

Flat patch mesh versus three-dimensional mesh (plug) for open umbilical or epigastric hernia repair.

A retrospective study



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Giuseppe Sangiorgio*, Umberto Falzone*, Enrico Sapienza*, Franco Michael Lombardo*
Dario Saguto***, Giovanni Tomasello***, Marta Zanghì****, Guido Zanghì**

*Department of General Surgery, General Surgery and Oncologic Section, School of Catania, Italy

**Department of General Surgery, General Surgery and Oncologic Section, School of Medicine, Director of Multidisciplinary Center for the study of Biomedical and Biotechnological, Catania, Italy

***Department of Biomedicine, Neurosciences and Advanced Diagnostics, (BIND), Institute of Human Anatomy and Histology, University of Palermo, Palermo, Italy

****Department of Biomedical and Biotechnological, Sciences, Human, University of Catania, Catania, Italy

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INTRODUCTION: *Hernia repair using prosthetic mesh materials has become the preferred method of repair, as the recurrence rates are much lower than with conventional repair techniques. The aim of this retrospective study was to compare open small- and medium-sized abdominal wall hernia repair with flat patch mesh versus three-dimensional mesh (plug) in terms of recurrence and complication rates.*

METHODS: *The medical records of 300 patients who underwent abdominal wall hernia repair using flat patch mesh versus three-dimensional mesh between January 2010 to December 2015 were reviewed. All patients were followed up after 1 month, 3 month and 1 year. The rate of recurrence, and short-term postoperative complications such as incidence of Surgical Site Infections (SSIs), hematoma and seroma were evaluated.*

RESULTS: *Short-term follow-up data were available for all patients. The first group was composed of 150 patients that were treated with a flat polypropylene mesh (68% presented umbilical hernia and 32% presented epigastric hernia). The second group was composed of 150 patients that were treated with a three-dimensional polypropylene mesh (60% presented umbilical hernia and 40% presented epigastric hernia). The majority of postoperative (1-month) complications were wound related, representing superficial SSI or seroma. Our results showed a statistically significant reduction of SSIs [3 (2%) vs 13 (8.6%); $p = 0.038$] and seroma [2 (1.3%) vs 12 (8%); $p = 0.030$] in the group of patients treated with plugs compared to flat-mesh group. There was no statistically significant difference in hernia recurrences.*

DISCUSSION: *Usage three-dimensional mesh for open small- and medium-sized umbilical or epigastric hernia repair represents a feasible and safe technique that significantly lowers the incidence of complications such as SSIs and seroma. Furthermore, compared to flat patch mesh, plugs displayed non-inferiority in terms recurrence. Further, well-designed clinical trials could be realized to investigate possible applications of plugs in treatment of small- and medium-sized umbilical and epigastric hernias.*

KEY WORDS: Mesh, Umbilical Hernia

Introduction

According to the European Hernia Society (EHS), umbilical hernia is defined as a primary hernia with the

defect located in the midline within the umbilical ring, while an epigastric hernia is defined as a primary hernia with the centre of the defect located in the midline above the umbilicus up to the xiphoid process. Umbilical and epigastric hernias are divided into small (0–1 cm), medium (more than 1 cm up to 4 cm) and large (over 4 cm) based on defect diameter¹. Despite being one of the most common surgical procedures performed in any department of surgery, the optimal repair method with the best short- and long-term outcomes remains debatable.

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Correspondence to: Prof Guido Zanghì, Department of General Surgery and Oncology Section, School of Medicine, University of Catania, Via S. Soglia 78, 95123 Catania, Italy (e-mail: gzanghi@unict.it)

ABBREVIATION

STROBE:	Strengthening the Reporting of Observational Studies in Epidemiology;
EHS:	European Hernia Society;
SD:	Standard Deviation;
SSI:	Surgical Site Infections

Over the years, many different surgical techniques have been used for hernia repair. Conventional methods include simple suture repair, Mayo repair ('vest-over-trousers' technique, introduced in 1901) ²⁻⁷. However, recurrence rates tend to be high after all of these procedures ^{2,6,8-12}. The use of prosthetic meshes for hernia repair was first introduced in 1958 by Usher et al. ¹³⁻¹⁸. Common methods for mesh hernia repair include the retromuscular approach and the laparoscopic approach ¹⁹⁻²². Initially, these techniques were considered to be too aggressive for the repair of umbilical, epigastric, and small ventral hernias. However, several studies have shown that mesh repair is associated with significantly lower recurrence rates compared to conventional repair techniques ^{2,9,10,23-25}, and the use of prosthetic meshes would, therefore, appear to represent a logical step forward.

Several studies report evidences that umbilical and epigastric hernias can be repaired safely using a synthetic polypropylene mesh ^{2,26-28}. The number of preformed meshes, plugs and prosthetics for repair of umbilical and epigastric defects is increasing. Although the use of these prosthetics may shorten operating time ²⁹⁻³¹ and reduce postoperative pain ³², there is no evidence to support their use instead of a conventional flat synthetic mesh. Most of these prosthetics are manufactured to allow their use in the intraperitoneal position with an antiadhesive barrier. There are a number of case series on their safety ^{6,10-12}. Concerns have arisen from a few reports of severe late complications, such as bowel obstruction, explantation owing to infection and enterocutaneous fistula formation ^{35,36}. For this reason, preperitoneal placement of a preformed patch should be considered, when possible ³⁷. In our department, umbilical hernia repair with three-dimensional mesh (plug) is the preferred procedure since 2010, although other procedures are also used when appropriate.

The aim of this study was to compare primary, small- and medium-sized umbilical and epigastric hernia repair with flat mesh and repair with plugs in term of complication rate and recurrence within 1 year after initial surgery.

Methods

This study was designed as a retrospective cohort study. This study was performed according to the Strengthening

The the Reporting of Observational Studies in Epidemiology (STROBE) Statement ³⁸. Adult patients over 18 years old with a single, primary, small or medium umbilical or epigastric hernia were enrolled for participation in the study. Patients with recurrent hernia, large hernia according to EHS were excluded ¹.

We analyzed data from a total of 300 consecutive patients, which were enrolled in the study from January 2010 to December 2015. The first group was composed of 150 patients that were treated with a flat polypropylene mesh (The Ventralex™ Hernia Patch); of these 68% presented umbilical hernia and 32% presented epigastric hernia. The second group was composed of 150 patients that were treated with a three-dimensional polypropylene mesh (PerFix™ Plug) (plug); of these 60% presented umbilical hernia and 40% presented epigastric hernia.

The outcome of this study was the complication rate within 1 year after initial surgery. Complications were described as re-operation due to early recurrence or evacuation of haematoma, occurrence of wound infection or seroma. We collected data on demographics variables such as age, gender, BMI, ASA class, previous abdominal surgeries. Follow up was 1 month, 3 months and 1 year. Both group were treated by the same equipe at our hospital in day hospital.

Surgical procedures

Before all procedures 1-2 g of cefazolin were given as prophylaxis according to the surgeon's opinion. In case of allergies to cefazolin, clindamycin 600 mg was used. Administering a local anaesthetic peri-operative was recommended. The standardize regime was the following: one ampoule of lidocaine hydrochloride diluted to 50% with physiological solution, and 2 ampoules of bupivacaine hydrochloride always diluted to 50% with physiological solution. Enlarging the herniation orifice for adequate mesh placement, was not done.

The flat mesh procedure started with a para-umbilical or median incision across the herniation, followed by dissection of the fascia and mobilization of the hernia sac. Dissection of the pre-peritoneal area took place after repositioning of the hernia. A flat large pore and lightweight polypropylene mesh with a minimum diameter of 6 cm were placed pre-peritoneal, to ensure 3 cm overlap. Fixation of the mesh was carried out with non-absorbable monofilament sutures.

For the plug procedure after the mobilization, the hernia sac was repositioned without reopening it. The plug was placed in the pre-peritoneal plane, fixed with U-shaped detached points with non-absorbable monofilament sutures. A subcutaneous mini-vac drainage was placed and the surgical wound was closed with an intradermal suture.

After both procedures we applied a moderately compressive dressing.

Statistical analysis

Data were expressed as mean \pm SD (standard deviation) versus median with range. The results are reported with 95% confidence intervals, and the level of significance was taken as 5%. SPSS statistics 21 (IBM) was used for processing the data. Comparison between the two interventions were subdivided into pre-operative and post-operative. Pre-operative parameters included differences in baseline characteristics and were presented in a baseline characteristics table. Post-operative measurements included the occurrence of complications and recurrence rates (1, 3, 12 months post-operative).

Results

No significant differences between groups were seen in age, gender, BMI, hernia type, diabetes mellitus, comorbidities between both groups. Detailed baseline characteristics are shown in Table I.

99% of patients were discharged on the first post-operative day with an appointment after 48 hours for drainage removal, while 1% was discharged on the second post-operative day for respiratory or cardiological problems secondary to their underlying diseases. All complications were reported according to the Clavien–Dindo grading system for surgical complications^{39,40}. No grade IV or V complications were seen. There were no peri-operative complications in either group. Within

1-month after the operation, 30 patients suffered a complication, ranging from Clavien–Dindo grade I–IIIb. In the Plug group, 3.3% (n = 5) of the patients suffered from at least one complication, and in the mesh-operated group 16.6% (n = 25) of the patients. There was a significantly higher incidence of complications in the flat-mesh group (p = 0.003). The majority of these complications were wound related, representing superficial surgical site infection (SSI) or a seroma. For the diagnosis of a SSI, the definition of the Centers for Disease Control and Prevention was used⁴¹. It was showed a statistically significant reduction of SSIs (p = 0.038) in the Plug group with 3 cases (2%) compared to the flat-mesh one with 13 cases (8.6%).

Furthermore, in the Plug group 2 patients (1.3%) presented seroma, while in the mesh-operated group 12 patients (8%) presented seroma, with a statistically significant difference (p = 0.030). Hematoma did not occur in either groups. There was no case of recurrence or re-operation within the first month. Three months post-operatively, no significant differences were seen between groups in terms of complications. After 1-year follow-up, no significant differences were seen in recurrence rates and re-operation rates. Two patients in the Plug group showed a recurrence (1.3%) at the 1-year follow-up clinical examination, and 1 patient in the mesh group (0.7%), p = 0.672. The 2 re-operated Plug patients at 1-year follow-up were operated due to symptomatic recurrence as well as the remaining mesh-operated patient. Results are shown in Tables II and III.

TABLE I - Patient characteristics

n = 300	Plug = 150	Flat mesh = 150	p value
Age (years, SD)	53 (20)	55 (18)	0.868
Gender (m/f)	98/52	105/45	0.827
BMI (kg/m ² , SD)	29.4 (3,5)	28.3 (4,5)	0,707
Hernia type (u/e)	90/60	102/48	0.746
Diabetes mellitus (n)	12(8%)	8(5.3%)	0.468
Cardiovascular Comorbidities	7(4.6%)	3(2%)	0.316
Pulmonary Comorbidities	3	6	0.418

TABLE II - 1 month post-operative findings.

n = 300	Plug = 150	Flat mesh = 150	p value
All complications (I–IIIa and b)a (n)	5 (3.3%)	25 (16.6%)	0.003
Seroma	2 (1.3%)	12 (8%)	0.030
SSI	3 (2%)	13 (8.6%)	0.038
Hematoma	0 (0%)	0 (0%)	-
Extended hospitalization (n) (days)	1 (0.7%)	2 (1.3%)	0.672
Recurrence (%)	0 (0%)	0 (0%)	-
Re-operation (%)	0 (0%)	0 (0%)	-

aClavien–Dindo classification of surgical complications, I–IIIa and b

TABLE III - 1 year post-operative findings.

n = 300		
Recurrence (n)		
Re-operation (n)		
e 3 1 year post-operative findings		
Plug = 150	Flat mesh = 150	p value
2 (1,3%)	1 (0,7%)	0.672
2 (1,3%)	1 (0,7%)	0.672

Discussion

To date, this study is the only that has compared a three-dimensional mesh (plug) with a low-weight polypropylene flat mesh for small- and medium-sized epigastric and umbilical hernia. The purpose was to find a surgical device or method that minimizes the complication rate. In fact, according to our experience plug device usage shows an easier and faster operating procedures. Our results showed that usage of plug significantly decrease the incidence of complication in our group of patients compared to flat mesh. There was no difference in recurrence rate. Nevertheless, this study evaluated only one specific type of patch; there are many different patches on the market.

Our data showed a statistically significant reduction of complication in patients treated with plug compared to the ones treated with flat mesh. A statistically significant reduction was seen in SSIs. It is known that postoperative wound infection is a significant complication in umbilical and epigastric hernia repair¹. It has to be stated that there is retrospective literature that supports this high wound complication rate⁴². In this study, there is a possibility that due to the recommendation given concerning the use prophylactic antibiotics a lower wound infection rate is reported. In 2016, the WHO⁴³ published guidelines on the prevention of surgical-site infection after surgery. These guidelines included a list of 29 concrete recommendations distilled by leading experts reviewing the latest evidence. However, these recommendations were not specifically aimed at hernia surgery, and did not address perioperative antibiotic prophylaxis. The use of prophylactic antibiotics is still a matter of debate in these small primary hernias and could be the subject of a randomized controlled trial itself. Another difficulty concerning this subject is that for wound infections and seromas, several definitions are used⁴⁴⁻⁴⁶. Moreover, the most frequently used definition for wound infections is multi-interpretable⁴¹.

Because of a relatively short follow-up, 1-year after surgery, no important conclusions can be drawn concerning measures like recurrence.

It is well known that recurrence can occur long after the first operative year⁴⁷. That is why longer follow-up

of the included patients is necessary for reliable results concerning these outcome parameters.

Our study has some limitations: firstly, we evaluated only short-term outcomes in a relatively small number of patients; secondly, repair with plug or flat mesh was decided according to the clinical advice of each surgeon. However, all operations were conducted by the same surgeon using standardized operative techniques in comparable groups of patients, which led to the achievement of consistent results.

Based on the results of our study, usage three-dimensional mesh (plug) for open, small- and medium-sized umbilical or epigastric hernia repair represents a feasible and safe technique that significantly decrease the incidence of complications such as SSIs and seroma in comparison to flat polypropylene mesh. Moreover, compared to flat patch mesh, plugs displayed non-inferiority in terms recurrence rates within the first year. Further, well-designed clinical trials could be realized to investigate possible applications of plugs in treatment of small- and medium-sized umbilical and epigastric hernias.

Riassunto

La riparazione dell'ernia utilizzando materiali a rete protesica è diventata il metodo di riparazione preferito, poiché i tassi di recidiva sono molto inferiori rispetto alle tecniche di riparazione convenzionali. Lo scopo di questo studio retrospettivo era di confrontare la riparazione dell'ernia della parete addominale di piccole e medie dimensioni con patch di rete a piatto rispetto a rete tridimensionale (plug) in termini di tassi di recidiva e complicanze.

Sono state esaminate le cartelle cliniche di 300 pazienti sottoposti a riparazione di ernia della parete addominale utilizzando un patch di rete a piatto rispetto a un plug di rete tra gennaio 2010 e dicembre 2015. Tutti i pazienti sono stati seguiti dopo 1 mese, 3 mesi e 1 anno. Sono stati valutati il tasso di recidiva e le complicanze postoperatorie a breve termine come l'incidenza di infezioni del sito chirurgico (SSI), ematoma e sieroma.

RISULTATI: I dati di follow-up a breve termine sono stati disponibili per tutti i pazienti. Il primo gruppo era composto da 150 pazienti trattati con una rete a piatto in polipropilene (il 68% per ernia ombelicale e il 32% per ernia epigastrica). Il secondo gruppo era composto da 150 pazienti trattati con plug di rete in polipropilene (il 60% per ernia ombelicale e il 40% per ernia epigastrica).

La maggior parte delle complicanze postoperatorie (ad 1 mese) erano correlate alla ferita, rappresentando SSI superficiali o sieroma. I nostri risultati hanno mostrato una riduzione statisticamente significativa delle SSI [3 (2%) vs 13 (8,6%); p = 0,038] e sieroma [2 (1,3%) vs 12 (8%); p = 0,030] nel gruppo di pazienti trattati con plug rispetto al gruppo con rete a piatto. Non c'è sta-

ta alcuna differenza statisticamente significativa nelle recidive di ernia.

DISCUSSIONE: L'utilizzo di un plug di rete per la riparazione di ernia ombelicale o epigastrica di piccole e medie dimensioni rappresenta una tecnica fattibile e sicura che riduce significativamente l'incidenza di complicanze come SSI e sieroma. Inoltre, rispetto al patch di rete a piatto, i plug hanno mostrato una analogie in termini di recidiva.

Ulteriori studi clinici ben progettati potrebbero essere realizzati per studiare le possibili applicazioni dei plugs nel trattamento delle ernie ombelicali ed epigastriche di piccole e medie dimensioni.

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