Cell coated mesh in Lichtenstein hernia repair: An open label trial

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DOI: https://doi.org/10.33545/surgery.2020.v4.i2d.419

Abstract

Background: Hernia is the common problem. It is estimated that 75% all abdominal hernia occurs in inguinal region. Operation is the only treatment and standard Lichtenstein hernia repair is the one of the popular method commonly used. But there are some postoperative complications like chronic groin pain and discomfort, seroma formation and mesh migration are associated with it.

Aim: To compare the effectiveness of standard Lichtenstein repair versus autologous bone marrow cell coated mesh in Lichtenstein repair.

Methods: This is an open label trial is conducted in department of general surgery, VIMSAR, Burla, Odisha over the period of 2 years. 128 patient falling into the inclusion criteria taken to study with randomisation. 64 in each group. Assessment of postoperative complication, recovery timing, duration of hospital staying and chronic groin discomfort is recorded.

Results: Postoperative complications like cord oedema, scrotal oedema, surgical site infection, seroma, fever, discharge from wound, chronic groin pain and foreign body sensation significantly less in autologous bone marrow cell coated mesh hernia repair compared to standard Lichtenstein repair.

Conclusion: The result of autologous bone marrow cell coated mesh repair is better than the result after standard Lichtenstein repair.

Keywords: Inguinal hernia; autologous bone marrow cells; mesenchymal stem cell.

Introduction

Inguinal hernia repair is probably the most commonly performed procedure under the domain of general surgery [1]. Estimates are that 20 millions of inguinal hernia repairs are performed globally every year. Various techniques have been described for repair. Tension free repairs presently lower rates of recurrences associated with them.

The use of mesh was first described by usher in 1958 [2]. Around 30 years later Lichtenstein popularized this method [3]. Presently one million meshes are being used across the globe annually over the years. The different types of meshes are available to the surgeons have grown tremendously. Light weight meshes are introduced in 1998 and now accepted superior to heavy weight meshes. Chronic postoperative pain and return to work are now primary outcomes over which the supremacy of any mesh is being evaluated.

Aim: To compare the hospital stays, postoperative complication, comorbidities, return to basic activity, return to home activity and recurrence of autologous bone marrow cell coated mesh repair in inguinal hernia along with conventional mesh hernia repair.

Materials and methods: The above study was conducted in the department of general surgery at VSSIMAR, Burla, Sambalpur, and Odisha over a period of 2 years from the year 2018 to 2020. All patients between the age group 15-60 years presenting to the outpatient door with inguinal hernia. Total 128 patients were included in the study. They were divided into 64 each, study group (group 1) and control group (group 2) using the randomized technique. We used polypropylene non absorbable synthetic surgical mesh (7.5cm x 15cm), salah bone marrow aspiration needle, container with heparin for storage, 10 ml syringe, insulin syringe, questionnaire, bed tickets, lab reports. Institutional ethical committee clearance taken. Informed consent of the patient and first degree relative taken.
Bone marrow harvested from sternum immediately stored in container containing heparin (10:1) during inguinal hernia repair bone marrow cell coated mesh is used.

Fig 1: Bone marrow harvesting

Fig 2: Stored in container containing heparin

Fig 3: Polypropylene mesh

Fig 4: Bone marrow cell coated mesh

Fig 5 & 6: Repair of inguinal hernia with bone marrow cell coated mesh and closure of skin
Inclusion criteria
- All inguinal hernia patients admitted are included in this study.
- Age must be from 15 to 60 years.
- Unilateral or bilateral hernia. Exclusion criteria:
  - Complicated hernia like obstructed and strangulated hernia.
  - Congenital hernia in children
  - Mentally retarded.
  - Patient not willing for bone marrow extraction.
  - Chronic and debilitating patient e.g. patients of multi organ failure.
  - Recurrent inguinal hernia.

Following parameters were analysed in the study subjects at the time of discharge after 1, 3, 6 months and 1 year and up to 2 years.
- Pain assessment using verbal analogue scale (VAS).
- Fever.
- Cord oedema/ scrotal oedema
- Groin discomfort.
- Sensation of heaviness.
- Seroma formation.
- Surgical site infection incidence.
- Duration of hospital stay.
- Recurrence.
- Mesh infection.
- Mesh migration.

Discussion: What is stem cell? Stem cells are characterized by the ability to self-renew and differentiate into multiple functional types. Stem cell are divided into two types based on their differentiation potential: pluripotent and multipotent. What are the pluripotent stem cell? Pluripotent stem cell are embryonic stem cells which can be differentiated into any cell in the body, whereas multipotent stem cells are adult stem cells which are limited to multiple cell lineage, but not all. The most studied and best characterized type of adult stem cell is hematopoietic stem cells, which has served as the experimental paradigm for basic studies into the biology of adult stem cells. Additional other categories of adult stem cells, mesenchymal stem cells and adipose stromal cells, which show considerable promise for use in regenerative medicine. Stromal fraction of adult bone marrow contains a heterogeneous population of cells that were originally described as supportive cells that were originally described as MSCs. This group of multipotent cells can differentiate into mesenchymal derived structures, such as bone, fat, cartilage and muscle. There are three phases of normal wound healing which is a dynamic and complex process involving a series of coordinated events. MSCs are involved in all three phases of wound healing to varying degrees. Studies have shown that the addition of MSCs to active immune responses decreases secretion of the pro-inflammatory cytokines TNF-alpha and interferon- gamma while simultaneous increasing the production of anti-inflammatory cytokines interleukin-10 and interleukin-4 [4, 7]. It is recognized that MSCs have antimicrobial activity, which is critical for wound clearance from infection. MSCs antimicrobial activity is mediated by two mechanisms: direct, via secretion of antimicrobial factors such as LL-37 [5, 7], indirect via secretion of immune-modulating factors, which will upregulate bacterial killing and phagocytosis by immune cells. MSCs secrete many mediators which are presence of lump at hernia site.
- Return to normal work activity.

Results: The two groups, group-1 (study group) and group-2 (control) were compared in the postoperative period for pain, fever, foreign body sensation, cord oedema /scrotal oedema, seroma formation/ soaked/discharge/haematoma formation, duration of hospital stay, postoperative complication, recurrence, mesh migration and mesh infection, presence of lump at hernia site and time to return to normal work activities. In this study we found that there is no statistical significance between the ages of the two groups, and the p value is 0.9 (table no. 1). The hospital stay, postoperative pain according to verbal analogue scale of postoperative day 2,7,30 and 90 found to be statistically significant and the p values are less than 0.01. Postoperative day 1 was not found to be significant, p value was 0.53 (table no. 2). Return to basic activity and home activity found to be statistically significant, p value was <0.001. Postoperative complications and recurrence rate found to be less in study group (group 1) as comparative to control group (group 2) as shown in table no. 3 & 4.

Table 1: Comparison of ages of two group.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (n=64)</th>
<th>Group 2 (n=64)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD)</td>
<td>49.72 ± 9.65</td>
<td>49.46 ± 9.11</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Table 2: Comparison of postoperative variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (n=64)</th>
<th>Group 2 (n=64)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital stay</td>
<td>4.67 ± 0.67</td>
<td>6.23 ± 1.33</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>POD 1</td>
<td>2.20 ± 0.40</td>
<td>2.25 ± 0.43</td>
<td>0.53</td>
</tr>
<tr>
<td>POD 2</td>
<td>1.09 ± 0.46</td>
<td>1.78 ± 0.48</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>POD 7</td>
<td>0.14 ± 0.35</td>
<td>0.63 ± 0.48</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>POD 30</td>
<td>0.06 ± 0.24</td>
<td>0.22 ± 0.41</td>
<td>0.01</td>
</tr>
<tr>
<td>POD 90</td>
<td>0.03 ± 0.17</td>
<td>0.16 ± 0.36</td>
<td>0.01</td>
</tr>
<tr>
<td>Basic activity (days)</td>
<td>3.25 ± 0.50</td>
<td>4.27 ± 0.80</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Home activity (days)</td>
<td>5.19 ± 0.43</td>
<td>6.55 ± 0.77</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Table 3: Comparison of early complication (<30 days) rates between two groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group 1 (n=64)</th>
<th>Group 2 (n=64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>2/64</td>
<td>7/64</td>
</tr>
<tr>
<td>Cord oedema</td>
<td>2/64</td>
<td>7/64</td>
</tr>
<tr>
<td>Groin discomfort</td>
<td>0/64</td>
<td>7/64</td>
</tr>
<tr>
<td>Seroma</td>
<td>0/64</td>
<td>6/64</td>
</tr>
<tr>
<td>Surgical site infection</td>
<td>0/64</td>
<td>6/64</td>
</tr>
</tbody>
</table>

Table 4: Comparison of late complication (>30 days) rates between two groups.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (n=64)</th>
<th>Group 2 (n=64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
<td>0/64</td>
<td>1/64</td>
</tr>
<tr>
<td>Neuralgia</td>
<td>0/64</td>
<td>0/64</td>
</tr>
<tr>
<td>Foreign body sensations</td>
<td>0/64</td>
<td>1/64</td>
</tr>
<tr>
<td>Recurrence</td>
<td>0/64</td>
<td>1/64</td>
</tr>
</tbody>
</table>
involved in tissue repair are growth factors, cytokines, chemokines like VEGF, PDGF, EGF, KGF and TGF-beta [6, 7]. This study is purely clinical and we have seen the effects of autologous bone marrow therapy, but the reason behind the healing process and effectiveness yet to be study in molecular level. As in this study we have small size of sample, we will continue our research in more number of patient in future.

Fig 7: Mesenchymal stem cell differentiation

**Conclusion:** In our study cell coated mesh in Lichtenstein hernia repair, we have seen that in the study group, there is lower rate of hospital stay, post-operative pain and postoperative complication as compared to control group. Return to the basic activity and home activity is also earlier in case of study group. So, bone marrow cell coated mesh in Lichtenstein repair has better result than standard Lichtenstein repair.

**Reference**