSSION

Several varieties of mesh have come up in the process of developing the ideal. The ideal hernia mesh is still far from being invented. Considering the several options now available in the market, studying their effects to know which is the best among the currently existing options is absolutely necessary so as to benefit patients may. The standard heavyweight polypropylene mesh has been in use in our institute ever since it's introduction in our country two decades ago. Lightweight meshes are designed to cause lesser pain, reduce mesh consciousness, and decrease the incidence of infection. We designed this study in order to back up our demand for the lightweight mesh to be established as the standard mesh at our institute with evidence in the local population. This study intends to prove or disprove perceived advantages of lightweight meshes enumerated in past studies. [4]

This study found a statistically significant difference in pain at rest, encountered by group A (lightweight mesh) patients in comparison to group B (heavy weight mesh) at the end of the 30^{th} and 90^{th} day post surgery. (Table I). The difference in pain at rest on day 15 after surgery was statistically insignificant although the incidence of pain was more in patients of group B. It can be seen that at all points of follow up pain was more in group B, as compared to group A whether at rest or during activity. Pain impeding activity was found to be significantly less in the lightweight mesh group (group A) as compared to the heavyweight mesh group on day 15 after surgery. (Table II) On days 30 and 90 post surgery the trend was the same but the difference was not statistically significant.

Postoperative groin pain is the main complication following inguinal hernia repair. Tension free mesh repair has brought down the incidence of postoperative pain but hasn't eliminated it. This pain may be somatic, neuropathic or visceral in origin. [5] Cunningham *et al* reported that the commonest type of chronic pain after surgery was somatic in origin. [6] Poobalan *et al* believed it to be predominantly neuropathic in character. [7] Simons *et al* hypothesized that the risk of chronic pain after mesh repair is lesser than that after non-mesh repair. [8] Further postoperative pain is a risk factor for chronic groin pain. Lightweight meshes are made up of thinner filaments with larger pores. This reduces the volume of foreign material and is thus associated with a reduced inflammatory response and lesser scar tissue. This may also explain the significantly reduced pain during activity at postoperative day 15 in the lightweight group, allowing early return to work after surgery. Post.S *et al*, in a randomized clinical trial evaluating the use of lightweight mesh for Lichtenstein repair, concluded that lightweight meshes were associated with lesser pain during activity. Pain during activity has been attributed to the degree of inflammation and wound healing. This depends upon the material of prosthesis and impedance to abdominal wall muscle movement. Heavy weight meshes have smaller pores, which cause bridging granulomas. This creates a rigid, inflexible scar, which amounts to greater pain during activity. [9] As the wound healing progresses and the mesh induces fibrosis and gets incorporated into it, pain at rest comes in play. Lightweight meshes having less material induce less pain. Whatever the origin - somatic, neuropathic or visceral, lightweight mesh has a definite advantage over the standard heavyweight mesh in being able to reduce pain impeding activity early on and pain at rest later on significantly. By decreasing the incidence of postoperative pain lightweight meshes also decrease chronic inguinal pain. Identifying the etiology of pain is beneficial in prevention of pain through modification of surgical technique or of help in selecting the mode of treatment of chronic pain alone. The risk of chronic pain increases with increasing age. We therefore matched the two groups for age.

Analgesia requirement in the immediate postoperative period and day 15 was almost similar in both groups, whereas at further follow up (30^{th} and 90^{th} postoperative days) the analgesic requirement was significantly more in heavy weight group than light weight group. (Table III) Lesser inflammation and a more flexible scar may perhaps be the reason for a reduction in requirement of analgesic medication in the lightweight group.

Implantation of a mesh can cause a foreign body sensation, due to inflammation, fibrosis and calcification leading to an inflexible scar. Post. S *et al* mentioned that the use of a lightweight mesh decreases the sensation of mesh consciousness to less than half of the reported incidence with conventional densely woven polypropylene meshes. The lightweight mesh (Ultrapro®, Ethicon) is a large pore composite mesh made up of monofilament polypropylene with a pore diameter of 3 to 4 mm, and is reinforced with poliglicaprone-25(copolymer of glycolide and Ɛ-caprolactone) monofilaments.

Initially, both components support the weakened posterior inguinal wall. As fibrosis progresses, the poliglicaprone component gets reabsorbed. Finally, fibrosis supports the posterior wall, while the large pore polypropylene mesh with lesser polypropylene content provides the additional support required. The weight of the mesh is approximately 28 g/m^2 of residual polypropylene, after absorption of the poliglicaprone component. The high degree of elasticity, exhibited by this mesh, after absorption of the poliglicaprone component, improves not only intra-operative handling but also reduces pain at rest and mesh consciousness. [10] The mesh is thus

designed optimally to withstand the physiological stress of the abdominal wall while maintaining its flexibility. As was found with most other studies, our study also showed a statistically significant decrease in the number of patients with mesh consciousness with the lightweight mesh versus the heavyweight mesh at all milestones of follow up. (Table IV) [3, 11] In the study by Bringman S *et al*. 37% people in light weight group had Mesh like sensation while in heavy weight group 55% had Mesh like sensation at 1 year follow up. The above results were statistically significant at a P value of 0.025. These results were comparable to our findings.

The incidence of mesh infection in most studies has been cited to be around 0.17-0.7%. [12] Theoretically, the risk of infection is determined by the type of filament used and pore size. Small pore meshes are at higher risk of infection because macrophages and neutrophils are unable to enter small pores (< 10 μm). This allows bacteria (< 1 μm) to survive unchallenged within the pores. According to Amid PK *et al*. the meshes at lowest risk of infection are, therefore, those made with monofilament and containing pores greater than 75 μm.[13]

The incidence of infection in both groups in this study was statistically not significant. This study could not prove the incidence of infection is less with the use of lightweight mesh. It would need a larger study to prove/disprove the difference in infection rates between the two groups.

In the study by Smietanski M *et al* at 1 month follow up 1% people in light weight group had wound discharge while in heavy weight group no persons had wound discharge (not significant P= 1.0) These findings are similar to our study results. [14]

Two thirds of the recurrences occur after three years. There were no recurrences in either group after five years of follow up. The type of material used does not relate to recurrence however. Lightweight meshes have large pores, which have been known to induce a higher type I/III collagen ratio as compared to heavyweight meshes and hence theoretically reduce the chance of recurrence.

CONCLUSION

Hence our study concludes the lightweight mesh has proven to be superior to the heavyweight mesh in terms of reduction in pain at rest, decreased analgesia requirement, and reduced mesh consciousness. Neither group has had a recurrence at 5 years follow-up. A larger sample size is required to prove or disprove other benefits like less wound infection.

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