

UNIVERSITY OF MEDICINE AND PHARMACY OF CRAIOVA

DOCTORAL STUDIES

PhD THESIS ABSTRACT

**USE OF SYNTHETIC PROSTHETIC MATERIALS IN SURGERY OF ABDOMINAL
PARIETAL DEFECTS -- INDICATIONS, TISSUE ANSWER, COMPLICATIONS,
SOLUTIONS**

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KEY-WORDS: abdominal parietal defects, surgical indications, synthetic prosthetic materials, post-operative complications, infections, classic, laparoscopic.

Hernia pathology represents an important problem with numerous medical, social and economic indications, even though at this moment there are numerous diagnosis and treatment techniques available.

Although it is quite a common condition, the causes of hernia pathology are multiple and varied, some of them known, other in the process of research in the specialty literature, with only the possible causing factors enumerated.

This pathology is characterized by a progression process, requiring a thorough monitoring, that is why it is quite important that the discovery should be made in a very early stage, and the treatment should be applied early and well-adjusted, in order to avoid possible severe complications and consequences that may occur, thus ensuring a higher chance for immediate and late survival and a better quality of life.

The treatment surgical strategy preferred by every doctor may vary, both in the management of primary hernia and their relapses, involving a multidisciplinary treatment consisting of anaesthetic-surgical treatment, pain therapy and associated co-morbidities.

The PhD thesis entitled *USE OF SYNTHETIC PROSTHETIC MATERIALS IN SURGERY OF ABDOMINAL PARIETAL DEFECTS -- INDICATIONS, TISSUE ANSWER, COMPLICATIONS, SOLUTIONS* has the main purpose of a more complete approach of this problem. The purpose of research was highlighting the epidemiological, treatment, progression particularities and complications of this condition.

The thesis is structured in 2 chapters, the general part containing data from the literature, structured in other sub-chapters, and the special part that represents personal contribution. At the end of the paper, there are presented the discussions and conclusions.

Chapter I Abdominal wall -- comprises anatomic aspects and their localization. The abdominal wall defines the inferior trunk region -- abdomen and pelvis, which it demarcates in the anterior, lateral and posterior parts; upper and lower, the abdomen is demarcated by the diaphragm, namely the bony pelvis and the pelvis diaphragm.

The abdominal wall, in its anterior-lateral part, has only soft parts, in the posterior region, in the stratification of the abdominal wall being found the last costal arches. The structures that make up the abdominal wall are the following, located from the anterior to posterior part: skin, subcutaneous tissue, muscular-aponeurotic layer, properitoneal fatty tissue and the last parietal peritoneal layer.

Chapter II Anatomy of the inguinal canal - there is described anatomically the inguinal canal, its walls, its orifices and the content of the inguinal canal. The inguinal canal represents a virtual anatomical orifice of the anterior abdominal wall located in the lower part, through which there is made the passage of some elements of the male and female genital system. Through the male inguinal canal there pass the elements of the sperm cord to the scrotum, while in females it is crossed by the round uterine ligament that represents a way of anchoring for the uterine body; in both sexes, thorough the inguinal canal there also passes the ilioinguinal nerve. The inguinal canal is formed between the muscular, aponeurotic and fascial plans of the lower abdominal wall, which functionally determines a valve mechanism through its different positioning of the two orifices and the fibromuscular structure of the walls, but also through his non-linear trajectory. It has an oblique trajectory to the lower part, from the lateral to medial and it prolongs from the deep inguinal orifice from the upper fascia transversalis to the superficial inguinal orifice, summing up a 4 cm length, being longer and broader in men in comparison women; its sizes vary according to age.

The structure of the inguinal canal is made of 4 walls and 2 orifices. - The anterior and lower walls are made of the external oblique muscle aponeurosis, which becomes more dense in the lower part and forms the inguinal ligament (it is also called the Poupart or Gilis ligament). The upper wall is represented by the lower margins of the transverse abdominal and internal oblique muscles, whose free margin in their lateral part becomes aponeurotic in the medial part, where it forms the conjunct tendon through their union. The posterior wall is made of the fascia transversalis medially strengthened by the conjunct tendon and the reflex ligament, and laterally by the Henle ligament and by the Hesselbach interfoveolar ligament. The superficial orifice is located in the aponeurosis of the external oblique muscle, its aponeurosis fibers being organized in the form of two cords, lateral and medial, with the intercrural fibers between them. The deep inguinal orifice represents a fourth of the posterior wall, being considered its weak spot, with an oval shape, namely an opening in the fascia transversalis.

The content of the inguinal canal differs in men and women.

Chapter III Biomechanics of the abdominal wall - Anterior abdominal muscles and their aponeurosis work together, in order to perform complex actions. This whole provides a series of functions in the body, such as: abdominal press, contributes to the respiratory times along with other muscles, provides orthostatism and movements of the spine, contributes to those reflexes of coughing, defecation, vomiting, urination, etc. These functions are fulfilled

when the abdominal wall is in a good state. The biomechanics of the abdominal wall comprises: dermo-hypodermic biomechanics and abdominal muscle biomechanics.

Chapter IV Etiopathogeny and morphology of parietal defects - the muscles of the anterior abdominal wall present mor weak points through which the intra-abdominal organs may externalize, thus leading to hernias. Hernias are present in both sexes, independent of age, and a first classification may be performed according to the localization: inguinal, femural, umbilical, epigastric, supravesical. Inguinal hernias may be classified according to various criteria. According to the onset point, they may be divided into congenital hernias and acquired hernias.

Within the inguinal hernia etiopathogeny, there may be reminded the following predisposing factors: repeated minor efforts, such as chronic coughing, dysuria, constipation, great efforts that come suddenly leading to pressure increase in the abdomen. The herniation process may also appear in preexisting bone or muscular deformations.

Chapter V Clinical features of parietal defects - The patient examination is quite important as, in this way, there may be avoided the diagnosis and treatment errors. The patient undergoes a general clinical examination and a local clinical examination, in search for the occurrence of a depressive swallowing, with a sudden onset after the increase of intra-abdominal pressure. The manner of its onset and disappearance, correlated with the physical effort, clinostatism, expansion and impulsion at palpation, represent almost pathognomic signs in diagnosing hernias. The main symptom accused by the patient is represented by pain, with a variable intensity.

Paraclinically speaking, the investigations performed for diagnosing hernias may be: herniography (peritoneography), ultrasound, CT scanning, MRI.

At present, The European Hernia Society elaborated a guide for the management of inguinal hernias, according to which symptom-free inguinal hernias with a potential for complications (strangulation and reclusion) have a surgical indication, being considered more safe and with a lower morbidity. The surgical treatment of inguinal hernias may be performed with more types of anaesthesia. The anaesthesia technique will be chosen according to various factors, such as the patient associated pathology, the type of surgery, available equipment, medical experience of the surgeon and anaesthetist.

Chapter VI Surgical treatment – Procedures - The objectives of the surgery, independent of the hernia type are: identification and treatment of the hernial bag, treatment of the hernial bag content, remake of the abdominal wall and its strengthening.

The main surgical techniques may undergo a distribution according to the type of surgical intervention, the technique of the parietal defect or the healing spot of the abdominal wall.

Surgical classic, open interventions may be divided into anatomical procedures and prosthetic material procedures, which, in their turn, may be divided into posterior and anterior procedures. Another classification may be performed according to the treatment of the anterior wall, the division being made as follows: total reconstruction of the posterior wall or a partial reconstruction of the posterior wall, through the re-calibration of the deep inguinal orifice -- used only in indirect inguinal hernias in children. Regardless of the chosen technique, for the surgical remake of the parietal defect, there is imposed the following of some intra-operative principles: avoidance of septic contamination, the assembly should not be in an over biological tension, there will be provided ischemial sutures, avoiding the excessive use of foreign materials, especially the ones of the multi filament type, as they cause infection, following a thorough hemostasis, placing of suctioning drainage when required.

Chapter VII - Types of prosthetic materials used in surgery of the abdominal wall. Prostheses may be divided into biological prosthetic materials, divided into: autologous or heterologous. Prosthetic materials combine the characteristics of a very thick liquid (flowing and thermosensitivity) with the ones of a solid (morphological stability, elasticity and mechanical resistance), thus being thick and elastic. According to these characteristics, it is more appropriate to be called biopolymers or bioprotheses. Biopolymers may be divided into 2 classes, thermolabile and thermoplast raisins. According to texture, synthetic prostheses may be classified into: plaques (rarely used, except for the plauqe of polytetrafluorethylene - Gore-Tex, Teflon, Dual Mesh) and knitted networks-bags, frequently used. According to the biomass behaviour, these may be non-resorbing and resorbing.

The basis polymer may be: polypropylene, polyethylene-terephthalate, Polytetrafluoroethylene, Polypropylene.

For the remake of the anterior abdominal wall, the prosthetic materials differ through shape, size and also by the material composition and the physical and chemical features.

The characteristics of the tissue answer to the prosthetic material: lysis, tolerance and in-building, extrusion.

The special part contains personal contributions.

The paper is based on a study performed between 2016 and 2017 within the Clinic of General Surgery I of the Emergency University Hospital of Bucharest, where there were diagnosed, investigated and treated 428 patients.

The main objective of this paper is to establish the type of prosthetic materials used in the surgery of abdominal parietal defects in order to offer the adequate solutions for the addressed pathology, through an analysis of the retrospective, non-randomized, based on the experience of the Clinic of General Surgery I of the Emergency University Hospital of Bucharest, between 2016-2017.

The type of study we used: retrospective, observational, non-randomized, one-centered study.

The criteria the patients were subjected to were: the group contains patients diagnosed and treated of hernias of the abdominal wall aged over 18 years old, from whom there was obtained a written consent for the surgery and prosthesis use, the accept for patient monitoring over a postoperative period of at least 3 months. Exclusion criteria: the patients presenting to the hospital, in the ER or the clinic, either refused admission or refused surgery.

The study objectives were distributed by sex, age, localization of hernia, associated conditions, used surgical technique, used prosthesis materials, and when used, their type, duration of pre and post-operative hospitalization, possible complications, post-operative evolution (early and late).

The complications were synthesized in intraoperative and post-operative.

Intraoperative complications may occur due to the damaging of the following anatomic structures: nerves, vessels, viscera, deferent canal.

The post-operative complications may be divided into general and regional.

The discussion of the PhD Thesis were synthesized as follows:

Inguinal hernia is a pathology that may be approached in many laborious, complex and minimally invasive ways. The studies show that it represents one of the most common pathologies, presenting to the hospital both in the clinic and in the ER, and for whom there is decided an emergency surgery, thus becoming an important consumer of human resources and materials.

At least one surgery out of 10 that took place during the period covered by the study was for a defect of the abdominal wall, regardless of its localization.

The extent to which this type of surgery is performed in hospitals also takes into account the availability of the patients, the section profile, equipment or the surgeon's experience.

Regarding the diagnosing of hernia, this is performed clinically. Rarely, the ultrasound, CT scan or MRI establish this diagnosis, yet these are irreplaceable regarding the differential diagnosis and the identification of the hernia bag.

In children and young people, this pathology is considered congenital, the older we get, this condition developing exclusively in old people, as a consequence of exerting a high pressure on an abdominal wall that is weakened, a situation that may occur in patients with chronic, consumptive diseases, neoplasias, tuberculosis or in patients that, due to associated pathologies, undergo a pressure on the abdominal wall, low-moderate intensity pressure, still with a high frequency, such as patients with prostate adenoma who increase their abdominal pressure in order to urinate, chronic coughers, like patients with chronic lung obstructive disease, with cirrhosis and others.

The cases of inguinal hernia in women are more rare in comparison to men. The present estimated data support that a man out of five will develop inguinal hernia, while only one woman out of 50 will suffer from this condition.

The true prevalence of inguinal hernias cannot be identified, due to the fact that this pathology is symptom-free in early stages.

In the study presented on the group of patients addressing the Clinic of General Surgery I of The Emergency University Hospital of Bucharest, between 2016 and 2017, with hernia pathology, the men/women ratio being 3:2, this value being included approximately at half the interval mentioned in the international reports.

Mainly, the defects of the anterior abdominal wall are found in men, in the age group over 50 years old, in the present study, the statistics being the following one: after group distribution by age of patients diagnosed with inguinal hernia, 23.72% were aged between 60-69 years old, followed by 20.47% in the age group 50-59 years old, 18.14% in the age group between 70-79 years old, 17.21% in the age group between 40-49 years old, followed by the age groups between 30-39 years old, <30 years old and 80-90+ years old that have 7.91%, 6.98% and 5.58%, respectively.

It is observed the predominance of inguinal hernia on the right side, this thing being explained through the anatomical particularities found in the right inguinal canal, as it should be mentioned that it is shorter than the one on the left side, his orifices are aligned less oblique, therefore it is more frequent a localization on the right.

There are more types of inguinal hernia of which we may specify right and left external oblique, the left and right direct, in all situations though the most frequent cases are localized on the right.

In the patients diagnosed with inguinal hernia, of any duration or size, these may address the doctor for a general check-up or in the ER, the doctor having the responsibility to decide, according to the clinical exam, co-morbidities and pathology complexity, whether it requires an immediate solution or not. The surgery is quite difficult as there appear complications in patients with severe, old and neglected co-morbidities.

In the present study, most of the patients were operated selectively, even though inguinal hernia may cause sub occlusive or occlusive syndromes, accompanied or not by peritonitis or by necrosis of an intestinal anseae, or of the epiploon, the most common situation, when the patient presents in the ER and there is decided an emergency surgery, for which there is practiced a minimum preparation or no preparation at all, thus increasing mortality or morbidity.

The treatment strategy applied in men with a minimum range of symptoms or even symptom-free, does not require first time surgery, the patients are monitored, examined periodically and timed as long as the symptoms are quite low and there is preserved a low risk for incarceration and strangulation.

Indication for surgery is required when in previously mentioned patients there appears pain and discomfort, which are associated with the presence of hernia, as well as to prevent the development of complications and to reduce the number of emergency surgeries, for this pathology, when there appears strangulation and incarceration, as in these situations, mortality and morbidity are high.

The criteria after which it is chosen the surgical procedure for the parietal defect may be influence by: the surgeon's experience, the patient's preferences, the clinic equipment, associated pathologies, co-morbidities, life and work conditions.

As it can be seen from the present study, from the classic procedures, the Lichtenstein II procedure remains the first intention one, being a tension-free procedure, using an alloplastic material, while regarding the techniques performed laparoscopically, the TAPP procedure are the first choice, even though there were also used other ones, with the same result and same safety.

The type of surgical procedure used in inguinal hernias is the classic one in 204 cases of a total of 215 and 11 cases where the treatment procedure was performed laparoscopically. This thing may be also performed due to the fact that the surgeries for surgical treatment of

inguinal hernia represent a relatively new technique for our country, and surgeons are still on the learning path, this thing leading to the increase of the use of general anaesthesia as well as and increased surgical time in accordance with the classic technique, resulting in high costs, high anaesthetic-surgical risks and also increased perioperative complications. We can also state that the number of laparoscopic surgeries is in an ascending trend.

At the surgeon's disposal there are lots of prosthesis materials, synthetic or biological, non-resorbable, partially resorbable or resorbable, some of them being used exclusively in classic surgery or in the laparoscopic one.

In making the alloplast material, the most used material is represented by polypropylene. The weight is affected by the net loops size, on which the embedding process depends on. Nowadays, these things led to being preferred ultra light or light nets, with large loops.

Every manufacturer tries to introduce on the market synthetic competitive, top nets, marked with wires of different colours to help orienting the net into the wound, but there are also used nets of standard, rectangular sizes, which allow the operator to cut and mould it according to the local situation. For open, classic surgery, there were used various nets ADESHIX® (Cousin Biotech Premilene Mesh®,) ProMesh T® (Péters Surgical), Dyna Mesh® – PP, Dyna Mesh® Lychtenstein, and for the laparoscopic surgeries – 3DMax Light Mesh® (Bard).

Just like in any other implant, synthetic nets may cause local complications, such as infection of the surgical scar, this thing leading to an increase of hospitalization time, requiring wound drainage or even reintervention for the source control; there were cases when the surgeon had to give up the synthetic implant and to practice an anatomical procedure, as it was considered a life-saving solution.

Post-operative complications, both early and late ones, are more frequently found in the older patients, who associate multiple comorbidities, their severity and number may vary a lot, from a simple high blood pressure, accurately treated, to consumption conditions like oncologic diseases or leukemias, in patients requiring chronic anticoagulant treatment for chronic fibrillation, thromboembolic pathology or in patients with unbalanced diabetes mellitus.

The classic technique, using procedures on open approach, is in a higher percentage accompanied by post-operative complications, but this technique is more accessible and less expensive.

The success of a surgery does not depend only by the surgical gesture, also being important the pre-operative preparation, monitorization and support of vital functions during surgery, and also the post-operative time.

All these surgical interventions cannot be performed without an anaesthesia, this making the intervention possible both for the surgeon and for the patient, as well.

At present, there are used more types of anaesthetic techniques, among which we have local anaesthesia, spinal anaesthesia and general anaesthesia. The anaesthetic risk is represented by local anaesthesia, in comparison to spinal or general anaesthesia.

When there is used local anaesthesia, there is required an anaesthetist team ready to intervene at any point.

When there is used general anaesthesia, the vital functions should be monitored and supported during the entire surgery, both the patient and the surgeon having a superior comfort in comparison to other situations, and the surgeon may acquire a relaxation of the upper abdominal wall necessary for the reintroduction in the peritoneal cavity of the viscera that lost their place. If we compare spinal anaesthesia with general and local anaesthesia, the latter allows a rapid mobilization of the patient, it has a low risk of bladder globe development and there are no symptoms like nausea, vomiting, vertigo, etc.

General anaesthesia represented the election technique in the present study, therefore, 263 patients out of a total of 428. Regarding the surgical intervention, this type of anaesthesia ensures the best bilateral comfort, both for the patient and for the surgeon.

Out of a total number of 428 surgeries included in the study, 32 were performed under local anaesthesia, 133 surgeries with spinal anaesthesia and 263 surgeries with general anaesthesia.

Regarding the mean duration of hospitalization for patients diagnosed and operated for inguinal hernia, there may be observed a mean duration of 6.85 days, with a mean duration of 2.08 days and a mean post-operative duration of 4.80 days.

More frequently there is a tendency for the introduction of “one day surgery” for the treatment of inguinal hernia, but due to the absence of a patient monitoring system at home, in Romania it is preferred the situation of patient hospitalization for a post-operative monitoring.

The success of a surgery for anterior abdominal wall remake may be evaluated by the low rate of relapses, as well as of complications, when they are present, the life quality being affected during the immediate and late period after surgery.

The mean duration of hospitalization for eventrations is 11.41 days, superior to other mean duration, eventrations being considered relapsing hernias. There is preserved the same

minimal duration of hospitalization of one day before surgery and a minimal one of 2 days after surgery.

When there are identified the risk factors, as well as the patients with a high risk of relapse, in association with associated pathology, as well as with life and work conditions, on one side it changes the surgical decision, and on the other hand it increases the level of attention for the whole team of surgeons and anaesthetists.

Inevitably, there appears the aging process and thus it may happen a downfall of various functions of the body, even when there are no other associated pathologies present. A high life expectancy and a continuous development of diagnosis and treatment means, leads to the fact that the doctors have to treat older patients with multiple comorbidities, this fact being confirmed in the present study, where a percentage of approx. 5% of the entire group of patients diagnosed and treated for hernia were older than 80 years old.

Present studies show that there is recorded a high mortality and morbidity in the emergency interventions performed in older patients, in comparison to scheduled surgeries. Postponing the surgical moment for the treated elder patients contributes to the patient's transformation into a patient where the symptoms complicated and thus the subacute pathology became acute, putting the patient's life at risk.

At present, the recommendations of the European Hernia Society regarding the treatment of inguinal hernias, in the last released guide, make reference only to the Lichtenstein technique and to laparoscopic ones.

Other important societies, such as NICE-National Institute of Clinical Excellence from England and ANAES- The National Agency for Accreditation and Evaluation in Health from France recommend the Lichtenstein procedure as surgical treatment for inguinal hernias, while the American College of Surgeons considers it a "Gold Standard".

The Lichtenstein procedure has the following advantages: low rate of relapse, a reduced number of complications during and after surgery, low costs, short-term hospitalization, possibility of performing this technique using local anaesthesia.

The laparoscopic procedure, when used by experimented surgeons, gives better results. Of the advantages of using this technique, there may be reminded: low intensity of post-operative pain, low number of over infection, the patient is reintegrated in society a lot faster. The European Hernia Society recommends TEP as a technique, in the case of using laparoscopy. There exist various studies published, such as the one led by McCormack and Wake that have the result that the duration of surgery and the number of recurrences are similar both in the use of TEP technique and the TAPP.

As the main disadvantages of the laparoscopic technique, there may be enumerated the following: high costs, long duration of the surgery in case of inexperienced surgeons.

At present, there is a wide range of synthetic tents, which makes the choice quite difficult. The present recommendations are that there should be used synthetic tents that have a non-resorbable component or are not resorbable at all. When used, complications are also present, like recurrence, over infection or local pain, but there may also be found specific complications, like migration, erosion or prosthesis dislocation.

There was observed that for the previous approach it is more appropriate to use twined tents, made of polypropylene mono filament, as this decreases the risk for seromas or chronic fistulas.

The rate of infection onset after hernias operated through classic procedures is higher in comparison to those where synthetic prostheses were used.

The new discoveries regarding materials and techniques require high attention from the surgeon, but also it does not resolve all the problems that may happen in a patient diagnosed with abdominal hernial pathology.

In order to be considered that a surgical act is successful, it is necessary a connection between the chosen surgical procedure, the practiced surgical technique, the choice of a synthetic prosthetic material adapted for every patient, a quality anaesthetic technique and absence of complications and relapses.

Conclusions of the PhD Thesis may be synthesized as follows:

- the parietal defects of the anterior abdomen represent one of the older conditions in surgical pathology and whose surgical treatment is in a continuous change and improvement.
- the incidence of inguinal hernias in the general population is difficult to estimate, as there are many undiagnosed cases. At present, their incidence is estimated according to the number of surgical interventions related to this pathology.
- at the beginning of this surgical pathology, the tendency was exclusively to an anatomical remake of the abdominal wall, layer by layer, subsequently, after the thorough use of thw abdominal wall biomechanics, there started to appear procedures related both to the anatomical shape and to the fact that the weak parts of the abdominal wall require to be strengthened.
- after the progress recorded in this area of expertise, surgeons started to use synthesis materials more often, which have been initially insufficiently adapted, therefore there were

recorded reactions of rejection, the transformation continued and, at present, there are used materials that are well-tolerated.

- the new laparoscopic techniques offer a new perspective regarding the surgical treatment of parietal defects, regardless of the peritoneal or transperitoneal manner in which they are approached.

- this condition occurs mainly in men.

- improving the quality of life represents the main argument for which the surgery is performed and requires a detailed and concise evaluation.

- sometimes, the alarming symptom is represented by inguinal pain that may be present even before the start of the inguinal bag growth.

- as they get older, the old patients that are diagnosed with this pathology, present associated cardiovascular, lung and metabolic diseases leading to the increase of complications occurring after surgery, and also to the increase of hospitalization costs, through the treatments that are administered before surgery.

- regardless of the chosen surgical technique, the observed complications did not present major differences regarding their type, incidence and magnitude.

- according to the chosen surgical procedure, there may be stated that, when the extra peritoneal prosthesis is used, the patient's reintegration into the society is a more rapid process.

- when there occurs suppuration in the synthetic prosthesis, there develop multiple sufferings that are associated with the psychological and physical discomfort, even though this implies the removal of the synthetic prosthesis.

- every patient's treatment is personalized according to the local situation.

- the ideal synthetic material does not exist, all the prostheses generating an inflammatory reaction that manifests or not, but which cannot be evaluated through laboratory tests.

- the inflammatory response is influenced by the biochemical composition from which the main polymer is made. In the patients where there was used a prosthesis made of polypropylene, the inflammatory markers are higher than in those where there was used a polyester prosthesis.

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