HERNIoplasty with and without mesh: analysis of the immediate complications in a randomized controlled clinical trial

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ABSTRACT - Background: Inguinal hernia repair is the most common procedure in general surgery and 80,000 operations are performed annually in Great Britain, 100,000 in France and 700,000 in the US. Given its high frequency has a major impact, both in the medical and economic aspects. Aim: Analyze the immediate postoperative complications comparing mesh versus non mesh hernioplasty. Method: Randomized control trial, with the enrollment of 263 patients underwent surgery for inguinal hernia randomized by randomization table. Treatment (mesh, Lichtenstein or without mesh, Bassini technique) was assigned using sequentially numbered opaque envelopes having fulfilled the inclusion criteria. The variables analyzed were: postoperative pain, seroma, hematoma, infection, return to normal activities and recurrence. Results: The mean age was 55.5 years, 88% patients were male and 12% female. The pain was higher in patients operated with mesh. Conclusions: The inguinal hernia repair mesh group had less immediate postoperative complications and significantly earlier return to work than hernioplasty without mesh, this being one of the most important conclusions.

INTRODUCTION

Hernia (Latin, disruption; Greek, bud) it’s defined as the organ protrusion through a gap in the abdominal wall. The abdominal wall hernias are the most common cause for major surgery. Despite of the high frequency of the surgical repair, surgeons still don’t get perfect results and the rate of surgical failure (recurrence) is important and variable. The hernias are among one of the most antique disease that affect men, being one of the first diseases to be detected due to the obvious signs. Surgical techniques with mesh or without produce different immediate postoperative complications.

METHODS

The project was reviewed and approved by the Bioethics and Research Committee of the Posadas National Hospital.

This is a randomized controlled clinical trial (RCT) enrolling patients who had indications for hernioplasties with unilateral or bilateral inguinal hernia and met the eligibility criteria before signing the informed consent. They were operated in Surgery Department, Posadas National Hospital, Buenos Aires, Argentina from March 1st 2003 and December 30th 2006.

The inclusion criteria were: nonsurgical risk or liable to compensation; primary inguinal hernia unilateral or bilateral; non complicated hernia; patients without coagulation disorder.

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The exclusion criteria were: elevated surgical risk; high blood pressure that did not respond to treatment; obstructed hernias; strangulated hernias; recurrent hernias; coagulation disorders.

Surgical randomization

The patients entered to the study in a randomized way and the following techniques were applied: Bassini procedure (without mesh) and Lichtenstein procedure (with mesh). The surgical technique to be performed was contained in sequentially numbered opaque envelopes, using a table of random numbers to produce the series of interventions. The envelopes were in an inviolable dispenser that could only be extracted per unit in a sequentially way, and its extraction was performed before the surgery, when the patient was in the pre-anesthesia room.

All postoperative outpatient monitoring informations were collected in the corresponding tracking forms, which were sent to the external evaluation committee. To evaluate the homogeneity of both study groups the following prognostic variables were taken into account: age, gender, unilateral or bilateral hernia, type of hernia (direct, indirect or mixed), type of work (forced, light) and duration and time of evolution of surgery.

Sample size

It was considered to obtain a 50% reduction of immediate complications in experimental group (technique with mesh).

Considering a type I or alpha error of 5%, a Beta or type II error of 20% and a ratio of 1: 1 to conform the two study groups, the total number of patients in each group was estimated at 220. At the end of the fourth year a preliminary analysis of the results was performed by a Monitoring and Data analysis independent committee to re-evaluate the sample size necessary and decided that it wasn’t necessary to continue with the inclusion of patients.

Statistical analysis

To evaluate the quantitative variables (age, disease evolution, duration of surgery) in both groups arithmetic means and standard deviations were calculated, and were compared by the Student’s t-test. For the remaining prognostic variables, percentages were calculated which were compared by using the Chi-squared distribution or the Fisher’s exact test according to the obtained frequencies. For the ordinal variables, the Chi-squared distribution of linear association was applied. The relative risk (RR) and confidence intervals of 95% were calculated where corresponded. A survival analysis considering the time to return to work (in days) as the dependent variable of the type of surgery performed (stratification variable) was calculated. The envelopes were in a sequentially way, and its extraction was performed before the surgery, when the patient was in the pre-anesthesia room.

RESULTS

The Figure 1 shows the intensity of pain, measured using the E.V.A. test. As can be seen, greater proportions of patients operated without mesh have high values in this scale.

Patients in which mesh was not applied showed a nearly fivefold greater risk of developing wound infection when compared to those that underwent with mesh technique surgery (ARR=5.5% NNT=18.1). Every 18 patients operated with the technique with mesh, one wound infection will be prevent (Table 2)

The patient’s general characteristics are shown in the Table 1, in which can be seen that no significant differences were found in the distribution by gender, age and type of work.

| Variables | Surgery | p |
|-----------|---------|---|
| Age (mean±DS) | With mesh | Without mesh | 0.59* |
| Gender (n, %) | With mesh | Without mesh | 0.22* |
| Male | 119 (88.2) | 106 (82.8) | 0.031** |
| Female | 16 (11.8) | 22 (17.2) | 0.37* |
| Work type (n, %) | With mesh | Without mesh | 0.031** |
| Heavy | 75 (55.6) | 64 (50) |
| Light | 60 (44.4) | 64 (50) |

Table 2 - Patient’s postoperative characteristics according to the type of surgery

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RESULTS

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As for variable pain is considered 0 as no pain, 1 to 3 as mild pain, 4 to 7 as moderate and 8 to 10 as severe. As is can be seen, the proportions of patients with moderate or severe pain were higher in the intervention group without mesh. Association between type of surgery and pain at the 7th day postoperatively was found (Chi-square test: p<0.0001). Mild pain was related to the surgical technique with mesh (7.4% had no pain and 86.7% had mild pain) and moderated pain was related to the technique without mesh (71.9% moderate pain and 8.8% severe pain – Table 3).

Association between the type of surgery and the pain at the 15th postoperative day was found (Fisher test: p<0.0001). In the group of patients operated with mesh 64.4% had no pain and 31.9% had mild pain, while in the group without mesh only 18% had no pain and 53.9% expressed moderate pain.

Statistically significant association was found between the type of operation and use of analgesics at seven days (Chi-square test: p<0.0001), being this item superior in the patients operated without mesh (87.5 % relative risk=1.60 (1.35<RR < 1.89).
When analyzing the presence of seromas at different evolution time it could be seen that the presence of them did not differ between both groups of patients (Table 4).

| Variable               | With mesh n | With mesh % | Without mesh n | Without mesh % | p       |
|------------------------|-------------|-------------|----------------|----------------|---------|
| Seroma at 7th day      |             |             |                |                | 0.71*   |
| Yes                    | 10          | 7.4         | 8              | 6.2            |         |
| No                     | 125         | 2.6         | 120            | 93.8           |         |
| Seroma at 15th day     |             |             |                |                | 0.49**  |
| Yes                    | 3           | 2.2         | 5              | 3.9            |         |
| No                     | 132         | 97.8        | 123            | 96.1           |         |
| Seroma at month #      |             |             |                |                | 0.61**  |
| Yes                    | 1           | 0.8         | 1              | 0.8            |         |
| No                     | 134         | 99.2        | 127            | 99.2           |         |

* Chi-square Test; **Fishers Test; # two missing data

The same happened with the presence of hematomas.

**DISCUSSION**

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existing procedures but also because none of them shows an indisputable superiority over the others. In order to choose the technique, the surgeon should be guided by some basic principles, which are: the hernia is a benign disease; with essentially a functional impact and that the operation should not expose the patient to serious complications or sequelae.

The selection of the technique it’s done by following three basic criteria: 1) the patient: the tissues solidity and the tension to which the tissues are submitted; 2) the hernia: a small indirect hernia with good muscular wall is very different from a major collapse of the groin with multiple recurrences; 3) the surgeon: the surgical training, experience and degree of specialization.

Inguinal hernia repair is the most common surgery in general surgery, about 80,000 interventions per year are performed in Europe, 100,000 in France and 700,000 in the United States. Given its high frequency, inguinal hernia has an important impact on both medical and economic fields.

The standard method for inguinal hernia repair, proposed by Bassini in 1887, has had little change in the last hundred years. The annual statistics from various countries show a recurrence rate of 10% including the most used techniques without mesh as Shouldice, Mc Vay among others.

The concept of tension free hernioplasty, postulated by Lichtenstein, is widely used nowadays. This method, which uses a synthetic mesh, seems to have more beneficial effects than the techniques without meshes, because it’s an easier technique, it has less postoperative pain, a faster work reinsertion and it can be performed with local anesthesia.

Among the hernioplasties without mesh, nowadays the Shouldice technique is considered the gold standard, due to its minor percentage of recurrence when compared with other techniques. Even though, most studies have a high percentage of patients lost, demonstrated in a meta-analysis that the best technique within hernioplasty with mesh is the Shouldice, with recurrence rate of 5%.

The choice for the use of prosthetic mesh or not depends largely on the patient's age and the type of hernia. Direct or mixed hernias carry a higher risk of recurrence due to the weakness of the tissue, justifying the placement of the mesh.

The mesh placement rate increased from 7% in 1992 to 51% in 1996 in Sweden. Nowadays, there is difficulty in choosing a surgical technique for the treatment of inguinal hernia.

According to the meta-analysis published by Scott N.W. at the Cochrane Library which included 12 randomized controlled clinical trials and whose objective was to compare all surgical techniques with mesh versus techniques without mesh, resulted in a significant reduction of recurrences O.R. 0.39 IC 95% (0.25,0.59). This paper shows that hernioplasty with mesh has approximately 40% less chance of recurrence (IC 25 to 60 times) compared with techniques without mesh. This meta-analysis has an appropriate methodology, and it is strong scientific evidence that can validate the choice of techniques with mesh if it is taken into account the benefit of reducing by 40 times the recurrence in the mesh group versus the group without mesh.

In this study it is clear that the recurrence was significantly lower in patients operated with mesh; so, this variable was clarified by conducting an RCT with a larger sample size.

To answer these questions mentioned above (immediate postoperative complications) was performed this research, with the objective of achieving the necessary power to provide adequate scientific response.

CONCLUSIONS

The hernia repair with mesh due to a tension-free technique is associated with less pain; patients undergoing surgery without mesh required higher doses of painkillers; seroma and hematoma presence did not differ between both groups; there is a tendency that patients with mesh hernioplasty have a lower rate of infection; and time from surgery to work reinsertion in patients operated with mesh, was shorter, and this is one of the most important conclusions of this paper.

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