

Str. Dionisie Lupu 37, sector 2, București, 020021, România, www.umfcd.ro, email: rectorat@umfcd.ro

UNIVERSITY OF MEDICINE AND PHARMACY 'CAROL DAVILA', BUCHAREST DOCTORAL SCHOOL FIELD OF MEDICINE

The impact of pelvic floor surgery on patients' quality of life ABSTRACT OF THE PhD THESIS

PhD supervisor: PROF. UNIV. DR. MISCHIANU DAN

> PhD student: MARCU RADU DRAGOŞ

YEAR 2024

Table of contents

Introduction6
I. General part9
Chapter 1: General notions regarding the anatomy of the pelvic floor supportive
structures9
Chapter 2: General concepts regarding the etiology, symptoms, diagnosis and the
treatment of pelvic floor static disorders16
2.1. Epidemiology16
2.2. Symptoms17
2.3. Clinical examination and paraclinical investigations
2.4. Surgical techniques applicable in pelvic floor static disorders23
2.5. Concepts regarding grafts used in the treatment of genital prolapse33
II. Original part (Personal contributions)37
Chapter 3: Working hypothesis and general objectives
Chapter 4: General research methodology39
Chapter 5: Data regarding the studied patient cohort42
5.1. Descriptive statistics of preoperative data42
5.2. Analytical statistics of preoperative data51
5.3. Surgical treatment of genital prolapse61
5.4. The evolution of preoperative symptoms in the postoperative period64
5.5. Complications65
5.6. Objective success, Recurrence and Subjective Success
Chapter 6. The evaluation of the patients' quality of life - Study I69
6.1. Introduction69
6.2. Materials and methods69
6.3. Results69
6.3.1. Preoperative evaluation of quality of life using the PFDI-20
questionnaire69
6.3.2. Evolution of PFDI-20 and UDI-6 values postoperatively at 6 and 12
months compared to the preoperative values70

6.3.3. Correlation between preoperative PFDI-20 values and the following menopause, type II diabetes, degree of prolapse, parameters: 6.3.4. Comparative evaluation of the evolution of patients' quality of life preoperatively and postoperatively (at 6 and 12 months) and between the two surgical techniques......74 6.3.5. Correlation between postoperative urinary symptoms and the type of 6.3.6. Correlation between de novo urinary urgency and the type of surgical 6.3.7. Correlation between the cases of postoperative urinary retention and the 6.3.8. Correlation between the type of surgery (technique I versus technique **6.3.9.** Correlation between the type of surgical intervention (technique I versus technique II) and the sensation of postoperative pelvic discomfort87 6.3.10. Correlation between the type of surgical intervention and the risk of postoperative vaginal erosion......90 6.3.11. Correlation between the type of surgical intervention and the risk of 6.3.12. Correlation between the surgical intervention and the factors involved in oxidative stress (type II diabetes, smoking, chronic cough, menopause, body mass index), factors that may be implicated in the process of maladaptive healing and, consequently, in the exposure of the polypropylene 6.3.13. Correlation between objective success and the type of surgical intervention (technique I versus technique II)......94 6.3.14. Correlation between objective success and the following factors: type II diabetes, smoking, menopause, body mass index.....94 6.3.15. Correlation between the type of surgical intervention and postoperative 6.3.16. Correlation between postoperative recurrence and the following factors: type II diabetes, menopause, chronic cough, degree of prolapse, body

6.4. Discussions and conclusions	98
Chapter 7. The evaluation of pre- and postoperative sexual quality of life	e - Study
П	
7.1. Introduction	
7.2. Materials and methods	99
7.3. Results	99
7.3.1. Preoperative evaluation of sexual function	
7.3.2. The evaluation of postoperative sexual function at 6 and 12	months
compared to preoperative PISQ-12 values	100
7.3.3. Correlation between preoperative PISQ-12 values and the f	ollowing
parameters: menopause, degree of prolapse, body mass index, type II	diabetes,
age, stress urinary incontinence	101
7.3.4. The evolution of sexual function preoperatively versus postop	eratively
between the two surgical techniques (technique I versus technique II)	104
7.3.5. Correlation between postoperative dyspareunia and the type of	surgical
intervention (technique I versus technique II)	107
7.3.6. Correlation between de novo dyspareunia and the type of	surgical
intervention (technique I versus technique II)	109
7.4. Discussions and conclusions	110
Chapter 8. Discussions	111
Chapter 9. Conclusions and personal contributions	115
9.1. Conclusions	115
9.2. Personal Contributions	
Bibliography	120
Appendices	

Introduction

Pelvic floor static disorders represent a complex chapter of urogynecology, considering the multitude of associated symptoms and their negative impact on patients' quality of life, as well as the numerous surgical techniques available. Often, the therapeutic approach to these cases proves to be a real challenge.

From the perspective of the multitude of associated symptoms and how they influence daily activities, patients with genital prolapse may develop various behavioral disorders such as low self-esteem, shame, anxiety, depression, fear of rejection, thereby tending to isolate themselves and also to neglect this pathology.

The treatment of genital prolapse offers a variety of surgical techniques, more or less effective, ranging from open approaches (abdominal or transvaginal) to laparoscopic or robotic approaches. For a long time, the treatment of choice has been represented by transvaginal hysterectomy in combination with classical colporrhaphy, but it has been observed that this surgical technique is associated with a relatively high recurrence rate of prolapse.

This study focuses primarily on the surgical treatment of anterior genital prolapse using a transvaginal approach with a four-arm polypropylene mesh.

The purpose of this study is to compare two surgical techniques in terms of their effectiveness (therapeutic success, impact on the quality of life and sexual function), as well as the safety of the transvaginal approach with polypropylene mesh in the surgical treatment of anterior genital prolapse.

The main objectives of the study are to evaluate the postoperative evolution of patients' quality of life and sexual function, as well as to identify notable differences between the two surgical techniques regarding these aspects.

The postoperative results revealed a significant improvement in the preexisting symptoms for both surgical techniques, as well as in achieving anatomical success. Statistical analysis of the postoperative outcomes demonstrated the superiority of one of the two techniques in terms of the positive impact on sexual quality of life, while the second technique provided superior results in terms of symptoms associated with prolapse, including urinary symptoms.

4

General part

Chapter 1. General notions regarding the anatomy of the pelvic floor supportive structures

The mechanisms of support at the level of the pelvic floor play an important role in preventing genital prolapse and stress urinary incontinence. The support of the pelvic organs (bladder, uterus, vagina, and rectum) is provided by the bony pelvis and the pelvic diaphragm. The constituent elements of the bony pelvis have numerous protrusions and prominences to which muscles, ligaments and fascia attach, which play a role in supporting the pelvic organs. The pelvis can be divided by an imaginary plane that passes through the sacral promontory and pubic symphysis into the greater pelvis, which contains the viscera of the lower abdomen (located above this imaginary plane), and the lesser pelvis, which extends inferiorly from the greater pelvis and is bordered caudally by the muscles of the pelvic floor. However, the closure of the lower opening of the pelvis is not complete, due to the presence of the urogenital hiatus, which allows for the elimination of fecal matter and urine, as well as sexual intercourse and childbirth [1].

Normally, the impact of physiological pressure from the abdominal cavity and gravitational forces on the pelvic floor is attenuated by a series of elements, so that a large portion of these forces is directly absorbed by the bony structures and to a lesser extent by the muscular and ligamentous structures of the pelvic floor. The lumbosacral lordosis, more evident especially in young patients in their reproductive period, as well as the sacrococcygeal concavity due to the anteriorly arched disposition of the sacrum and coccyx, which contributes to reducing the diameter of the lesser pelvis, are elements that cause the aforementioned pressures to be absorbed primarily by the constituent elements of the bony pelvis and less by the muscular structures that occlude the inferior opening of the bony pelvis when they are in an upright position. Aging and the physiological processes associated with aging lead to the progressive attenuation of the lordosis. As a result, these forces will be increasingly absorbed by the muscles of the pelvic floor, favoring the occurrence of genital prolapse [1, 2].

At the level of the tip of the coccyx, there is a dense ligamentous structure that results from the fascial condensations of the levator ani muscles and continues anteriorly to the level of the anus. This structure is known as the sacrococcygeal raphe or levator plate and plays a role in supporting the pelvic organs, absorbing some of the forces acting on the pelvic floor [3].

The urinary bladder, urethra, uterus, and vagina are connected to the walls of the bony pelvis through a connective tissue known as the endopelvic fascia. This fascia is actually a fibroelastic connective tissue composed of collagen, elastin, smooth muscle fibers, fibroblasts, and vascular elements. The endopelvic fascia is essentially a continuation of the subperitoneal connective tissue, forming a unified structure located between the pelvic peritoneum and the plane of the pelvic diaphragm muscles, which continues with the visceral fascia on the surface of the pelvic organs. The segment of fascia that inserts at the level of the uterus is called the parametrium, while the segment that inserts at the level of the vagina is known as the paracolpium [2, 4].

The endopelvic fascia exhibits areas of condensation in certain regions, giving rise to ligamentous structures that play a role in supporting and stabilizing certain segments of the pelvic organs (the uterosacral ligaments, cardinal ligaments, pubourethral ligaments), as well as fasciae or septa that separate the vagina from the urinary bladder and rectum (the pubocervical septum, rectovaginal septum) [3].

Under normal conditions, the musculofascial and ligamentous elements of the pelvis provide the pelvic organs with adequate support, imparting significant resistance against the force of gravity and the tendency to prolapse.

Chapter 2. General concepts regarding the etiology, symptoms, diagnosis and the treatment of pelvic floor static disorders

2.1 Epidemiology

According to the available data in the specialized literature, it is estimated that approximately 50% of women will develop some degree of genital prolapse during their lifetime. However, it should be noted that the presence of prolapse is not necessarily associated with specific symptoms, especially in patients with mild prolapse [5].

This condition is more prevalent with increasing age. Studies have reported an incidence of prolapse in young patients of up to 6%, with the incidence significantly increasing with advancing age (approximately 30% for patients aged between 50 and 60 years, and potentially reaching up to 50% around the age of 80). Additionally, according to

published data, the average age of patients presenting to a doctor due to associated symptoms is approximately 60 years [6].

2.2. Symptoms

Mild forms of genital prolapse are usually asymptomatic and do not require surgical treatment. The clinical symptoms include the presence of a vaginal bulge, a sensation of pelvic pressure, pain in the lower abdominal and lumbar areas, as well as sexual difficulties. The lower back pain in genital prolapse occurs due to increased tension on the uterosacral ligaments. The associated symptoms of genital prolapse are represented by urinary urgency or urinary incontinence, as well as the inability to have a complete bowel movement and the onset of constipation. [7].

2.3. Clinical examination and paraclinical investigations

The clinical examination should include the evaluation of the patient's body systems to identify any musculoskeletal, connective tissue, neurological or pulmonary disorders that may affect the pelvic muscles and the supporting structures located at this level. The external genitalia, vagina, and estrogenic status should be assessed. Any signs of hypoestrogenism, such as changes in vaginal mucosa or perineal skin, should be noted [8].

As part of the clinical examination, it is important to assess the quality of life of patients diagnosed with genital prolapse. In this regard, several questionnaires have been validated, including the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ) [9].

Uroflowmetry can be used to evaluate the time until complete emptying of the urinary bladder, as well as to assess post-void residual urine. Investigations such as urine analysis and urine culture are necessary to identify any urinary tract infections.

Transabdominal ultrasound examination allows for the evaluation of the bladder wall contour, measurement of bladder wall thickness and also for the determination of post-void residual urine volume. Renal ultrasound is useful for assessing the presence of ureterohydronephrosis in patients undergoing surgical treatment for prolapse [6].

2.4. Surgical techniques applicable in pelvic floor static disorders

Regarding the topographic organization of the pelvis in the horizontal plane, it consists of three compartments, separated by the pubocervical fascia and the rectovaginal septum. The anterior compartment contains the urinary bladder and urethra, the middle compartment houses the uterus and vagina, and the rectum is located in the posterior compartment [10].

The establishment of the therapeutic approach must take into account the mechanism of prolapse development, the patient's age, the degree of prolapse, sexual activity (present or absent), the concomitant presence of stress urinary incontinence or other types of prolapse, as well as any associated conditions.

2.5. Concepts regarding grafts used in the treatment of genital prolapse

These grafts used in the treatment of pelvic floor static disorders must meet a series of conditions in order for their use to yield superior results compared to classical techniques. Therefore, a graft must be composed of a safe and sterile material, without any potential for allergies or carcinogenicity. It should be physically and chemically inert, avoiding any marked inflammatory response. It should also be mechanically strong, exhibiting a degree of elasticity and flexibility, while presenting a low risk of infection and rejection. Additionally, it should be readily available and provide good anatomical and functional outcomes [11].

Original part (Personal Contributions)

Chapter 3. Working hypothesis and general objectives

The approach to this topic was due to the fact that pelvic floor static disorders represent an important chapter in urogynecology, often negatively affecting the patients' quality of life. The main objective of this study is to comparatively evaluate two surgical techniques in terms of efficacy (therapeutic success, impact on patients' quality of life and sexual function), as well as the safety of the transvaginal approach with polypropylene mesh in the surgical treatment of anterior genital prolapse (complications occurring in the postoperative period).

Chapter 4. General research methodology

This study is a prospective, observational and comparative analysis of patients diagnosed with symptomatic anterior genital prolapse (at least grade II) who underwent surgical treatment through the transvaginal approach with a four-arm polypropylene mesh, using one of two surgical techniques (Technique I - all four arms of the mesh passed through the obturator foramen versus Technique II - two arms passed through the obturator foramen and two passed through the sacrospinous ligaments). The study included 118

patients and was conducted at the Urology Clinic of the Central Military Emergency Hospital "Dr. Carol Davila" from January 1, 2018, to December 31, 2021.

Patient data was stored using the Excel program. Statistical analysis was performed using IBM SPSS version 28 for Mac iOS.

Chapter 5: Data on the study population

Age of the patients

The average age of the patients included in the study was $57,3 \pm 7$ years, with a median of 57,5 years, ranging from 46 to 74 years. The distribution of patients according to age groups was as follows:

- <50 years 23 patients (19,49%);
- 50-59 years 52 patients (44,07%);
- 60-69 years 39 patients (33,05%);
- >70 years 4 patients (3,39%).

Number of Births

The average number of births was 2,07 +/- 0,5, with a median of 2 births, ranging from one to three births. The distribution of patients according to the number of births was as follows:

- 1 birth: 11,01%;
- 2 births: 71,2%;
- 3 births: 17,79%.

Menopause

Regarding this parameter, 81 patients (68,64%) were at menopause at the time of study initiation, compared to 37 premenopausal patients (31,36%).

Diabetes Mellitus

The percentage of patients diagnosed with diabetes mellitus at the time of study enrollment was 22,88% (27 patients out of a total of 118).

Chronic Cough

31,36% of patients (37/118 patients) had chronic cough, which is recognized as a factor involved in the development of pelvic floor static disorders.

Surgical History

18 out of the 118 patients (15,25%) had a history of abdominal-pelvic surgeries, which is also a possible risk factor in the etiopathogenesis of genital prolapse.

Type and degree of genital prolapse

All patients included in the study presented with anterior prolapse (grade ≥ 2), and only a certain percentage also presented with posterior prolapse.

Anterior Prolapse – 118 patients (100%):

- Grade II 30 patients (25,4%);
- Grade III 74 patients (62,7%);
- Grade IV 14 patients (11,9%).

Posterior Prolapse – 43 patients (36,4%):

- Grade II 24 patients (20,3% out of the 118);
- Grade III 16 patients (13,6% out of the 118);
- Grade IV 3 patients (2,5% out of the 118).

Surgical treatment of genital prolapse

• Anterior Prolapse

For the surgical correction of anterior prolapse, Technique I (4TOT) was used in 57 out of 118 cases (48,31%), while Technique II (2TOT+2SS) was used in the remaining cases (61 out of 118 patients -51,69%).

• Posterior Prolapse

For patients who also presented with posterior prolapse (43 out of 118 patients), two additional surgical techniques were performed for its correction. These included either a second polypropylene mesh with two arms passed through the sacrospinous ligaments (posterior mesh) - Technique III, or posterior colporthaphy - Technique IV.

Objective or anatomical success was defined as the absence of prolapse during the postoperative follow-up period or the detection of a prolapse of no more than grade I. Thus, the objective success rate was 93,25% (110 out of 118 patients).

Postoperative recurrence of the prolapse, which required subsequent surgical intervention, was detected in 7 out of 118 patients (5,9%).

Subjective success was evaluated through question number 3 of the PFDI-20 questionnaire and recorded an increase of 76,3% following surgical treatment, p<0,001.

Chapter 6: The evaluation of the patients' quality of life - Study I

6.1 Introduction

Pelvic floor static disorders invariably have a negative impact on the pacients' quality of life due to the multitude of associated symptoms, with numerous implications both on a personal level and also on a social and professional level.

6.2 Materials and methods

The aim of the study was to comparatively evaluate two different surgical techniques and their impact on the patients' quality of life, using the PFDI-20 questionnaire and the UDI-6 subscale. The evaluation was conducted preoperatively and postoperatively at 6 and 12 months.

6.3 Results

6.3.1 Evolution of PFDI-20 and UDI-6 values postoperatively at 6 and 12 months compared to the preoperative values

Surgical treatment resulted in a significant improvement in the patients' quality of life, as evidenced by a progressive and consistent decrease in the values obtained in the PFDI-20 and UDI-6 questionnaires, both at 6 months postoperatively and at 12 months, p<0,001.

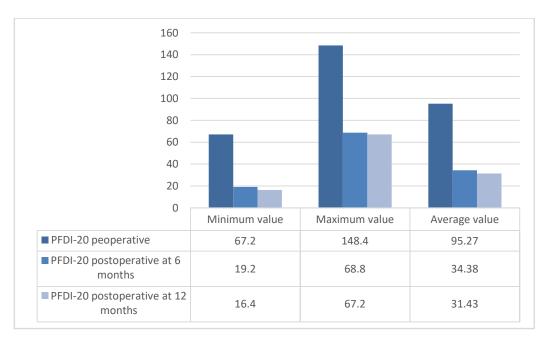


Fig. 6.1. Distribution of preoperative versus postoperative PFDI-20 values

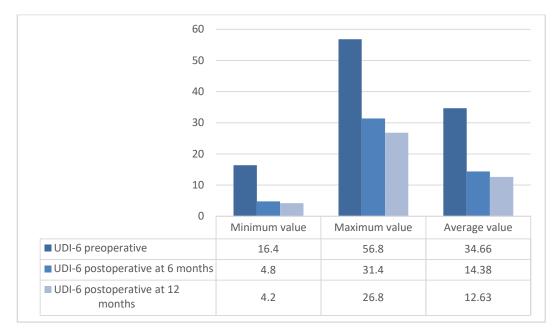


Fig. 6.2. Comparative evolution of UDI-6 preoperative versus postoperative at 6 and 12 months.

6.3.2. Comparative evaluation of the evolution of patients' quality of life (PFDI-20 and UDI-6) preoperatively and postoperatively (at 6 and 12 months) and between the two surgical techniques

Regarding the difference between the two surgical techniques (technique I versus technique II) in terms of how they improved the quality of life for the patients (in terms of reducing the PFDI-20 score), there was no statistically significant difference observed, neither postoperatively (at 6 months postoperatively p=0,13 and at 12 months postoperatively p=0,15), nor preoperatively between the two analyzed groups (group I - technique I versus group II - technique II) p=0,17.

Regarding the difference between the two surgical techniques (technique I - 4TOT versus technique II - 2TOT+2SS) in terms of how they improved the urinary symptoms (in terms of reducing the UDI-6 score), it should be noted that patients who underwent technique II had lower postoperative UDI-6 values compared to those who underwent technique I, p<0,001.

6.3.3. Correlation between postoperative urinary symptoms and the type of surgical intervention

Preoperatively, urinary symptoms (other than stress urinary incontinence - SUI) were identified in 103 out of 118 patients (87,35%). Postoperatively, this percentage decreased to 17,8% (21 out of 118 patients), p<0,001.

Both surgical techniques were associated with a significantly lower number of cases of postoperative urinary symptoms (other than SUI). Although the number of cases of postoperative urinary symptoms was lower in the group of patients who underwent technique II compared to technique I (9 cases versus 12 cases), the statistical analysis could not clearly differentiate between the two techniques due to insufficient statistical power, p=0,47.

6.3.4. Correlation between de novo urinary urgency and the type of surgical intervention

Considering the similar number of patients who experienced postoperative de novo dyspareunia, as well as the percentage of these patients within the total number of patients in each group (technique I group versus technique II group), the statistical analysis was unable to demonstrate a direct correlation regarding the superiority of one of the two techniques and the occurrence of de novo dyspareunia in the postoperative period, p=0,77.

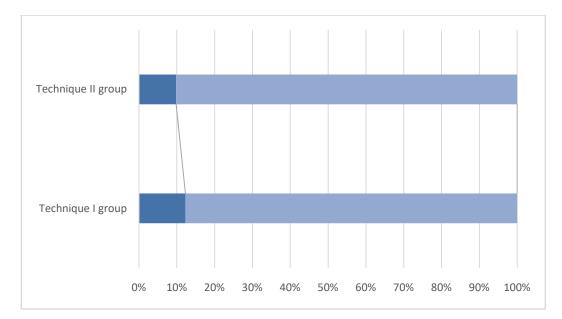


Fig. 6.3. Comparative distribution of de novo urinary urgency between the two techniques

6.3.5. Correlation between the type of surgical intervention type (technique I versus technique II) and postoperative pelvic discomfort sensation

Regarding the evolution of postoperative pelvic discomfort, a significant reduction in the number of patients experiencing this symptom was observed, with statistically superior and significant results in favor of technique I: postoperative technique I - 10 cases (17,5% of the total patients who underwent technique I) versus 13 cases for technique II (34,4% of the total cases who underwent technique II); p=0,05, RR=0,51, 95% CI (0,23-0,98).

According to the statistical analysis, technique I demonstrates a superior degree of protection in the occurrence of postoperative pelvic discomfort.

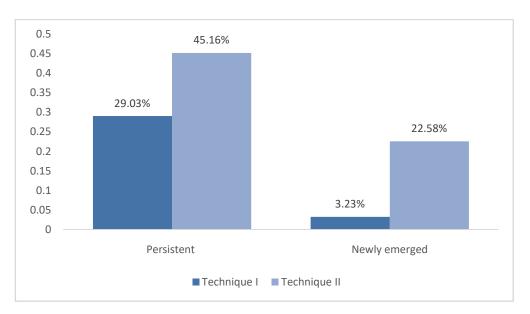


Fig. 6.4. Distribution of postoperative pelvic discomfort based on the timing of occurrence and the performed surgical technique

6.3.6. Correlation between the type of surgical intervention and the risk of postoperative vaginal erosion

Although fewer patients who underwent technique I (4TOT) developed postoperative vaginal erosion compared to the other group, statistical analysis failed to establish a direct correlation between the type of surgical intervention (technique I versus technique II) and the risk of postoperative vaginal erosion, p=0,27.

6.3.7. Correlation between the type of surgical intervention and the risk of postoperative mesh exposure

During the postoperative period, 5 out of 118 patients (4,2%) were found to have vaginal mesh exposure.

Statistical analysis did not reveal a direct correlation between the type of surgical intervention (technique I versus technique II) and the risk of postoperative mesh exposure, p=0,67.

6.3.8. Correlation between objective success and the type of surgical intervention (technique I versus technique II)

Postoperatively, a higher number of cases of objective success were identified among patients who underwent technique II compared to technique I (p=0,028). Therefore, a

significant difference is observed between the two techniques in terms of achieving objective success, favoring technique II.

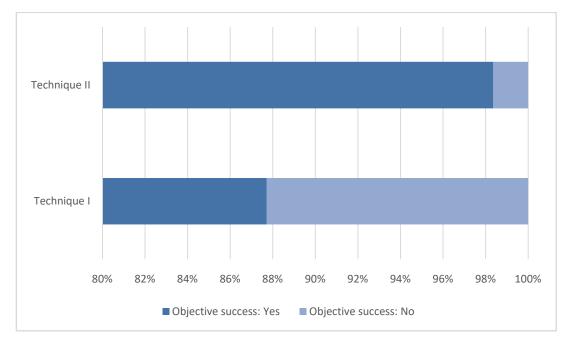


Fig. 6.5. Distribution of objective success according to the performed surgical technique

6.3.9. Correlation between the type of surgical intervention and postoperative recurrence

Postoperatively, 7 patients have experienced recurrence, all of whom underwent Technique I. Statistical analysis revealed the superiority of Technique II, p=0,005.

• Recurrence - Technique I: 7/57 patients (12,3% of the total patients who underwent Technique I);

• Recurrence - Technique II: 0/61 patients.

6.4. Discussion and conclusions

Both surgical techniques significantly improved the values of the PFDI-20 score and consequently the quality of life, but no superiority could be demonstrated between the two techniques in this aspect. However, a statistically significant difference between the two surgical techniques was observed in the case of the UDI-6 subscale, which evaluates urinary symptoms. Thus, the superiority of Technique II could be demonstrated.

Chapter 7. Assessment of Pre- and Postoperative Sexual Quality of Life -Study II

7.1 Introduction

The occurrence of pelvic floor static disorders throughout life will have a negative impact on the sexual function of these patients. Surgical techniques aimed at correcting genital prolapse, by addressing the anatomical defect, can greatly improve the quality of sexual function. However, at the same time, they can also be accompanied by the onset of new symptoms that could affect the sexual function.

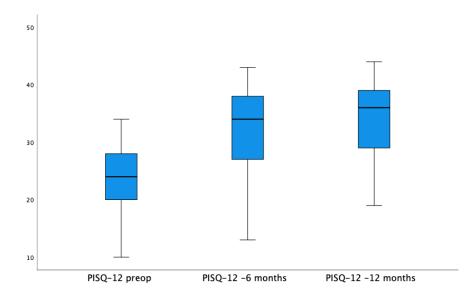
7.2 Materials and methods

This study comparatively evaluated two different surgical techniques in terms of their impact on the progression of sexual function using the PISQ-12 questionnaire. This questionnaire was used both during the preoperative evaluation and subsequently during the postoperative evaluations at 6 and 12 months.

7.3 Results

7.3.1 The evaluation of postoperative sexual function at 6 and 12 months compared to preoperative PISQ-12 scores

Following the surgical interventions, a significant improvement in sexual function was observed, as confirmed by a progressive increase in the PISQ-12 test score both at 6 months postoperatively and subsequently at 12 months (p<0,001).





7.3.2. The evolution of sexual function preoperatively versus postoperative (at 6 and 12 months) between the two surgical techniques (Technique I - 4TOT versus Technique II - 2TOT+2SS)

Statistical analysis revealed a significant difference between the preoperative and postoperative PISQ-12 scores (at 6 and 12 months) between the two patient groups (Technique I versus Technique II), with superior and statistically significant results in favor of Technique I.

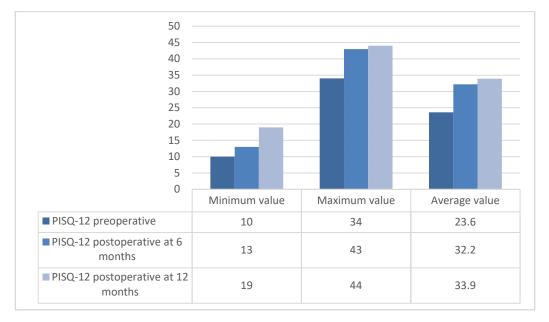


Fig. 7.2. Comparative evolution of PISQ-12 preoperative versus postoperative at 6 and 12 months.

7.3.3. Correlation between postoperative dyspareunia and the type of surgical intervention (technique I versus technique II)

Regarding the evolution of postoperative dyspareunia, a significant reduction in the number of patients with dyspareunia was observed, with statistically superior and significant results in favor of technique I (p<0,001): postoperative technique I - 1 case of dyspareunia (1,75% of the total patients who underwent technique I) versus 13 cases of postoperative dyspareunia for technique II (21,33% of the total cases who underwent technique II); p<0,001, RR=0,082, 95% CI (0,011-0,60).

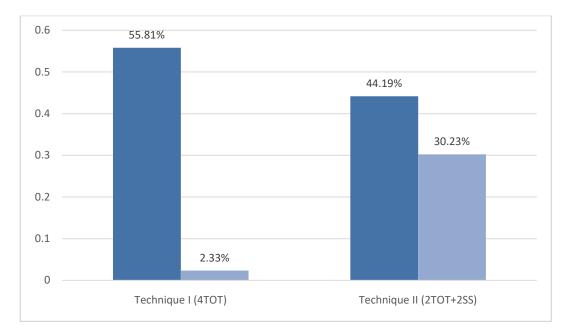


Fig. 7.3. Comparative evolution of preoperative versus postoperative dyspareunia for each reported technique as a percentage of the total number of dyspareunia cases.

7.3.4. Correlation between de novo dyspareunia and the type of surgical intervention (technique I versus technique II)

Postoperatively, it was found that all cases of de novo dyspareunia were recorded in the group of patients who underwent technique II (either technique II alone or in combination with technique IV): technique I - 0 cases of de novo dyspareunia versus technique II - 6 cases (9,83% of the total number of patients who underwent technique II), p=0,028.

7.4. Discussions and conclusions

Both surgical techniques showed a significant improvement in postoperative sexual function, with better results in favor of technique I. Regarding the evolution of preoperative dyspareunia cases, a reduction in the number of cases was observed in the postoperative period, with technique I providing superior results. It should be noted that this aspect also remained true for patients with de novo dyspareunia, as the majority of these new cases of dyspareunia were associated with technique II.

Chapter 8. Discussions

The preoperative analytical statistics revealed a direct correlation between the degree of genital prolapse and the following parameters:

• Number of childbirths, p<0,001. The statistical data revealed that a higher number of childbirths was correlated with a significantly higher degree of genital prolapse.

• Menopause, p<0,001. The correlation between menopause and the degree of prolapse was most evident in patients diagnosed with grade III and IV prolapse.

• Type II Diabetes, p<0,001. This correlation was statistically significant only in patients diagnosed with grade IV genital prolapse. It is important to highlight that these patients had high body mass index values, categorizing them as overweight or obese patients, and it is well-known that there is an association between high body mass index values and type II diabetes.

• Chronic cough, p=0,01. The correlation was evident only in patients with grade IV prolapse.

There was no proven association between smoking (as a factor that negatively affects the oxidative stress) and the degree of genital prolapse, p=0,26.

Regarding the correlation between the degree of prolapse and the presence of stress urinary incontinence, the statistical evaluation of preoperative data demonstrated a direct association only in patients diagnosed with grade III and IV prolapse.

The statistical analysis of preoperative data showed a direct correlation between the degree of genital prolapse and the value of post-void residual urine, p<0,001. Thus, the value of post-void residual urine varied significantly depending on the degree of prolapse, with a higher value in patients with grade III prolapse and especially in those with grade IV prolapse.

The presence of ureterohydronephrosis in this study was preoperatively detected in 7 out of 118 patients (5,9%):

- Grade II UHN 5/118 patients (4,2%);
- Grade III UHN 2/118 patients (1,7%).

The value of preoperative ultrasound-evaluated post-void residual urine in all seven cases varied between 240 ml and 350 ml. Additionally, these patients also had elevated values of serum creatinine, ranging from 1,56-2,42 mg/dl.

In all seven cases with preoperatively detected UHN, the surgical interventions proved to be effective in addressing this aspect, resulting in postoperative resolution of UHN and significant improvement in renal function, with normalization of serum creatinine values in 4/7 cases. In the remaining three cases, the persistence of renal dysfunction (as indicated by elevated serum creatinine levels) can be explained by the

preexistence of diabetes mellitus, as it is well-known that this condition is often accompanied by the development of nephropathy.

Regarding the postoperative complications, the following should be mentioned:

• Postoperative bleeding - 13/118 cases (11%), with no statistical significance between the two surgical techniques. In all these cases, a vaginal mesh was inserted for hemostatic purposes and surgical re-intervention was not necessary.

• Urinary retention - 6/118 (5,1%), with no statistical significance between the two surgical techniques (technique I - 3 cases versus technique II - 3 cases). In all these cases, urethral catheterization was performed for several days, along with the administration of non-steroidal anti-inflammatory drugs.

• Urge incontinence - 13/118 (11%). It is important to note that in 3 cases, urge incontinence was newly developed, while in the remaining 10 cases, it was present preoperatively but of lesser intensity. Treatment for these symptoms involved the administration of antimuscarinic medication for a period of 3-6 months. Considering the close distribution of these cases in both patient groups (technique I - 3 cases versus technique II - 2 cases), no statistical superiority of one intervention over the other could be demonstrated.

• Vaginal erosion - 8/118 (6,8%). Statistical analysis did not demonstrate the superiority of one surgical technique in terms of the risk of this complication, although fewer cases of vaginal erosion were identified in the group of patients who underwent technique I (2 patients in technique I versus 6 patients in technique II). The treatment for this complication was conservative and involved the administration of topical estrogen (1-3 months), which was effective in all 8 cases.

• Exposure of the polypropylene mesh - 5/118 (4,2%). In this case as well, statistical analysis could not demonstrate the superiority of one intervention over the other in reducing the risk of this complication (technique I - 3 patients versus technique II - 2 patients). In all these cases, reintervention was necessary, with the excision of the exposed mesh segment (central portion of the mesh).

• De novo dyspareunia - 6/118 (5,1%). All these cases were identified in the group of patients who underwent technique II. The therapeutic approach for these cases involved the administration of estrogen suppositories for a period of 1-2 months.

20

Chapter 9. Conclusions and personal contributions

9.1. Conclusions

The analysis conducted in this study regarding the comparative evaluation of two surgical techniques in the treatment of genital prolapse demonstrated a significant improvement in the patients' quality of life, as well as regarding the sexual function, for both techniques. It is important to emphasize that the analysis of the postoperative evaluation data revealed that one of the two techniques showed superior results in terms of the quality of postoperative sexual function, while the other technique showed superior results in terms of the improvement of preexisting urinary symptoms, leading to their remission.

9.2. Personal Contributions

1. Correlation between the performed surgical technique and the postoperative evolution of sexual function (PISQ-12). Postoperatively, an increase in the PISQ-12 score was observed for both surgical techniques, but it is worth mentioning that patients who underwent Technique I had higher postoperative PISQ-12 scores compared to those who underwent Technique II. Therefore, Technique I was associated with superior results in improving sexual function compared to Technique II, p<0,001.

2. Correlation between the type of surgical technique and the postoperative evolution of dyspareunia compared to preoperative results. Postoperatively, a significant reduction in the number of patients with dyspareunia was observed, with statistically superior results in favor of Technique I (p<0,001): postoperatively for Technique I – 1 case of dyspareunia (1,75% of the total patients who underwent Technique I) versus 13 cases of postoperative dyspareunia for Technique II (21,33% of the total cases who underwent Technique II).

3. Correlation between the type of surgical technique used and the occurrence of de novo dyspareunia. Postoperatively, it was found that all cases of de novo dyspareunia were recorded in the group of patients who underwent Technique II: Technique I – 0 cases of de novo dyspareunia versus Technique II – 6 cases (9,83% of the total patients who underwent Technique II), p=0,028. Thus, a direct correlation between Technique II and the risk of de novo dyspareunia could be proven.

4. Correlation between the performed surgical technique and the postoperative evolution of quality of life compared to preoperative values (PFDI-20). Postoperatively, a significant decrease in the values of the PFDI-20 questionnaire was

recorded for both surgical techniques compared to preoperative values (p<0,001), thus demonstrating a significant improvement in the quality of life for these patients. Regarding how the two surgical techniques improved the quality of life, superiority of one of the interventions could not be proven, as relatively similar results were obtained between the two techniques (p=0,13 at 6 months postoperatively and p=0,15 at 12 months postoperatively).

5. Correlation between the performed surgical technique and the postoperative evolution of preexisting vaginal foreign body sensation. The evolution of this symptom was favorable postoperatively for both surgical techniques, in terms of a significant reduction in the number of patients experiencing the persistence of this symptom (p<0,001). As for the superiority of one of the surgical techniques in reducing the number of patients with vaginal foreign body sensation in the postoperative period, statistical analysis did not detect a significant difference between the two surgical techniques (p=0,63).

6. Correlation between the type of surgical intervention (Technique I versus Technique II) and the postoperative evolution of preexisting pelvic discomfort sensation. Both surgical techniques have proven effective in significantly reducing the number of patients who continue to experience postoperative pelvic discomfort, p<0,001. Regarding the superiority of one of the surgical techniques in relation to this symptom, Technique I has shown superior results compared to Technique II (1 case for Technique I versus 13 cases for Technique II), p=0,05.

7. Correlation between the performed surgical technique and the postoperative evolution of urinary symptoms compared to preoperative values (UDI-6 subscale). Data analysis has demonstrated a statistically significant decrease in the values of the UDI-6 subscale postoperatively, p<0,001, which translates clinically to a significant improvement in urinary symptoms. As for the superiority of one of the two techniques, Technique II has been associated with significantly better results than Technique I, both at 6 months postoperatively and at 12 months postoperatively (p<0,001).

8. Correlation between de novo urinary urgency and the type of surgical intervention. Statistical analysis could not demonstrate a direct correlation regarding the superiority of one of the two techniques and the occurrence of de novo urinary urgency in the postoperative period, p=0,77. Postoperatively, 13 cases of de novo urgency were identified, 7 cases in the group of patients who underwent Technique I and 6 cases in the group who underwent Technique II.

9. Correlation between objective success and the type of surgical intervention. Postoperatively, more cases of objective success were identified among patients who underwent Technique II compared to Technique I, p=0,028 (objective success: 98,4% of total patients who underwent Technique II versus 87,7% in the case of Technique I).

10. Correlation between objective success and the presence of Type II Diabetes. Statistical analysis demonstrated that patients with type II diabetes had lower chances of achieving absolute objective success compared to non-diabetic patients, p=0,002, RR=0,79, 95% CI (0,64-0,97). Absolute objective success was achieved in 97,8% of total non-diabetic patients versus 77,8% of total diabetic patients.

11. Correlation between objective success and body mass index (BMI). Patients with objective success had a significantly lower BMI than those without objective success (p=0,005); the mean BMI in patients with objective success was $25,86 \pm 2,31$ compared to $29,13 \pm 2,74$ in those without objective success.

12. Correlation between objective success and menopause. The data obtained from the analysis were at the limit of statistical significance, p=0,055 (objective success - 100% of total patients who were not in menopause versus 90,1% of total patients in menopause).

13. Correlation between the type of surgical intervention (Technique I versus **Technique II**) and postoperative recurrence. Statistical analysis revealed the superiority of Technique II, p=0,005, with 7 cases of recurrence identified postoperatively, all of which were in the group of patients who underwent Technique I.

14. Correlation between postoperative recurrence and the presence of type II diabetes. More patients with type II diabetes experienced postoperative recurrence compared to non-type II diabetes patients (p<0,001).

15. Correlation between postoperative recurrence and the value of body mass index (BMI). Patients with higher BMI values were prone to higher rates of postoperative recurrence of prolapse. The average BMI value in patients with recurrence was 29,57 +/-2,63 compared to 25,86 +/- 2,30 in patients without recurrence.

16. Correlation between the type of surgical intervention and the risk of postoperative vaginal erosion. Statistical analysis could not demonstrate a direct correlation between the type of surgical intervention (Technique I versus Technique II) and the risk of postoperative vaginal erosion (p=0,27), although fewer patients who underwent Technique I developed postoperative vaginal erosion (2 cases versus 6 cases in the group of patients who underwent Technique II).

17. Correlation between the type of surgical intervention and the risk of postoperative exposure of the polypropylene mesh. Statistical analysis could not demonstrate a direct correlation between the type of surgical intervention and the risk of postoperative exposure of the mesh (p=0,67). Out of the 5 cases of mesh exposure, 3 were identified in the group that underwent Technique I and 2 cases in the group that underwent Technique II.

References

1. Corton MM. Anatomy of the pelvis: how the pelvis is built for support. Clin Obstet Gynecol. 2005 Sep;48(3):611-26.

Corton MM. Anatomy of pelvic floor dysfunction. Obstet Gynecol Clin North Am. 2009 Sep;36(3):401-19.

3. Albright TS, Gehrich AP, Davis GD, et al. Arcus tendineus fascia pelvis: a further understanding. Am J Obstet Gynecol 2005;193(3 Pt 1):677–81.

4. DeLancey JOL, Starr RA. Histology of the connection between the vagina and levator ani muscles: implications for the urinary function. J Reprod Med 1990; 35(8):765–71.

5. Siddiqui NY, Edenfield AL. Clinical challenges in the management of vaginal prolapse. International Journal of Women's Health. 2014; 6: 83–94.

6. **Marcu D**, Diaconu C, Iorga L, Bratu O, Mischianu D. Mesh colposacropexy in the management of anterior vaginal compartment prolapse. J Med Life. 2019 Jan-Mar;12(1):65-70.

7. Lumley J, Hakim N. New techniques in genital prolapsed surgery. Editura Springer, Londra, 2011, chapter 1 New considerations about pelvic floor anatomy, 3-7.

8. Guerette N, Neimark M, Kopka SL et al. Initial experience with a new method for the dynamic assessment of pelvic floor dysfunction in women: the Colpexin Pull Test. Int Urogynecol J. 2004;15(1):39-43.

9. Schaffer JL, Way CY, Boreham MK. The etiology of pelvic organ prolapse. Clin Obstet Gynecol. 2005;48(3):639-647.

 HO MH, BHATIA NN. Treatment of the Postmenopausal Woman (Third Edition).
Academic Press, 2007, capitoloul 52 - Pelvic Organ Prolapse in Postmenopausal Women, pag 739-764. ISBN 9780123694430

11. Seifalian A, Basma Z, Digesu A, Khullar V. Polypropylene Pelvic Mesh: What Went Wrong and What Will Be of the Future? Biomedicines. 2023 Mar 1;11(3):741.

List of publications

1. **Marcu D**, Diaconu C, Iorga L, Bratu O, Mischianu D. Mesh colposacropexy in the management of anterior vaginal compartment prolapse. J Med Life. 2019 Jan-Mar;12(1):65-70. doi: 10.25122/jml-2019-0018. PMID: 31123527; PMCID: PMC6527416, chapter 5

https://medandlife.org/all-issues/2019/issue-1/original-article-issue-1/meshcolposacropexy-in-the-management-of-anterior-vaginal-compartment-prolapse/

2. **Marcu RD**, Mischianu DLD, Iorga L, Diaconu CC, Surcel M, Munteanu AN, Constantin C, Isvoranu G, Bratu OG. Oxidative Stress: A Possible Trigger for Pelvic Organ Prolapse. J Immunol Res. 2020 Sep 1;2020:3791934. doi: 10.1155/2020/3791934. PMID: 32953891; PMCID: PMC7481916, IF- 4,1, chapter 2 and 6 https://onlinelibrary.wiley.com/doi/full/10.1155/2020/3791934