REDUCTION OF THE COMPLICATION RATE IN LICHTENSTEIN HERNIA REPAIR

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Abstract

**Background.**
Inguinal hernia is one of the most common pathologies in the surgical setting. The introduction of the Lichtenstein technique in 1989 (tension-free hernioplasty with polypropylene mesh) represented one of the most significant breakthroughs in the treatment of this condition since Bassini’s hernia repair. The aim of this study was to know the most significant predictive variables of complications in Lichtenstein hernioplasty and if some changes introduced in the technique could reduce these complications.

**Study Design.**
A prospective study of 2002 inguinal hernias in 1592 patients, operated on during 17 years, using the Lichtenstein tension-free technique for hernia repair with a heavy polypropylene mesh. The early and late complications and the outcome of modifications introduced in the technique over the study period have all been studied.

**Results.**
The modification in the type of closure reduced the complications rate from 14.4% down to 2.7%. The introduction of antibiotic prophylaxis reduced the infection rate from 1.2% down to 0.2%.

**Conclusions.** The most significant predictive variables of complications in Lichtenstein hernioplasty are the type of closure, antibiotic prophylaxis, ASA risk and the presence of previous recurrence.

Introduction

Inguinal hernia is one of the most prevalent pathologies in surgery consultation. Hernia repair had been attempted on several occasions throughout medical history with no satisfactory results.

In 1871 Marcy introduced carbolised catgut sutures to avoid infections, applying Lister’s aseptic basis. For the next one hundred years the gold standard surgical technique for hernia repair was herniorrhaphy as described by Bassini in 1884. Other techniques were also proposed such as the Halsted, Mc Vay or the Shouldice techniques; however, all presented the common problem of tension along the suture line.

In 1958 Usher and Wallace introduced the polypropylene mesh, which was the first prosthesis compatible with human tissue, even in the presence of infection.

The big breakthrough in hernia repair surgery came with the application of the tension-free repair by means of a prosthetic mesh described by Lichtenstein in 1986 for all types of hernias. In 1989 Lichtenstein published his results of 1000 cases with nearly no recurrences (practically nil according to the author), with a 5-year follow-up, results which were reconfirmed in his subsequent publications.

The reading of Lichtenstein’s paper in 1989 urged us to reconsider the treatment approach used in our patients, whom until then had been operated on using Bassini’s technique, not without a significant number of recurrences.

In his novel technique, Lichtenstein proposed a new type of repair to be used in all types of hernia that caused no anatomic alteration or suture tension. The new technique consisted in the placement of a polypropylene prosthetic mesh, the use of local anaesthesia, immediate deambulation of the patient, and discharge on the same day of surgery.

The description of the technique predicted simplicity, reproducibility, decreased pain, and, as a result, an earlier return to normal physical activity. In the light of these claimed advantages, we decided to implement the technique immediately.

The standing of Lichtenstein hernioplasty (LH) as the reference technique was only called to question when the laparoscopic technique burst into the scene back in the 90’s.

Different studies comparing laparoscopic hernioplasty (LAPH) versus LH concluded that LAPH afforded certain advantages in terms of decreased postoperative pain and earlier return to work, but on the contrary, severe complications were reported with LAPH, with earlier life-threatening complications being 10 times more frequent with this technique (1.1% versus 0.1%).

The advantage of LH is that it can be carried out under local anaesthesia at a much lower economic cost.

The work presented herein is the result of a prospective study aimed at analysing the results obtained by our team using Lichtenstein’s technique in order to know the most significant predictive variables of complications in Lichtenstein hernioplasty and if some changes introduced in the technique could reduce these complications. The study was initiated at the time when the only results published were those of Lichtenstein. All surgical procedures and
collection of data were performed by the same surgical team (permanent staff and no residents) with a follow up at 1 day, 15 days, 3 months and 1 year.

**Patients and methods**

A prospective study of 2002 LH carried out by the same surgical team (8 senior surgeons) between 1989 and 2007 on 1592 patients, of whom 1446 (90.8%) were men and 146 (9.2%) were women. 1796 primary hernias and 206 recurrent hernias were operated on. 241 were bilateral. 188 cases were lost during the follow up at 3 months and 316 at one year. The different surgeons employed the same technique and materials in all the procedures, with no variations. Mean age was 59 years for both genders (non-significant $t$ Student test).

All patients over the age of 40 were administered LMWH (enoxaparin 40 mg SC) as antithrombotic prophylaxis. The administration of antibiotic prophylaxis (amoxicillin + clavulanic acid, 2g IV 30 minutes prior to surgery) was introduced in 2002 to all patients. Of the total number of hernias, 1952 (97.5%) were operated on under intrathecal anaesthesia, with the remaining 50 being performed under local or general anaesthesia.

The postoperative regimen was ambulatory for patients under 40 and short hospitalization (24h) for the rest.

**Surgical technique**

All patients were operated on using LH technique. The indirect hernia sac was dissected, ligated and sectioned using 000 reabsorbable polyglycolic acid suture. The large direct sacs were invaginated and plicated using 00 reabsorbable polyglycolic acid suture. A heavy polypropylene mesh of 75 x 150 mm was used in all cases. The mesh was fixed in place using uninterrupted 00 polypropylene suture that was started at the limit between the shared tendon and the sheath of the anterior rectal muscle and finished at the inguinal ligament, extending beyond the orifice of the internal ring where the tails of the mesh are fixed in place without having to change the suture. Between 1989 and 1996, the closure was performed in three planes (aponeurosis of the great oblique muscle, subcutaneous and skin planes) using 2 independent suture lines and skin staples (a closure known as 3:3). After 1997, that type of closure changed and the three layers were closed using a single suture of 000 polyglycolic acid, knotting the end of aponeurotic closure first (no section), then the subcutaneous trajectory and finally the skin using the intradermal technique (a closure known as 1:3). The aim of this change was to avoid dead spaces and fix all three layers as one block. We thought this could lead to a reduction of complications. As the rest of variables remained without changes, including surgeons and materials, we decided not to start a new comparative study, but to compare the results of the new technique with those obtained until then.
The wound infection rate led us to think that antibiotic prophylaxis should be mandatory in all cases. So, we started doing so in order to compare results of wound infection with previous cases without prophylaxis, but using the same closure technique.

**Follow up.**
Follow up visits were carried out at 1 day, at 15 days, at 3 months, and at 1 year. Early local complications such as seroma, haematoma, infection, rejection and orchitis, as well as late complications such as chronic inguinal pain, testicular atrophy and recurrence, were all directly collected by each surgeon at the time of the visit using a standardized protocol. General medical complications related to the actual surgical procedure such as urological, cardiac, neurological, pulmonary and vascular complications were also assessed. A wound was considered to be infected if it met any of the CDC’s criteria for SSI 1992 with no differentiation between superficial and deep infection. All other complications were also described in the protocol to unify criteria. Hernias were classified as direct, indirect and mixed, and also according to the Nyhus anatomical classification as type I, II, III (A,B), and recurrent IV (A, B). The epidemiology of inguinal hernia and the factors that might influence its onset were also included in the study. In 2007 we decided to stop the prospective collection of data and evaluate the results.

**Statistical analysis**
The SPSS v17.0 statistics programme was used to describe each of the clinical and health care variables of the patients as well as the procedures included in the study. Once the values of the different variables were verified to be normally distributed, a bivariate description analysis was carried out. The $X^2$ test was used for qualitative variables and the *Student’s t test* was used for quantitative variables, which enabled us to establish a relationship between both types of variables. If the values of the quantitative variables were not assumed to be normally distributed, the Wilcoxon T test and the Mann and Whitney U test were used.

Bivariate analysis allowed us to establish the different associations among the tested variables. Variables found to be significant were used to construct a prediction model in which the dependent variable was complication of the surgical wound and the independent variables were the type of closure and the administration of antibiotic prophylaxis, among other complications. Hypothesis contrasts with a probability of error below 5% ($p<0.05$) were accepted.

**Results**
116 patients (5.86%) developed non-surgical complications within 30 days after surgery. The mean age of these patients was 7 years more ($p<0.05$) than that of patients who presented surgical complications. The most common non-surgical complication was acute urine retention (77%).
52 patients (2.6%) had emergency surgery, their age being significantly higher (9 years) than that of patients scheduled to undergo elective surgery (*Student T* test, p<0.05).

1220 (61%) wounds were closed using the 1:3 technique (one single reabsorbable suture for the three layers) whereas 776 wounds (39%) were closed using the 3:3 technique (2 different suture lines and skin staples).

In overall numbers, 155 (7.7%) wounds developed complications, 74 of which (3.7%) were haematomas, 44 (2.2%) infections, 27 (1.3%) seromas, and 10 (0.5%) were complications from other causes.

The mean age of patients with wound complications was significantly greater (4.2 years) (*Student t test*, p<0.05).

The percentage of complicated wounds also increased significantly as the ASA score increased. Hence, ASA I patients presented a 3.7% rate of complicated wounds, ASA II patients an 8.4% and ASA III patients an 11.2%.

1796 primary hernias were operated on, of which 121 (6.7%) developed complications. In contrast, of the 206 recurrent hernias operated on, 34 (16.5%) presented complications.

If we take a look at the group that did not receive antibiotic prophylaxis and in which the only variable was the type of closure used (n=1424), it can be observed that the incidence of local complications in the 1:3 group was 28 (4.1%) and 107 (14.4%) in the 3:3 group. Focusing only on the infection of the wound, it is observed that the infection rate was 8 (1.2%) in the 1:3 closure group, whereas it was 31 (4.2%) in the 3:3 group.

Of the 1220 wounds closed using the 1:3 technique, 538 received antibiotic prophylaxis; of these 538, there was only one (0.2 %) case of infection. In contrast, among the 682 wounds that did not receive prophylaxis, there were 8 (1.2 %) cases of infection (Table 1).

**Discussion**

The aim of this study was to know the most significant predictive variables of complications in Lichtenstein hernioplasty and if some changes introduced in the technique could reduce these complications.

In order to provide valid results, variables need to be minimised. In our study, the team of surgeons (8 members) was homogenous, as were the technique and materials used. The described technical modifications were introduced in unison by the whole team.

When assessing the results, it is important to point out that hernias that were operated on an emergency basis, patients with a high ASA score, elderly
patients, and recurrent hernias presented a significantly higher complication rate.

It must also be pointed out that the frequency of urgent hernioplasties has been decreasing over time, dropping from 4.8% in the period between 1989-1994 to 1.1% in the period between 2000-2006 ($X^2$, $p<0.05$). We are of the opinion that these improvements are owed to the fact that since the introduction of LH, all hernias can now be managed via elective surgery; and, consequently, only those patients who have had no prior consultation, those who have not consented to undergo surgery, or those whom, whilst on the waiting list, have been unlucky enough to have an incarceration, are the ones that end up having to undergo an emergency procedure. Contrary to the opinion of some authors who advocate refraining from surgery and keeping patients with minimal symptoms under observation\textsuperscript{16}, and on the basis of our results, we are of the opinion that the performance of LH surgery on any patient diagnosed with a hernia decreases the incidence of emergency surgery and the incidence of post-operative complications.

According to our results, the two most important variables to reduce local complications in the surgical wound are antibiotic prophylaxis and the closure technique.

In the meta-analysis conducted by Sánchez-Manuel et al. conclude that the administration of antibiotic prophylaxis cannot be recommended for elective repair of inguinal hernias in all cases\textsuperscript{17}. It must be taken into account that this study includes herniorraphies (with no mesh), hernioplasties (with a mesh), different hernioplasty techniques and different antibiotics for prophylaxis. Perez et al. do also support that preoperative administration of single-dose antibiotic did not markedly decrease risk of wound infection\textsuperscript{18}. In contrast, Sanabria et al. conclude that the results obtained in their meta-analysis make the routine use of antibiotic prophylaxis advisable in patients subjected to inguinal hernioplasty\textsuperscript{19}. Neither of these studies make reference to the study conducted by Nienhuijs et al. in which a 9% infection rate was reported in the absence of antibiotic prophylaxis\textsuperscript{20}.

In our study, when antibiotic prophylaxis was introduced as the single variable, the results supported the systematic use of antibiotic prophylaxis preoperatively to reduce the infection rate. The results yielded by our study show that most important variable to reduce the risk of surgical wound complications was the introduction of the 1:3 closure. This significance was maintained upon stratification of the different complication types. We think these results could be explained because of the lack of dead spaces fixing all three layers as one block and the complete isolation of skin bacteria because of the intradermic skin closure.

Upon adjustment by a logistic regression model with variables such as the type of closure, ASA anaesthetic risk, surgical management of a recurrence or antibiotic prophylaxis, it was observed that all variables are significant predictive variables (Table 2). Thus, subjects who receive a 3:3 closure have a four-fold
probability of suffering a complication of the surgical wound than those who receive a 1:3 closure. The Confidence Interval (CI) of the “odds ratio” (OR) tells us that the probability to develop a complication of the surgical wound is at least double.

If the operation was required due to a recurrent hernia, the probability to develop a complication nearly doubles, with a probability of 20% (CI) minimum.

As regards the anaesthetic risk, an ASA III score multiplies by three the probability to develop a complication in comparison with an ASA I score, with a probability of 50% (CI) minimum.

On the other hand, the adjusted OR of antibiotic prophylaxis informs of its preventive effect on the surgical wound. Thus, subjects who receive antibiotic prophylaxis present half the complications when compared to those that do not, with a reduction of 20 % (CI) minimum.

In conclusion, the two variables upon which the surgeon can act to significantly reduce the complications rate of the surgical wound are the type of closure and the administration of systematic antibiotic prophylaxis.
Acknowledgements

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References


Table 1. Distribution of complications according to the type of closure without prophylaxis

<table>
<thead>
<tr>
<th>Type of closure</th>
<th>Wound complications</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Haematoma</td>
<td>Infection</td>
</tr>
<tr>
<td>3:3</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>54</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>7.2%</td>
<td>4.5%</td>
</tr>
<tr>
<td>1:3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>2.3%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>4.8%</td>
<td>2.9%</td>
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Table 2. Results yielded by logistic regression analysis to predict complications in the surgical wound

<table>
<thead>
<tr>
<th></th>
<th>&quot;Odds ratio&quot;</th>
<th>95% Confidence Interval of the &quot;Odds ratio&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closure 3:3</td>
<td>4.16</td>
<td>2.4 – 7.2</td>
</tr>
<tr>
<td>Recurrence</td>
<td>1.91</td>
<td>1.2 – 2.9</td>
</tr>
<tr>
<td>Antibiotic prophylaxis</td>
<td>0.44</td>
<td>0.2 – 0.8</td>
</tr>
<tr>
<td>Anaesthetic risk</td>
<td></td>
<td></td>
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<tr>
<td>ASA II</td>
<td>2.63</td>
<td>1.5 – 4.6</td>
</tr>
<tr>
<td>ASA III or greater</td>
<td>2.93</td>
<td>1.5 – 5.7</td>
</tr>
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