Clinical comparison between wall defects surgery using conventional and low-adhesion mesh materials
Preliminary results

Marco Basile*, Elisabetta Ranieri**, Maria Di Nicola**, Elia Mascitelli**

*Department of General Surgery, "Spirito Santo" General Hospital, Pescara, Italy
**Department of Experimental and Clinical Science "G. D'Annunzio" University, Chieti, Italy

Clinical comparison between wall defects surgery using conventional and low adhesion mesh materials. Preliminary results

PURPOSE: The use of prosthetic materials for hernia repair has become a standard procedure. Still the optimal material has not yet been found. Primitive hernia with loss of substance and big incisional hernia repair requires a prosthetic material which not induce, especially in the area of visceral peritoneal contact, chronic inflammation and fibrosis. The aim of this study is to clinically compare two different mesh materials: uncoated monofilament polypropylene and polypropylene-polyurethane double surface mesh.

METHODS: Forty eight primitive hernia and incisional hernia affected patients were included in the study. They were randomly allocated in two groups. In each group a different type of mesh was utilized, respectively uncoated monofilament polypropylene mesh and polypropylene-polyurethane double surface synthetic mesh. Lichtenstein and Rives surgical techniques were utilized. Intra-operative, early and late post-operative complications were clinically evaluated.

RESULTS: Uncoated monofilament polypropylene meshes treated patients showed higher abdominal pain, inflammatory diseases and hernia recurrence incidence than polypropylene-polyurethane double surface meshes. Abdominal wall hypo-mobility, discomfort and atypical sensation were the same in the two groups of treated patients.

CONCLUSIONS: Given the limited number of our patient's set, from our preliminary results is possible to assert that polypropylene-polyurethane double surface meshes have revealed superior bio-functional and bio-compatible efficacy.

KEY WORDS: Adhesion, Hernia, Mesh, Polypropylene, Polyurethane

Introduction

The surgical repair of abdominal wall defects, which includes both primitive hernias and incisional hernias, implies the use of bio-functional and bio-compatible prosthetic materials.

Worldwide, over 20 million abdominal repair procedures, including primitive hernia and incisional hernia repairs, are performed every year and more than 90% of these operations requires the use of mesh prosthesis 1,2. Although the use of mesh materials has obtained a substantial reduction of recurrence (from 55% to 5%) 3,5, still several complications like adhesions can be observed 6. Indeed the main point in most of published studies on this subject, is the evaluation of biomaterial-peritoneum interface, and the need to identify a material which guarantees not only restrictive and reparative qualities but also the ability of adhesions prevention 7,9. Nowadays polypropylene, polyester and expanded ptfe meshes have been the most used meshes for abdominal
wall defects repair on the ground of their capacity to promote cellular tissue growth and mesh incorporation into the abdominal wall, thus providing a strong barrier formation and less chance of recurrence development; nevertheless none of these meshes is ideal, in terms of avoiding adhesions. For this reason double surface synthetic composite meshes were created. They permitted to take advantage of polypropylene adhesive property placed on the abdominal wall side but avoid visceral adhesion on the other side.

The aim of this study is to clinically compare a double surface synthetic composite mesh, specifically the one named Combi Mesh Plus, to conventional polypropylene meshes; to understand advantages or defects of each of this different materials in the clinical environment.

The innovative Combi Mesh Plus prosthesis, until now only evaluated in experimental studies, are validated in this study particularly in cases of substance loss primitive hernias and big incisional hernias.

Materials and Methods

After obtaining approval by the local ethical committee, the study is started. This study is based on a clinical comparison between two groups of abdominal wall defects surgical treated patients. In 5 year time frame, from 2008 to 2012, at General Surgery Department – “Spirito Santo” General Hospital, in Pescara (Italy), 48 substance loss primitive hernias (inguinal and umbilical hernia) and big incisional hernias (median and epigastric) affected patients were included in the study. All of them were submitted to abdominal wall defect surgical repair with implantation of two meshes types: uncoated standard monofilament polypropylene mesh (PP) and double layer polypropylene- polyurethane synthetic composite mesh Combi Mesh Plus (PP-PU) (Angiologica B.M. S.R.L., San Martino Siracuario, P.V., Italy).

A computer-generated randomization list will be prepared. Patients will be assigned to one of the two treatments with the probability of 0.5 for each group. The two different groups were respectively nominated: Group A – uncoated monofilament polypropylene mesh (PP) and Group B - Combi Mesh Plus (PP-PU).

All patients were informed and signed an informed consent. All patients were eligible for a local and general anesthetic approach. Prior to the study, the surgical approach was standardized for all operators. All primitive hernia defects were repaired by Lichtenstein surgical technique and all incisional hernia with Rives surgical technique.

Direct office follow up was carried out at one week, one month, six months. After that, a telephone interview was conducted at one year, two years, three years. During follow up examinations the patients underwent clinical examination, risk factor analysis, quality of life assessment. Abdominal pain was measured using VAS scale and quality of life was measured using the Short-Form health survey questionnaire.

Patient’s characteristics were estimated pre-operatively, intra-operatively and post-operatively. Preoperative analysis was based on: age, gender and comorbidities. Intraoperative complications were evaluated as well. Postoperative analysis was based on: post-operative hospital stay, early post-operative complications (superficial wound infection, seroma, haematoma, abscess), and late postoperative complications (abdominal pain, mesh infection, abdominal wall hypo-mobility, discomfort, atypical sensation, sub obstruction or total obstruction, intestinal erosions, fistula and hernia recurrence).

To rule out the onset of adhesions, due to the impossibility to surgically verify them (as it is done in animal models), we estimated some indirect signs, such as recurrence of abdominal pain, abdominal wall hypo-mobility, discomfort, atypical sensation, intestinal obstruction (complete or incomplete).

STATISTICAL ANALYSIS

Qualitative variables were summarized by absolute frequencies and percentages, quantitative variables by mean and standard deviation (SD). The evaluation of the statistical significance of the differences between two groups regard to qualitative variables was performed using the chi-square test with the appropriate corrections for continuity or Fisher’s exact test, when necessary and appropriate. The evaluation of the statistical significance of the differences between the two groups regard to quantitative variables was performed using the non-parametric Mann-Whitney U test. All statistical tests of hypotheses were performed two-tailed and threshold of statistical significance was set equal to 0.05.

Statistical analysis was performed by SPSS® Advanced Statistical™ 13 (2004, Chicago, IL, USA) software.

Results

Altogether patients signed up in the study was 48, 33 of them were male (68.7%) and 15 were female (31.3%). No significant differences were found between the two groups respect to baseline characteristics (Table I). Group A – uncoated monofilament polypropylene meshes (PP) included 24 patients, 19 patients were male (79.2%) and 5 were female (20.8%). The mean age was 62.6 ± 15.9 years. This group included 10 inguinal hernia cases (41.7%), 3 umbilical hernia cases (12.5%), 9 median incisional hernia cases (37.5%), 2 epigastric incisional hernia cases (8.3%). Thirteen patients (54.2%) had comorbidities (diabetes mellitus type 2, lung
Clinical comparison between wall defects surgery using conventional and low-adhesion mesh materials. Preliminary results

Table I - Characteristics of patients: 48 patients were enrolled in two groups according to the type of mesh used in the intervention of reparative surgery for hernia pathology (respectively PP monofilament mesh, Group A and Mesh Combi Plus PP-PU, Group B).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (n=24)</th>
<th>Group B (n=24)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td>0.119*</td>
</tr>
<tr>
<td>Male</td>
<td>19 (79.2)</td>
<td>14 (58.3)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>5 (20.8)</td>
<td>10 (41.7)</td>
<td></td>
</tr>
<tr>
<td>Age (years), mean±SD</td>
<td>62.6±15.9</td>
<td>62.9±14.6</td>
<td>0.757**</td>
</tr>
<tr>
<td>Type of hernia, n (%)</td>
<td></td>
<td></td>
<td>1.000*</td>
</tr>
<tr>
<td>Inguinal</td>
<td>10 (41.7)</td>
<td>10 (41.7)</td>
<td></td>
</tr>
<tr>
<td>Umbilical</td>
<td>3 (12.5)</td>
<td>3 (12.5)</td>
<td></td>
</tr>
<tr>
<td>Median incisional hernia</td>
<td>9 (37.5)</td>
<td>9 (37.5)</td>
<td></td>
</tr>
<tr>
<td>Epigastric hernia</td>
<td>2 (8.3)</td>
<td>2 (8.3)</td>
<td></td>
</tr>
<tr>
<td>Comorbidities, n (%)</td>
<td></td>
<td></td>
<td>0.726*</td>
</tr>
<tr>
<td>Yes</td>
<td>13 (54.2)</td>
<td>13 (54.2)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>11 (45.8)</td>
<td>11 (45.8)</td>
<td></td>
</tr>
<tr>
<td>Length of Hospitalization (days), mean±SD</td>
<td>3.9±3.4</td>
<td>3.9±3.4</td>
<td></td>
</tr>
</tbody>
</table>

*Chi-Square test; **Mann-Whitney U test.

disease – BPCO, arterial hypertension, previous laparotomy) and 11 patients had not evidence of comorbidities. The length of hospitalization was 3.9 ± 3.4 days. Group B – Combi Mesh Plus (PP-PU) included 24 patients, 14 patients were male (58.3%) and 10 was female (41.7%). The mean age was 62.9 ± 14.6 years. This group included 10 inguinal hernia cases (41.7%), 3 umbilical hernia cases (12.5%), 9 median incisional hernia cases (37.5%), 2 epigastric incisional hernia cases (8.3%). 13 patients (54.2%) had comorbidities (diabetes mellitus type 2, heart failure, arterial hypertension, obesity (BMI ≥ 30Kg/m²), previous laparotomy) and 11 patients had not evidence of comorbidities. The length of hospitalization was 3.9 ± 3.4 days.

The average duration of surgical intervention to meshes positioning, in open surgery, was 2 hours (1.3 hours range), for both types of meshes (PP and PP-PU). The Combi Mesh plus have a coloured guide yarn located in the polypropylene layer which consent a great manageability in surgical positioning.

In none of operation intra-operative complications occurred. In group A – uncoated monofilament polypropylene meshes (PP), we observed post-operative abdominal pain in 4 cases (16.7%), superficial wound infection, seroma, haematoma, abscess, in 3 cases (12.5%), abdominal wall hypo-mobility, discomfort, atypical sensation in one case (4.2%), hernia recurrence in 3 cases (12.5%), no cases of sub obstruction or total obstruction, intestinal erosions, fistula have occurred.

The recurrences were observed in one case of umbilical primitive hernia, in one median incisional hernia patient (coming from previous post-traumatic laparotomy), and in one patient with large loss of substance inguinal primitive hernia. In this last case, the patient reported abdominal pain, abdominal wall hypo-mobility, discomfort, atypical sensation. The further three abdominal pain cases with superficial wound infection, seroma, haematoma, abscess, have occurred in two patient with loss of substance inguinal hernia either affected long since by diabetes mellitus type 2 and arterial hypertension, and in a patient which had a big median incisional hernia coming from an emergency laparotomy for diverticulitis.

In group B - Combi Mesh Plus (PP-PU) cases, we observed post-operative abdominal pain in one case (4.2%), superficial wound infection, seroma, haematoma, abscess in two cases (8.3%), abdominal wall hypo-mobility, discomfort, atypical sensation in one case (4.2%), recurrence in one case (4.2%). We never observed intestinal obstruction, intestinal erosions or fistula. The single recurrence in which we observed abdominal wall hypo-mobility, discomfort, atypical sensation case, had occurred in a patient affected by loss of substance primitive inguinal hernia and previously treated with laparotomy. The single abdominal pain case had occurred in a patient with loss of substance inguinal primitive hernia affected by heart failure and diabetes mellitus type 2. The two cases of superficial wound infection, seroma, haematoma, abscess have occurred in patients both operated for big median incisional hernia (Fig. 1).

Discussion

The abdominal wall defects treatment with use of prosthetic meshes has become the actual standard and has decrease a lot the hernia recurrence incidence that, instead, occurred with traditional surgical reparation techniques. The adequate prosthetic material choice has assumed a focal role to obtain a successful result. The required char-
acteristics has been infection resistance ability, tissue absorption capacity, adhesion preventing attitude and hernia recurrence reduction.

Standard polypropylene meshes provide some of the above-mentioned capabilities but do not guarantee adhesions prevention and cannot be placed directly in contact of visceral peritoneum (in cases of large substance loss abdominal wall defects). The Combi Mesh Plus prosthesis combine a virtually low adhesions surface with mechanical capabilities thanks to its polyurethane coated aspect, and can be placed into the peritoneal cavity. From our data it appears that the comparison between standard polypropylene prosthesis and Combi Mesh Plus has proved that the latter holds analogous surgical manageability, comparable surgical times and significantly less intra-operative complications. Indirect evidence of modest adhesion formation is lower rate of hernia recurrence, abdominal pain, abdominal wall hypo-mobility, discomfort and atypical sensation. No evidence of direct damage to noble structures such as bowel or viscera in general, appeared (no cases of erosions or fistulas).

Conclusions

To our knowledge there is no available study that compares the performances of polypropylene and polyurethane-coated meshes in the clinical setting. On the basis of our preliminary results is possible to assert that polyurethane-coated mesh (Combi Mesh Plus) has revealed bio-functional and bio-compatible efficacy, and has met investigated requirements. On the strength of our results, we could affirm that surgical manageability is comparable to polypropylene meshes. Tissue absorption capacity and anti-inflammatory characteristic are better than polypropylene meshes. Adhesion preventing attitude is same as polypropylene meshes but with a lower incidence of recurrence. A larger set of cases will be useful to confirm our preliminary results.

The study complies with the current laws of Italy, and was started after obtaining approval by the local ethical committee. All patients were informed and they have signed an informed consent.

Riassunto

OBIETTIVO: L’uso di materiali protesici per la riparazione delle breccie erniarie è divenuto ormai una procedura standard benché il materiale protesico ottimale non ancora sia stato individuato. Le ernie primitive con perdita di sostanza ed i grossi laparoceli richiedono l’utilizzo di un materiale protesico che non induca, soprattutto nell’area di contatto con i visceri pelvici, infiammazione cronica e fibrosi. Lo scopo di questo studio è quello di effettuare una comparazione clinica tra due differenti materiali protesici: le reti in polipropilene monofilamento non ricoperte e le reti a doppia superficie polipropilene-poliiuretano.


RISULTATI: I pazienti trattati con le reti in polipropilene monofilamento non ricoperte hanno presentato maggiore dolore addominale, infiammazione e recidiva rispetto ai pazienti trattati con le reti a doppia superficie polipropilene-poliiuretano. L’ipo-mobilità della parete addominale, discomodo e sensazione di corpo estraneo sono risultati paragonati in entrambi i gruppi di pazienti.

CONCLUSIONI: Dato il numero limitato di pazienti trattati, dai nostri risultati preliminari è possibile asserire che le reti a doppia superficie polipropilene-poliiuretano hanno dimostrato maggiore efficacia sia sotto il profilo bio-funzionale, sia in termini di biocompatibilità.

References


Clinical comparison between wall defects surgery using conventional and low-adhesion mesh materials. Preliminary results