Randomised Trial Comparing Polypropylene Mesh and Polyvinylidene Fluoride Mesh in the Surgery

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We started this study considering the fact that, in our surgical clinic, the association of umbilical and inguinal hernias in cirrhotic patients was found in 47,6% of cases. Although this joined pathology is quite frequent, the data comparing surgical complications and long-term recurrence when using the two mesh procedures are limited.

Keywords: mesh, polipropylen, umbilical, hernia, polyvinylidene, inguinal, cirrhosis

We thought that it is important to publish our experience in the surgical repair of hernia in cirrhotic patients because of two main reasons: first of all, because of the rising incidence of hernias through all the weak points of the abdomen; and secondly, because we would like to share our experience in associating the two types of procedures.

The main reason for the high frequency of this two joined lesion is the higher life expectancy in liver cirrhosis.

The area most prone to hernias depicted in medical literature in patients with cirrhosis complicated by ascites is the umbilical one. Our experience related to parietal pathology in this class of patients highlights both the high frequency of umbilical and inguinal hernias (in a considerably different percentage compared to non-cirrhotic patients) and, most of all, the association of the two pathologies in a meaningful percentage. Unfortunately, throughout time, the elective methods of treatment for all types of hernias in patients with cirrhosis have been dissuaded, due to the high rates of morbidity and mortality. Moreover, the association of the two types of hernia has been considered an extremely dangerous background in the face of any elective therapeutic method.

Because of this, we consider it important to publish the data reached to by a study of the 3rd Surgery Clinic of the University Hospital in Bucharest, which wish to report and sustain other existing data connected to both the pathology and the materials used for meshing.

During our surgical activity we have shown special attention to the abdominal parietal pathology in patients with cirrhosis, but our results have only improved starting with the use of the polyvinylidene fluoride mesh. On the other hand, we have not relinquished the use of polypropylene meshes, due to their variety of benefits, which have been confirmed throughout time

At present, for the double umbilical and inguinal hernia pathology we use an association of the two types of meshes.

Experimental part

This study, extended over a one year period, included a total number of 32 patients – 22 males and 10 females, diagnosed with double umbilical and inguinal hernia and cirrhosis.

The degree of severity of cirrhosis was measured by means of the Child-Turcotte-Pugh scale, only patients suffering from class A Child-Turcotte-Pugh cirrhosis being included in our study.

All the patients included in the study have been prospectively registered and retrospectively analyzed.

The surgical intervention type was elective in all cases, and decided by a mixt team of doctors pertaining to the gastroenterology, anaesthesiology and surgery domains.

All patients gave written informed consent and were over 45 years of age.

Out of our number of cirrhosis cases, 47.6% of the patients suffered from coagulopathies at the moment of admission in our clinic, and two patients out of 32 which were initially admitted to the surgical ward later required the transfer to the Intensive Care Unit, in order to treat their metabolic and coagulation imbalances. The surgical procedure practiced by our clinic, the results of which we wish to public, is the surgical cure of the inguinal hernia – through the Liechtenstein alloplastic method and the surgical cure of the umbilical hernia – through an alloplastic procedure which implies securing the mesh in the rectus sheath of the rectus abdominis muscle when a polypropylene mesh is used. Both are open surgeries.

Although we do not electively use suction drainage neither during the surgical cure of either of the two types of hernia, nor of their association, we have used suction drainage in all cases included in this study, a separate one for each lesion and a unique abdominal drainage which was always suppressed at least 3 days after suppressing the separate ones. 24 h after suppressing the abdominal drainage the patients were transferred to the gastro-enterology ward. We mention that all patients wore an abdominal contention belt starting 24 hours after the surgery.

Next we wish to highlight some ideas relating to the mesh material used. What we want to mention from the very beginning is that for securing any of the two meshes we used 2.0 polypropylene surgical wires.

PVDF is a polymer with improved textile and biological properties (10.); in comparison to polyester, PVDF is more resistant to hydrolysis and degradation. Furthermore, aging

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does not increase the stiffness of the mesh, which is seen with polypropylene. Although it has been used in vascular surgery for years, there are just limited types of surgical meshes until now.

For many years, polypropylene has been recognized as an inert suture material because of its excellent biostability and mechanical properties, Its molecular weight was believed to be too high for the polymer to be readily broken down by enzymatic degradation and used as an energy source by microorganisms. Several studies have demonstrated that polypropylene monofilament sutures induce minimal loss of tensile strength and low tissue response *in vivo.* There is evidence to suggest, however, that polypropylene monofilament sutures are sensible to iatrogenic trauma. Compared with polypropylene, PVDF monofilament sutures showed better long-term stability in vitro by retaining 92.5% of the initial tensile strength after a period of 9 years, whereas polypropylene retained only 54.3 %. The PVDF suture also exhibited minimal cellular and tissue reactions *in vivo.*

Polypropylene is susceptible to oxidation due to its chemical structure. During oxidation of polypropylene, the C__H bonds along the polymer backbone are broken, leading to bulk degradation of the polymer. The severity of the oxidation of the polypropylene material is likely affected by the implantation time, as well as other unique, patient factors such as age, history of smoking, body mass index (BMI), pulmonary disease, diabetes, and potential genetic variation, including variable inflammation and collagen defects.

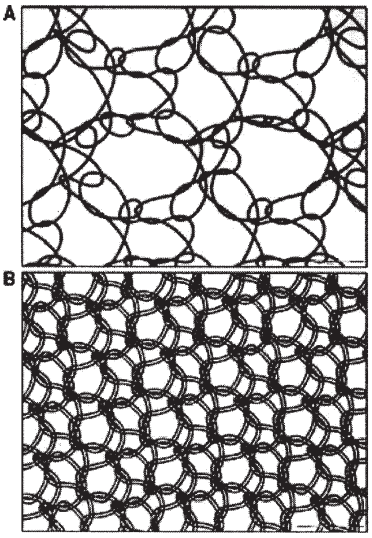

Fig.1. A. Large-pore and elastic mesh made of polyvinyliden flouride monofilaments (PVDF) B. A small-pore and stiff mesh made of polypropylene monofilaments (PP) (9)

Results and discussions

Before presenting you with the results of our study, we wish to highlight some aspects which point out our inclination towards this pathology.

Cirrhosis, notwithstanding its etiology, has a high prevalence in our country. What we consider to be important is that, along with the improvement of this disease's prognosis, the number of patients with abdominal hernia pathology which require a surgeon attention has also risen.

Medical information regarding this complex association of pathology is little, although the frequency of umbilical hernia in patients suffering from cirrhosis is approximately 20%.

This is why we wish to communicate the results of a study which was underwent at first sight on a small, but large, considering the number of patients operated on each year by our service, number of cirrhosis patients.

We once again mention the fact that we wish to draw attention on the materials used for meshing, and not on the surgical procedure method.

The characteristics of the 32 patients included in the study were analysed attentively, seeing how our vast 20 year long experience of dealing with this type of pathology in patients has determined us to set a strictly defined series of criteria for including a case in a study. Thus, 68.75%, meaning 22 of the patients, presented ascites when they were first diagnosed, but were all class A Child-Turcotte-Pugh cases. We used a polypropylene mesh for the cure of the umbilical hernia and a PVDF for that of the inguinal hernia in 16 of the patients, and a polypropylene mesh for the surgical cure of the inguinal hernia and PDVF for that of the umbilical one in the other 16 patients.

The most important aspect which has captured our attention was that of the complications studied. The rate of complications could not be correlated to the evolution stage of the basic disease or to the presence of ascites at the time of the surgery. A patient that did not present ascites at the time of the surgery (6.25%) died. From a post-operatory mortality point of view we can also conclude that it cannot be correlated to the presence of ascites. Thus, the only post-operatory deceased patient was one without ascites. On the other hand, a conclusion is to be drawn based on an analysis conducted together with gastroenterologists and anaesthesiologists, that mortality is correlated with the evolution of the disease, without any surgical involvement.

From a recurrence point of view, analysing the cases which have returned to our clinic due to this, we have concluded that there are significant differences in the rate of recurrence of the umbilical hernia after the use of PVDF. Thus, out of 16 patients in which the surgical cure of the umbilical hernia was practiced with a PVDF mesh, recurrence was seen in only 4 of them, unlike in the case of the other 16 patients, where polypropylene was used and where recurrence was observed in only 2 patients. Analysing these cases we could draw the conclusion that recurrence is rather correlated with the type of mesh material used, than with the presence of ascites at the time of the surgery.

Analysing and comparing the 2 groups of patients studied, no significant differences were noticed in terms of hospital treatment period required.

The average follow-up period after discharge was of 22.7 months.

From the point of view of developing a counter-lateral inguinal hernia in addition to the one submitted to surgery, it has been observed to happen frequently in patients who underwent a surgical procedure with a polypropylene mesh for the umbilical hernia and a PVDF one for the inguinal hernia. Thus, 6 out of 16 patients treated this way developed counter-lateral inguinal hernia.

All these ideas provide reason to encourage the undergoing of surgical procedures for hernia pathologies of the abdomen in an elective manner. Also, we believe that the favourable results that we have obtained are due to tight interdisciplinary gastroenterologist - anaesthesiologist - surgeon collaboration.

Conclusions

Attempting to summarize our experience in a series of clear conclusions, we wish to further present all the complications that we have had to deal with while conducting this study in a trenchant manner, which will hopefully remain in the memory of those dedicating their work to this type of pathology.

Table 1
COMPLICATIONS

Complication Types	Polypropylene – Umbilical Hernia / PVDF – Inguinal Hernia	PVDF – Umbilical Hernia/ Polypropylene – Inguinal Hernia
Seroma	6 (37,5%)	6 (37,5)
Haematoma requiring new surgery	2(12,5)	0
Minor haematoma	2 (12,5)	2 (12,5)
Suppuration of the surgical wound requiring new surgery	0	0
Minimal suppuration	0	2 (12,5)
Bruising	0	0
Recurrence	2 (12,5)	4 (25%)
Pain	6 (37,5)	0

What we wish to highlight is that the indication of securing this types of materials is yet relative and unfortunately unstandardized, both due to the presence of very few results in medical literature, and to the idea, that we disagree upon, of avoiding elective surgeries in patients suffering from cirrhosis.

Where exactly are we after this study? In a point from where we can advance towards an exact surgical standardization in this pathology. It is clear that there are advantages and disadvantages in using each of the two types of materials, but we believe that if we keep the above table clearly in mind, we can choose the correct type of material depending on the patient.

We must not forget the fact that when a surgeon is faced with this type of lesion association he has a severely afflicted patient under his care. Cirrhosis often comes with complications, and is frequently associated with additional pathologies that might influence the disease prognosis.

At the same time, our experience dictates the elective procedures required by such patients, given the fact that life expectancy for cirrhotic patients has grown in recent periods.

Our experience in this domain is encouraging and sustaining: that in the case of the association of a double abdominal parietal defect in a cirrhotic patient, of the type inguinal hernia – umbilical hernia, the combination of PVDF in the surgical cure of the umbilical hernia and of polypropylene in the Liechtenstein procedure for the inguinal hernia be used.

The most important properties of meshes were found to be the type of filament, tensile strength and porosity. These determine the weight of the mesh and its biocompatibility. The tensile strength required is much less than originally presumed and light-weight meshes are thought to be superior due to their increased flexibility and reduction in discomfort. Large pores are also associated with a reduced risk of infection and shrinkage. For meshes placed in the peritoneal cavity, consideration should also be given to the risk of adhesion formation. A variety of composite meshes have been promoted to address this, but none appears superior to the others. Finally, biomaterials such as acellular dermis have a place for use in infected fields but have yet to prove their worth in routine hernia repair.

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