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CONFERENCE REPORT

Prospective randomized, double-blind, controlled trial comparing Lichtenstein's repair of inguinal hernia with polypropylene mesh versus Surgisis gold soft tissue graft: preliminary results

Luca Ansaloni, Fausto Catena, Luigi D'Alessandro

Department of Anesthesiological and Surgical Sciences, Unit of Emergency Surgery, Sant'Orsola-Malpighi Hospital, University of Bologna, Italy

Abstract. *Introduction:* Although polypropylene mesh are the preferred prosthesis materials for the tension-free hernioplasties because they handle well and become quickly integrated, having reduced the recurrence rate below 1%, some problems with their use are still to be addressed (postoperative pain, long-term discomfort, infections, intestinal obstruction and fistulization). In order to answer to these disadvantages, a new degradable and reabsorbable material, the porcine small intestinal submucosa (SIS mesh gold, Surgisis), has recently been used in humans for laparoscopic hernia repairs. Aim to our study is to evaluate the safety and efficacy of the Lichtenstein's hernioplasty using the Surgisis gold soft tissue graft, as a mesh, and to compare it with the traditional Lichtenstein procedure performed with polypropylene mesh. *Methods:* A prospective, randomised, double-blinded comparison of Lichtenstein's repair of inguinal hernia with polypropylene mesh versus Surgisis ES soft tissue graft was carried out at the Department of Emergency Surgery of St Orsola-Malpighi University Hospital with the participation of 4 surgeons who accept to standardise the Lichtenstein's procedures with the two different types of meshes. *Results:* From july 2002 up to now 20 patients submitted to Lichtenstein's repair of inguinal hernia using Surgisis gold mesh with a 6 month minimum follow-up were enrolled. 12 subjects were treated with Surgisis ES mesh, while 8 were treated polypropylene mesh. There were not intraoperative or postoperatively complications. No recurrences and wound infections were observed. The post-hernioplasty acute and chronic pain/ discomfort (tested with visual analogue scale and simple verbal scale) and parenteral/oral analgesic consumption were lower in Surgisis ES group. *Conclusions:* Lichtenstein's hernioplasty using the Surgisis gold soft tissue graft has a promising safety and efficacy.

Key words: Lichtenstein's repair, polypropylene mesh, surgisis gold, inguinal hernia

Introduction

Although debate still persists as to which repair is best for primary inguinal hernias, published reviews by specialized hernia centers and metanalisis, involving large numbers of patients, have demonstrated that mesh repair can be performed with less postoperative pain and less recurrence rate, historically the two most important primary outcome variables for herniorrhaphy, compared with non-mesh methods (1-5).

Although polypropylene meshes are the preferred prosthesis materials for the tension-free hernioplasties because they handle well and become quickly integrated, having reduced the recurrence rate below 1%, some problems with their use, such as postoperative pain, long-term discomfort, infections, intestinal obstruction and fistulization, are still to be addressed.

In order to answer to these disadvantages, a new degradable and reabsorbable material, the porcine small intestinal submucosa (SIS mesh, Surgisis® Cook

Biotech Inc.), has recently been used in humans for laparoscopic hernia repairs (6).

Aim of our study is to evaluate the safety and efficacy of the Lichtenstein's hernioplasty using the Surgisis Gold soft tissue graft, as a mesh, comparing it with the traditional Lichtenstein procedure performed with polypropylene mesh.

Methods

A prospective, randomised, double-blinded comparison of Lichtenstein's repair of inguinal hernia with polypropylene mesh versus Surgisis Gold soft tissue graft is carried out at the Department of Emergency Surgery of St Orsola-Malpighi University Hospital, Bologna, Italy with the participation of 4 surgeons.

The sample size will be 35 patients for each group (70 patients for the whole study) and has been calculated to reach a confidence level of 95% with a power of 80%.

Inclusion criteria are: male, adult, ASA I-III patients, with I-VI (Gilbert's classification, modified according to Rutkow and Robbins) non-complicated primary inguinal hernia, repaired, after the obtaining of informed consent, in non-emergency setting with a Lichtenstein's hernioplasty using polypropylene or Surgisis Gold mesh.

Exclusion criteria are: recurrent hernias, any condition preventing a correct evaluation of pain (non-cooperative patient, blind patient, drug addicted), hypersensitivity to any drug in study and patients with an intra-operative findings of different pathology. Prophylactic antibiotics are sulbactam and ampycillin 3g or claritromycin 300 mg (in case of known hypersensitivity to penicillin).

Preoperative data collected are patients' demographics, presence of comorbid conditions (genitourinary, cardiac, pulmonary, gastrointestinal, renal, or rheumatologic), baseline pain/discomfort degree and general health status evaluation.

All the surgical procedures are performed in general or spinal anaesthesia according to the choice of the patients and the anaesthesists. In the polypropylene group the mesh (preshaped, Angimesh 9 - PRE 9 6x14, Angiologica BM S.r.l., Via Giovanni XXIII, 4, 27028, S. Martino Siccomario, PV) is fixed with Prolene 3/0. In the Surgisis group a 8x13 cm Surgisis Gold sheet is used, cut and fashioned as appropriate. The pre-shaped mesh is placed for at least 10 minutes into a sterile dish with sterile room-temperature normo-saline to be rehydrated. Then using aseptic technique, the rehydrated Surgisis sheet is transferred to the already prepared and dissected inguinal region and is fixed with PDS II 2/0.

Intraoperative data collected include: operative time, American Society of Anesthesia (ASA) classification, type of anesthesia (general or spinal) and the eventual onset of intraoperative complications.

Early mobilisation as soon as possible after surgery is suggested to the patients of both groups.

Postoperative data collected include: length of hospital stay, pain evaluation, wound infection and other complications. Subsequent outpatient clinic follow-up (1 week, 1 month, 6 months, 1 year, 3 years, 5 years) with evaluation of pain, discomfort, general health status, wound infection, other complications and recurrence is carried out.

In the recruitment preoperative evaluation, baseline pain is investigated using a questionnaire similar to that used by the participants of the Danish Hernia Database (7) and two different pain-rating scale systems: a 100-mm visual analogue scales (VAS) (0=minimal and 100=maximal) and simple verbal scale (SVS) (none, mild, moderate, severe, unbearable); the pain level is measured at rest, on coughing and on movement. In the recruitment preoperative evaluation, baseline discomfort is investigated using a questionnaire and two different discomfort-rating scale systems: a 100-mm visual analogue scales (VAS) (0=minimal and 100=maximal) and simple verbal scale (SVS) (none, mild, moderate, severe, unbearable); the discomfort level was measured at rest, on coughing and on movement. The same pain and discomfort evaluation is done during the follow-up period (3 months, 6 months, 1 year, 3 years and 5 years). The recurrence is evaluated by direct clinical examination and defined as a presence of a lump or a bulging under cough in the inguinal region previously repaired.

The study was authorized by the ethical Committee of the S'Orsola-Malpighi Hospital, Bologna, Italy. The continuous numerical data are subjected to

analysis of variance (ANOVA), meanwhile discrete data are analysed by the chi-squared test or Fisher exact test, as appropriate.

Results

From July 2002 up to now 20 patients submitted to Lichtenstein's repair for inguinal hernia with a 6 month minimum follow-up were enrolled: 12 subjects were treated with Surgisis Gold mesh, while 8 with polypropylene mesh.

We did not find any differences in patients'characteristics. There were not intraoperative or postoperatively complications. No recurrences and wound infections were observed in both groups.

The post-hernioplasty acute and chronic pain/ discomfort (tested with visual analogue scale and simple verbal scale) and parenteral/oral analgesic consumption were significant lower in Surgisis ES group without any statistically significant difference (figure 1 and 2).

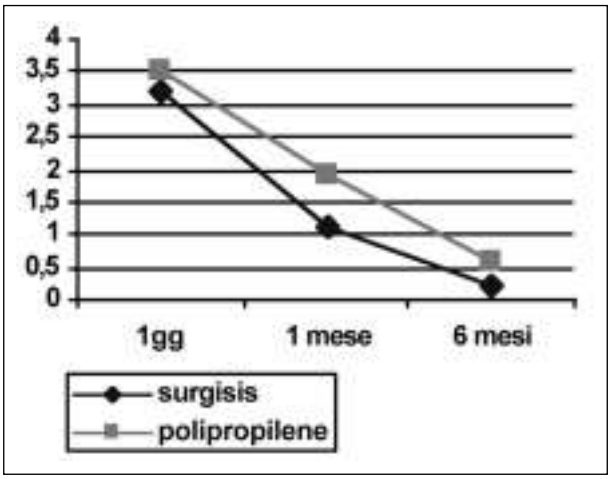

Figure 1. VAS on rest

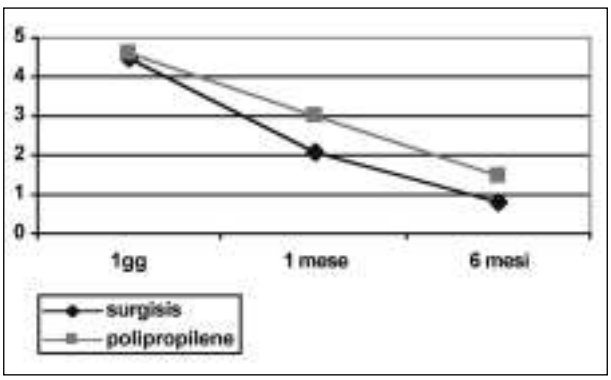

Figure 2. VAS on coughing and movement

Discussion

Since the initial reports of hemiorrhaphies by H.O. Marcy and E. Bassini at the end of the eighteen century, there have been reports of countless operative techniques to treat inguinal hernia and these numbers have been continued to grow with the description in the mid-1980s of the tension free repairs with alloplastic materials (8, 9) and the more recent implementation of laparoscopic technique into this surgical arena (10, 11).

Regarding prosthetic material for hernioplasty, it has to be pointed out that at present nondegradable and biologic-tolerant synthetic mesh prostheses are readily available. The materials proven useful are: expanded polytetrafluoroethylene (PTFE, or Teflon), the polyester Dacron and polypropylene. In particular the most used mesh are those composed of knitted monofilament fibers of polypropylene (like Marlex, Prolene, Trelex). All are porous, slightly elastic, semirigid, and relatively heavy, and they contain plastic memory and buckle when bent in two directions at once. The prostheses made of polypropylene desirably incite a prompt fibroblast response and are rapidly integrated in the body with variable inflammation reaction.

But polypropylene permanent prostheses should never contact abdominal viscera directly: they provoke binding and intimate adhesions that are difficult to divide and can cause intestinal obstruction and fistulization (12, 13). As all the synthetic materials, polypropylene meshes and plugs can become sequestered and, acting like a foreign body, can provoke, aggravate and prolong infections: for these reasons the infection of nonabsorbable polypropylene prostheses is a well known risk (14). Although reduced in comparison with non-mesh techniques, the postoperative pain and especially the long-term discomfort is still present in hernioplasties with the use of polypropylene meshes

(15, 16). Furthermore some doubts remain regarding the placement of a long-life foreign material in contact with the human tissues.

Actually it is well known that the mammalian extracellular matrix (ECM) can be used as a bioscaffold to support and enhance tissue repair (17, 19). The ECM can be harvested from such sources as the small intestinal submucosa (SIS) and urinary bladder submucosa. Porcine derived SIS, as Surgisis, has been implanted in several species, including humans, and there has been no evidence of an adverse immune response by any host species. Studies suggest that this acellular xenogenic scaffold elicits an immunologic recognition but it does not prevent acceptance of the xenograft (20). Several studies have shown that SIS is rapidly degraded when used as an in vivo bioscaffold. So Surgisis can be considered an acellular resorbable biomaterial, that provides a collagen matrix in which fibroblasts migrate and proliferate and can serve as scaffolding for new tissue growth. As a matter of fact Surgisis is an acellular xenograft consisting primarily of type I porcine collagen. Because this xenograft material is minimally antigenic, is not rejected but is gradually colonized by host tissue cells, blood vessels, and additional extracellular matrix provided by the host. A mild inflammatory response to Surgisis encourages active tissue deposition by the cells and natural cytokine production and healing normally associated with inflammation and tissue repair. As organized tissue deposition occurs, Surgisis is gradually resorbed by the host, yelding a repaired tissue structure that is enterely host-derived (21-23). In the experimental and clinical ground Surgisis has already been used as a graft material for ligaments (24, 25), tunica albuginea (26), ureter (27, 28), urethra (29), intestine (30, 31), veins (32) and arteries (33-35). Animal investigation have shown that Surgisis is effective in repairing abdominal wall hernias (36, 37) and more recently was used in humans for repair of abdominal hernias in infected fields (38) and in laparoscopic repair of paraesophageal hernia (39).

Objectives of our study were:

a) to determine the safety of the Lichtenstein's hernioplasty with Surgisis ES by noting any complications observed intraoperatively and postoperatively;

b) to determine the efficacy of the Lichtenstein's hernioplasty with Surgisis ES in comparison with the traditional method with polypropylene mesh by noting the grade of postoperative pain, discomfort, quality of life, the rate of wound infection and other complications, and the recurrence rate.

The same type of tension-free surgical procedure was carried out in the two groups: the Lichtenstein's hernioplasty. Different type of mesh were used in the two groups. In the control group, a polypropylene mesh (the usual that at present we use in our daily surgical practice) whereas in the studied group Surgisis Gold was employed.

There were not intraoperative or postoperatively complications. No recurrences and wound infections were observed. The post-hernioplasty acute and chronic pain/ discomfort (tested with visual analogue scale and simple verbal scale) and parenteral/oral analgesic consumption were significant lower in Surgisis ES group without any statistically significant result (figure 1 and 2).

From this preliminary results Lichtenstein's hernioplasty using the Surgisis gold soft tissue graft has a promising safety and efficacy.

In memoriam of Orazio Campione, Professor of Surgery, head of Emergency Surgery Department S. Orsola-Malpighi, University of Bologna, Italy, from 1955 to 2003.

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Correspondence: Dott Luca Ansaloni
Unit of Emergency Surgery
Sant'Orsola-Malpighi Hospital
University of Bologna
Via Massarenti, 9
40138 Bologna Italy