

**UNIVERSITY OF PHARMACY AND MEDECINE
OF CRAIOVA**

PhD THESIS

ROBOTIC ASSISTED LAPAROSCOPIC PRMONTOFIXATION
AS A THERAPEUTICAL OPTION FOR THE TREATEMENT
OF THE PELVIC ORGAN PROLAPSE

- ABSTRACT-

COORDINATOR:
Prof. Dr. RĂDUCU NEMEȘ

PhD STUDENT:
MARIUS STANIMIR

Craiova 2017

This thesis is structured in the following chapters:

INTRODUCTION

CHAPTER I. PELVIC ANATOMY

1. Pelvis
2. Perineum
 - 2.1. Pelvic diaphragm
 - 2.2. Urogenital diaphragm
 - 2.3. Tendon center of the perineum
 - 2.4. Perineum vascularization
 - 2.5. Perineum innervation
3. Pelvic genitalia organs
 - 3.1. Uterus
 - 3.2. Bladder
 - 3.3. Rectum

CHAPTER II. PELVIC ORGANS PROLAPSE

1. Definitions and general concepts
 - 1.1. Definition
 - 1.2. Classification
2. Epidemiology
 - 2.1. Prevalence of the pelvic organs prolapse
 - 2.2. Incidence of the pelvic organs prolapse
3. Etiopathogenesis
 - 3.1. Risk factors
4. Physiopathology of the pelvic organs prolapse
 - 4.1. Generalities
 - 4.2. The alteration of collagen, smooth muscles of the vagina and its supporting tissues
 - 4.3. Pregnancy, birth and pelvic floor
 - 4.4. The pathophysiological mechanism of injury of the pelvic floor during childbirth
5. Clinical aspects
 - 5.1. Exteriorization symptoms
 - 5.2. Urinary symptoms
 - 5.3. Digestive symptoms
 - 5.4. Sexual dysfunction
6. Clinical examination
7. Clinical, imagistic and laboratory tests
 - 7.1. Cystography
 - 7.2. Ultrasound echography
 - 7.3. Dynamic MRI (dMRI)
 - 7.4. Video-urodynamic tests
 - 7.5. Cystoscopy
 - 7.6. Upper urinary tract imaging
8. Treatment
 - 8.1. Non-surgical treatment
 - 8.2. Surgical treatment

CHAPTER III. STUDY MOTIVATION. OBJECTIVES. MATERIAL AND METHOD

CHAPTER IV. RESULTS

1. Epidemiology

- 1.1. Incidence, age, environmental origin, occupation
- 1.2. Etiopathogenesis. Risk factors
2. Diagnosis
 - 2.1. Clinical diagnosis
 - 2.2. Biological diagnosis
 - 2.3. Pre-operative anatomo-pathological diagnosis
 - 2.4. Imagistic and endoscopic diagnosis

CHAPTER V. CLASIFICATION

CHAPTER VI. TREATMENT OF THE PELVIC ORGANS PROLAPSE

1. Operative technique

CHAPTER VII. POSTOPERATIVE RESULTS

1. Objective evaluation of the results
2. Subjective evaluation of the results

CHAPTER VIII. DISCUSSIONS

CHAPTER IX. CONCLUSIONS

CHAPTER X. REFERENCES

Pelvic organs prolapse represent the descending of the pelvic organs (uterus, bladder, rectum or colon) through the vaginal wall due to the loss of their mechanisms of support or suspension. Development of POP is caused by a weakness of the support structures of pelvic floor which allows the pelvic organs to descend through the genital hiatus. Although it is not a life-threatening pathology, very often is associated with the deterioration of the quality of life and may disrupt the smooth functioning of the bladder, bowel or sexual life.

The thesis encompass ten chapters that are briefly presented below: anatomy of the pelvis, the pelvic organs prolapse, the aim of the study, the objectives, materials and methods, the results, the classification of the pelvic organs prolapse, the treatment of the pelvic organs prolapse, the postoperative results, the discussion, the conclusions and the bibliography.

Knowing the anatomy of the pelvis and pelvic organs, its innervation and vascularization are very important both for understanding the physiopathology and for the reconstructive surgical treatment of the pelvic organs prolapse.

The incidence of the pelvic organs prolapse is about 50% among multiparous women and is associated with a variety of urinary, digestive and sexual symptoms. The prevalence of the disease is increasing and the probability to require surgical correction is greater than 10%.

The risk factors incriminated in the disease development are represented by the bowel dysfunction, obesity, history of pelvic or pelvic organ prolapse surgery, maternal and obstetrical factors and genetic factors.

In the physiopathology of the pelvic organs prolapse development are involved the alteration of the collagen, of the smooth muscles of the vagina and of the supporting tissue, the pregnancy, the childbirth, the muscle trauma and the nerve injuries.

When presenting to a doctor, the patients often complain of genitourinary, gastrointestinal and musculoskeletal symptoms; because of this, physical examination should be conducted carefully in order to determine the symptoms of prolapse and their effect on daily activities.

The clinical examination is definitive for the diagnosis of the pelvic organs prolapse and should be done with the patient both in gynecological position and standing with full bladder. The examination begins with the patient at rest and afterwards is requesting to produce a high abdominal pressure (ex. Valsalva maneuver). The purpose of this examination is to determine the degree of the prolapse, the anatomical defects, the presence of urinary incontinence or the prolapse of other organs.

Additional imaging investigations are reserved for cases in which the clinical examination is not eloquent and it cannot make the difference between a cystocele, a rectocele or an enterocele. In this regard, imaging investigations must provide accurate information about the structures that are prolapsed, if there is any urinary retention, urinary incontinence or urethral hypermobility. These investigations are represented by the urethral cystography, dynamic magnetic resonance imaging, video-urodynamic study, cystoscopy and urinary tract ultrasonography. Computed tomography, urography and intravenous magnetic resonance imaging are used in selected cases.

The therapeutic options for the treatment of the pelvic organs prolapse are divided into: conservative treatment represented by pessary and exercises of the pelvic floor muscles and surgical treatment, which is benefiting from impressive number of therapeutic procedures (obliterated procedures and reconstructive procedures).

The obliterated procedures are the Lefort colpocleisis and the total colpocleisis. The major reconstructive procedures are the anterior colporaphy, abdominal sacrocolpopexy the suture of the vaginal apex to the sacrospinous ligament, the fixation of the vaginal vault to the uterosacral ligament, the Mayo/McCall culdoplasty, the levator ani myoraphy, the transvaginal tapes, the

posterior colporaphy, the correction of the specific points of failure or the modified sacrocolpopexy.

The main objective of the surgical treatment of the prolapse is the repositioning of the pelvic organs in their anatomical position and it intends to achieve the following four major goals: reducing the prolapse, no functional symptoms, improvement of the life quality and avoid complications. Two approaches are used for the surgical treatment: abdominal or vaginal approach.

This thesis represents a retrospective, observational, descriptive and single center study. The research and study were conducted on a total of 158 patients who were admitted and treated in the Department of Urology Hospital Clinique de l'Europe, Saint-Elisabeth site from Brussels, in a period of 8 years (January 2008 - October 2015). All the patients underwent surgical correction of the pelvic organs prolapse by robotic assisted laparoscopic promontofixation. In the study were included symptomatic patients with prolapse grade II, III and IV, according to Baden-Walker classification.

The purpose of the paper aims to present the professional experience gained during the surgical treatment of the pelvic organs prolapse by using the robotic assisted laparoscopic promontofixation. Also, the anatomical and functional results obtained using this technique were compared with those from the literature.

The results obtained after processing the data from the personal study were as follows: in respect of the age, this was situated between 40-92 years with a mean of 70.8 years. The maximum incidence was located in the decades VI and VII, the second were patients from the decade V, followed by the eighth decade. The decades IV and IX have been the least represented.

Regarding the number of the patients operated per year, we noted a linear trend in the number of robotic assisted laparoscopic promontofixation procedures for pelvic organs prolapse correction. This is ranging between 2 and 38 years with an average of 19.75 new cases per year.

In our study we also found that a higher incidence of POP occurs in rural areas, whereas 56% versus 44% in urban areas.

Different causes were recognized as common during the study. Namely, the family history, personal physiological and pathological history were identified in several cases. Precisely, a total of 13 patients (8.22%) had a family history, but only in 12 cases (7.6%) were representative in terms of etiology. They were represented

by 7 cases (4.43%) to which mothers were diagnosed with pelvic organs prolapse and 5 cases (3.16%) to which the sisters were diagnosed with the same pathology.

All the patients were multiparous with an average of 2.32 births, and an interval between 1-4 births. Namely, 150 were vaginal births (94.9%) and only 8 (5.1%) were realized by caesarean section. In 27 cases (18%) of the 150 vaginal births, the birth was achieved before the schedule and in 8 cases (5.33%) the fetuses were diagnosed with macrosomia. Furthermore, 83 patients (55.33%) of those who gave birth vaginally needed episiotomy.

Digestive dysfunction represented by constipation, difficulty emptying the rectum, incomplete defecation or defecation assisted manually, fecal emergency and irritable bowel syndrome were incriminated in the etiopathogenesis of the pelvic organs prolapse. In our group of patients, 83 of them (53%) were identified as suffering from chronic constipation.

The postmenopausal hormonal disorders, found in our study in 75% of the patients, are incriminated in the occurrence of digestive dysfunction, reflected by chronic constipation. Consequently, this can lead to damage of the pelvic floor musculature and innervation, causing the pelvic organs prolapse develop.

None of the examined patients showed grade III obesity (BMI > 40). Only one patient (0.63%) was recorded with grade II obesity (BMI 35 to 39.9) and 15 patients (9, 49%) with grade I obesity (BMI 30 to 34.9). Most of the patients, 83 of them (52.53%), were overweight (BMI 25 to 29.9) and 59 of them (37.34%) were normal weight (BMI 18.5 to 24.9).

The incidence of the pelvic organs prolapse occurred after hysterectomy was estimated at 36 cases per 10,000 patients per year. In the personal study 29 patients (18.30%) had a history of hysterectomy, which is similar with the results in the literature.

All the patients enrolled in the study had an insidious onset of the disease. The time between the beginnings of the symptoms and the diagnosis onset varied between 1 and 6 months, with an average of 6 weeks.

The most frequent symptoms observed in 120 cases (75.94%) was the sensation of a bubble in the vagina or vaginal pressure, but 20 patients (12.65%) complained of urinary incontinence and 18 patients (11.39 %) of dyspareunia. The interval elapsed between onset of the symptoms and diagnosis onset ranged from 1 to 36 months, with an average of 2.71 months. As for the grades of the prolapse for

patients of our study, the result of clinical examination revealed grade II pelvic organs prolapse in 30 cases (18.98%), grade III in 93 cases (58.86%) and grade IV in 35 cases (22.15%).

The urodynamic study conducted on all the patients have shown that 54 patients (34.17%) were already suffering from stress urinary incontinence, only 7 of them (4.43%) were affected by detrusor hyperactivity and 97 patients (61.39 %) did not show any type of urinary incontinence.

The operative technique used in this study for all the patients was robotic assisted laparoscopic promontofixation. We used the daVinci® surgical system with 4 arms and 5 trocars to realize the operation. Simultaneously associated operations were performed: total or subtotal hysterectomy, placing of TVT-O sling (Tension Free Vaginal Tape Shutter - TVT-O) ovariectomy and cure of inguinal hernia.

Objective assessment of the postoperative outcomes was based on clinical examination and was focused on the following parameters: the degree of prolapse, presence of urinary incontinence, constipation or other complications.

Healing was defined as the absence or presence of the prolapse or the persistence of prolapse degree less than 2. Recurrence was defined as the presence of a prolapse degree ≥ 2 at the postoperative controls.

The presence of any symptom that is found at the postoperative controls and it was also present before the operation is considered to be persistent. The symptoms which were not present prior to surgery, but appeared after the surgery were considered to be *de novo* cases.

In the immediate postoperative period, there has been one complication (0.63%) recorded. It occurred due to intestinal obstruction that required laparoscopic adhesiolysis with slow resumption of the intestinal transit. Another complication was the abdominal wound infection in one case (0.63%) which was treated conservatively (daily disinfection and oral antibiotic).

A bladder catheter was placed for all the patients for a period of 48 hours. In two cases (1.26%) an "in-out" catheterization was used due to an important urinary residue (post-TVT-O). In these latter cases, at the two weeks postoperatively control, urinary residue was insignificant.

The late postoperative complications were represented by constipation, coccygeal pain, hypogastric and inguinal pain and abdominal pain after physical exercise in one case (6.32%).

The length of hospital stay ranged from 5 to 17 days with an average of 5.12 days, and postoperative follow up was in 7 months average. The first check was carried out 2 weeks after discharge. At the end of the postoperative follow-up, one patient (0.63%) was diagnosed with recurrence of prolapse grade 3. No intervention was needed in this case giving the fact that the patient was asymptomatic.

The operating time ranged between 100-250 minutes (depending on concurrent surgical interventions) with an average of 142.37 minutes. The average length of stay was 5.12 days with a range between 5 and 17 days. During the surgery we noted minimal blood loss ranging from 10-50ml with an average of 26,48ml per operation.

Regarding the costs of the robotic assisted laparoscopic promontofixation, they varied, in our study, between 220.46 and 1788.2 Euro with an average of 961.24 Euro per operation.

For the subjective evaluation of the results, the questionnaires contained questions designed to assess patients' quality of life and were used both in clinical practice and in clinical trials. Subjective assessment of the patients in our study group proved that the questionnaires were reliable to provide information about the impact on the pelvic floor and pelvic floor pain. These two questionnaires evaluate the results of anatomical and functional long-term results after surgery.

It is important to mention that the patients who were interrogated responded to all the questions. Thus, they describe a significant improvement in symptoms such as loss of the sensation of vaginal pressure, discomfort or pain in the genital area; also they reported the physical disappearance of the prolapse and improving of the micturition and defecation act after surgery.

After completing the questionnaire, 98% of patients considered the robotic assisted laparoscopic promontofixation to be successful and 96% of them would appeal to the same type of surgery if they happen to be subjected to surgery for pelvic organs prolapse cure again.

Surgery treatment is the essential solution for the severe pelvic organs prolapse (grade II-IV classification Baden Walker). Therefore, the surgical treatment goals are clear: reducing prolapse, disappearance of functional symptoms, patient satisfaction and to avoid complications.

However, whether the surgical technique shall be conducted is determined by the following criteria: age, the health condition of the patient, the degree pelvic

organs prolapse evaluated after Baden-Walker classification, the preferences of the patient, the logistics of the service and the expertise of the surgical team.

The robotic assisted laparoscopic promontofixation, as a minimum invasive technique was the subject of this study (158 cases). It is considered to be a safe technique, precise, with anatomical and functional results comparable to other surgical techniques that use the abdominal approach.

The advantages of using daVinci® robotic system are: reduced postoperative morbidity, zero postoperative mortality (in the study conducted by us) and the reduced rate of late postoperative complications and relapses.

The questionnaires for to assessing the quality of life are helpful in order to better understand the complex pathology of the pelvic organs prolapse. They also contribute to the improvement of the surgical techniques which aim to reach four major goals: reducing prolapse, disappearance of functional symptoms, patient satisfaction by giving a better quality of life and avoid complications.

Key words: pelvic organs prolapse, robotic assisted laparoscopic promontofixation, quality of life questionnaires.