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RCT to Assess Groin Pain Following Inguinal Hernioplasty using Light Weight Mesh versus Heavy Weight Mesh

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Abstract

Background: The Lichtenstein mesh repair is the present gold standard for open repair of the inguinal hernia. As a result the recurrence of hernia has come down from 40% to less than 1%. However, the problem of chronic inguinodynia remains. The aim of the present study was to assess whether chronic inguinodynia could be influenced by using partially absorbable monofilament light weight mesh as compared to heavy weight prolene mesh. *Methods:* The study randomised 200 patients undergoing elective inguinal hernia repair into two groups of 100 each according to the type of mesh used. Group I underwent HW (prolene) mesh repair and group II underwent LW (vypro) mesh repair. Follow up for chronic groin pain was done using VAS (1-10), for a period varying between 06 months and 02 yrs with an average period of 15 months. The patient and the assessor of pain during the follow up, were blinded to the type of mesh used. *Results :*. The chronic pain was observed to be of mild severity (VAS 1-3) in both groups. The pain difference between the two groups at 03 months was not statistically significant (p=0.197), whereas at 06 months , 01yr and at 02 yrs pain was although mild (vas1-3) but was statistically significant, p=<0.001, p=0.001 and p=<0.001 respectively, more in prolene group. The foreign body sensation was 16% in group I and 0% in group II. *Conclusions :* The chronic pain seen in both groups has been of mild variety (VAS 1-3), though slightly more among the prolene group.

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Keywords: Chronic Pain; Lichtenstein Hernioplasty; Light Weght (Vypro) Mesh; Heavy Weight (Prolene) Mesh.

Introduction

Inguinal hernia is the most frequently performed operation in general surgery and so even modest improvements in clinical outcome are important. The important criteria for the choice of method are recurrence rates and the risk of chronic groin pain. The present gold standard for hernia repair is Lichtenstein's open anterior tension free repair which has shown good results [1,2,3,4].

The use of mesh has reduced the incidence of hernia recurrence. Concern remains regarding postoperative chronic pain (varying between 9.7% to 51.6%) and the feeling of foreign body sensation in the groin (43.8%) [5,6]. Some trials have shown that patients with lightweight (LW) mesh experienced less pain after surgery than those who received heavyweight (HW) mesh. However, other studies have not confirmed this observation. The earlier used heavy type of meshes had smaller pore size, greater weight/area (> 90G/sq mtr), lesser elasticity and higher burst pressure. The later generation of meshes, the light weight meshes have larger pore size resulting in smaller interface between the mesh and surrounding tissues, lower weight (< 30G/sq mtr), greater elasticity and lower burst pressure. It has been surmised that the inflammatory reaction with its provoked scar tissue to the foreign material is correlated with the amount and structure (pore size) of the synthetic material used [7,8,9]. One of the newer mesh used in this study consists of equal parts of absorbable polyglactin multifilament and nonabsorbable polypropylene thread (Vypro mesh). In comparison to Vypro I, Vypro II mesh has additional

strengthening with rhombically arranged thread of polyglactin and polypropylene.

Material and Methods

This was a prospective study conducted in the Department of Surgery,of our Institution from Mar 2008 to May 2010. 200 patients who reported with inguinal hernia during this period were randomly divided into two groups of 100 each. Group I underwent heavy weight (Prolene) mesh repair and Group II light weight (vypro II) mesh repair, all under spinal anaesthesia. Both the patients and the examiner assessing the patient for pain during the post-operative follow up period, were blinded to the type of mesh used. Operative technique consisted of modified anterior open tension free (Lichtenstein) technique.

The minimum experience of the operating surgeon was 25 hernioplasties done independently. A 7.5x15 cms size prolene (Ethicon, Germany) and 6x11 cms size vypro II (Ethicon, Belgium) meshes were used. Ilioinguinal nerve was preserved whenever identified. Neurectomy at the lateral end was done whenever this nerve got accidentally injured. Suture 2/0 prolene was used to anchor the mesh at four points, to inguinal ligament close to pubic tubercle, to rectus sheath just above pubic symphysis, to inguinal ligament just lateral to deep ring and one over conjoint tendon (quilt stitch). Laterally the mesh was split to enclose the cord, upper leaf overlapped over lower leaf stitched and then anchored to inguinal ligament just lateral to deep ring,thereby creating a new deep ring. The remaining part of remaining mesh was spread underneath external aponeurosis. Both male, female patients, unilateral, bilateral and pantaloon hernias were included. Complicated hernia, recurrent hernia more than once, pregnant patients and below 20 yrs age group patients were excluded from the studies. All patients were given three doses of antibiotics periopertively analgesics were given SOS. The patients were followed up and reviewed in OPD at 03 months, 06 months, 01 yr and 02 yrs. The primary outcome noted was groin pain and secondary outcome noted was foreign body sensation. The follow up period varied between 06 months and 02 yrs with an average period of 15 months. Pain complaint was recorded on VAS scale from 1-10 and either presence or absence of foreign body sensation was noted.

Results and Observations

Pre-op pain score difference between Group I and Group II was 2.87 (SD: 1.01), not statistically significant.

Table 1: Age distribution: a comparison between two groups

Age in years	Group I		Group II	
	No	%	No	%
20-29	10	10.0	10	10.0
30-39	10	10.0	4	4.0
40-49	19	19.0	21	21.0
50-59	13	13.0	18	18.0
60-69	28	28.0	27	27.0
70-79	14	14.0	17	17.0
80-89	6	6.0	3	3.0
Total	100	100.0	100	100.0
Mean ± SD	54.55±16.68		55.35±15.87	

Samples are age matched with p=0.729

Table 2: Gender distribution of patients studied

Gender	Group I		Group II	
	No	%	No	%
Male	95	95.0	98	98.0
Female	5	5.0	2	2.0
Total	100	100.0	100	100.0

Samples are gender matched with p=0.445

Table 3: Type of hernia

Diagnosis	Group I		Group II	
	No	%	No	%
Inguinal hernia fresh	91	91.0	87	87.0
Pantaloon hernia	3	3.0	7	7.0
Recurrent ing.hernia	6	6.0	6	6.0
Total	100	100.0	100	100.0

Distribution of fresh or recurrent hernia and pantaloon hernia is statistically similar between two groups with p=0.473

Table 4: Fresh or recurrent

Fresh /Recurrent	Group I		Group II	
	No	%	No	%
Fresh	94	94.0	94	94.0
Recurrent	6	6.0	6	6.0
Total	100	100.0	100	100.0

Distribution of fresh or Recurrent hernia is statistically similar between two groups with p=1.000

Table 5: Comparative evaluation of pain score in two groups (Mean/SD)

Time points	Group I	Group II	P value
Pre-op	3.08±0.99	2.87±1.01	0.140
Post operative pain			
Immd. Post op	3.55±1.39	3.32±1.25	0.220
4 weeks	1.50±0.92	1.12±0.74	0.001**
3 months	0.59±0.74	0.44±0.89	0.197
6 months	0.86±0.98	0.22±0.79	<0.001**
1 year	0.53±0.53	0.26±0.57	0.001**
2 years	0.60±0.59	0.06±0.24	<0.001**

Postoperatively at 6 months, the pain score for Group I was 0.86 (SD:0.98) and for Group II, it was 0.22 (SD:0.79), the pain score was statistically higher in Group I compared to Group II with p<0.001**. Similarly at 01yr and 02yrs, the pain score for Group I was higher 0.53 (SD :0.53) & 0.60 (SD:0.59) compared to Group II 0.26 (SD:0.57) & 0.06 (SD:0.24) with p=0.001** & p=<0.001** respectively.

However, the severity of pain was only mild (VAS less than 4) in both the Groups. 16% of patients in Group I had foreign body sensation in the operated area. None (0%) of the patients in Group II had foreign body sensation during the postoperative follow up period.

Table 6: Comparative post op FB sensation/heaviness

post op FB sensation/heaviness	Group I	Group II
Yes	16(16.0%)	0
No	84(84.0%)	100(100.0%)
Total	100	100
Inference	Post op FB sensation/ heaviness is significantly more in 16.0% in Group I compared to 0.0% Group II with P<0.001**	

Statistical Methods

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean±SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups Inter group analysis) on metric parameters, Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

Significant Figures

+ Suggestive significance (p value: 0.05<p<0.10)

* Moderately significant (p value: 0.01<p £ 0.05)

** Strongly significant (p value: p £ 0.01)

Statistical Software

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Discussion

The aim of this study was to study impact of whether the usage of LW mesh has advantages over the usage of HW mesh with respect to chronic groin pain or foreign body sensation post operatively. Post et al. noted that more patients had the feeling of a foreign body sensation after hernia repair with HW mesh compared with LW mesh (43.8% vs 17.2%) [10]. It has been shown that the amount of material and the structure of the mesh significantly influence scar tissue formation and chronic inflammatory reaction. Consequently, patients with LW mesh presumably experience less post-operative chronic groin pain. To improve biocompatibility, a large variety of newly developed meshes have been introduced to the market. Mesh construction and composition as characterized by pore size and filament structure appear to be more implant determinant of foreign body reaction than absolute reduction of mass (G/M^2) of the mesh [11,12,13]. Lt Col Shyam et al did a prospective study of 470 patients and found very low incidence (0.78%) of chronic groin pain [14].

S Bringman et al randomised 600 patients of inguinal hernia into two groups of standard mesh and LW mesh. At 03 yrs follow up there was no major difference in response to pain questionnaire except that fewer men with LW mesh had pain when rising from lying to sitting position (7.6% vs 13.6%: p=0.029 x^2 test) [15,16]. Significantly more men with standard mesh felt the mesh sensation in groin (22-6% vs 14.7%; p=0.025 x^2 test). In our study only 16% of patients with HW mesh and none with LW mesh had foreign body sensation.

The international Association for the Study of Pain (IASP) has defined chronic pain as pain lasting for longer than 3 months after surgery [17]. Unfortunately, the definition of chronic pain and the methodology of its evaluation are highly variable among different publications, which makes the comparison of trials difficult. The incidence of postoperative pain has been reported to be as high as 53%. Chronic inguinodynia can be divided into pain of nociceptive and neuropathic etiologies. Nociceptive pain caused by tissue damage is further divided into somatic pain due to local tissue damage (groin pain) and visceral pain (painful ejaculation) due to vas deferens damage or due to somatic/sympathetic nerve damage. Neuropathic pain is caused by direct nerve damage (nerve stretching,crushing,electrocautery etc.), nerve entrapment by suture or scar tissue [18]. Smeds et al.

in their study showed reduction in incidence of postoperative pain following nerve identification and nerve resection during surgery [19]. However, this study has not been supported by other studies [20,21,22,23,24].

Œmietañski et al. demonstrated a low incidence of chronic groin pain after inguinal hernioplasty occurring in 10.7% of the patients in the HW group and in 9.9% of patients in the LW group at 6 months follow-up [25]. C Nikkollo et al. in their study "RCT comparing LW mesh with HW mesh for inguinal hernioplasty in 135 patients and reported significantly more patients with pain at rest in HW mesh group than in LW mesh group at 06 months follow up (6.3% vs 0% p=0.038). The feeling of foreign body sensation at the operation site was experienced by 32.8% of the HW group and 20.0% of the patients in LW group after 06 months postoperatively (p=0.123). There was no significant difference in any dimension of quality of life on the SF 36 between the two study groups at 06 months after surgery. They concluded no difference in the feeling of foreign body sensation and quality of life between two groups [26].

In our study also most of the patients had only mild pain (VAS 1-3). In HW mesh group, 45% of patients at 03 months, 50.5% at 06 months, 52.1% at 01 yr and 55% of patients at 02yrs had mild pain (VAS 1-3). In LW mesh group 27% at 03 months,10.1% at 06 months, 20.7% at 01 yr and 5.8% of patients at 02 yrs had mild pain (VAS-1-3). Comparable results were reported by O'Dwyer et al. [27].

Weyhe D et al. reviewed the current literature on the use of various implants for hernia repair and found that LW mesh offered no advantage with respect to alleviating pain. They however seem to have some advantage over standard mesh with respect to postoperative pain and foreign body snesation [28]. Picchio M Palemento D et al. did a study aimed to evaluate the effect of preservation or elective division of ilioinguinal nerve on pain and postoperative symptoms after open inguinal hernia repair with mesh. Conclusion of this study was that pain after open hernia repair with polypropylene mesh is not affected by selective division of ilioingunal nerve. On the other hand sensory disturbances in the area of distribution of the transected nerve are significantly increased [29].

A study was conducted by Nadim et al. at the department of lady reading Hospital, Peshawar from January 01 2007 to December 31 2008. Patients were divided into two groups based on the type of mesh implanted. As per their observations modern day LW meshes do not promise the prospects of comparatively reduced incidence of chronic pain in patients undergoing Lichtenstein technique of tension free repair for inguinal hernia. Neither do they exhibit a higher incidence recurrence nor infection following repair of inguinal hernia when compared to polypropylene meshes [30]. Newer methods of mesh fixation using fibrin glue have demonstrated less pain and better tolerance following mesh repair [31,32].

Conclusion

Both light weight mesh (LWM) and heavy weight mesh produce only mild pain (VAS 1-3) during immediate and later post operative period, LWM marginally lesser than HWM. The foreign body sensation is significantly less in light weight mesh group.

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Conflicts of interest: Nil

Permissions: Nil

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