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ARAŞTIRMA / RESEARCH

Comparison of effectiveness of laparoscopic and transvaginal mesh operations in uterus protective surgery of women in reproductive-age with pelvic organ prolapse (stage ≥2).

Pelvik organ prolapsusu olan üreme çağındaki kadınların uterus koruyucu cerrahisinde laparoskopik ve transvajinal meş operasyonlarının etkinliğinin karşılaştırılması (evre ≥2)

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Abstract

Purpose: The aim of this study was to compare the efficiency of laparoscopic and transvaginal mesh operations with conservative surgery of reproductive-age women with pelvic organ prolapse (stage≥2) (POP).
Materials and Methods: In this study, we retrospectively evaluated 22 cases of 105 patients who diagnosed with symptomatic POP-Q stage 2 and above pelvic prolapse, part of whom underwent laparoscopic surgery (Group-1) while the other part composed of those who underwent transvaginal mesh (TVM) surgery (Group-2). Urogenital prolapse Pelvic Organ was graded using POP-Q.As the current TVM surgical kits four-arms mesh was used.
Results: The mean age of the patients of both groups was 42.2±11.4 and 38.3±12.8 years, respectively. The mean duration of hospitalization for the patients underwent laparoscopy was 2.3 days (range:1-4 days), that period was observed as 3 days in Group-2 (range:2-4 days). None of our patients had any adverse reactions in the early or late stages. The rate of success was 95.45% for patients who underwent laparoscopic surgery, while it was 98.10% for the group of TVM surgery.
Conclusion: Transvaginal mesh surgery was found to be a relatively successful technique in pelvic organ prolapse surgery owing to the high rate of success and minimal rates of complications.
Keywords:. Pelvic prolapse, laparoscopic surgery, transvaginal mesh surgery

Öz

Amaç: Bu çalışmanın amacı, pelvik prolapsusu (POP) olan (evre≥2) üreme çağındaki kadınlarda laparoskopik ve transvajinal meş ameliyatlarının etkinliğini ile karşılaştırmaktır.
Gereç ve Yöntem: Bu çalışmada, semptomatik POP-Q evre 2 ve üzeri pelvik prolapsus tanısı alan laparoskopik cerrahi geçiren 22 hasta ile (Grup-1), transvajinal meş (TVM) uygulanan 83 olguyu (grup 2) retrospektif olarak değerlendirdik. Prolapsus Pelvik Organ POP-Q kullanılarak derecelendirildi. Mevcut TVM cerrahi kitleri olarak dört kollu mesh kullanıldı.
Bulgular: Her iki gruptaki hastaların ortalama yaşı sırasıyla 42,2 ± 11,4 ve 38,3 ± 12,8 yıldı. Laparoskopi yapılan hastaların ortalama hastanede kalış süresi 2,3 gün (1-4 gün), bu süre Grup-2'de 3 gün (2-4 gün) olarak gözlendi. Hastalarımızın hiçbirinde erken veya geç dönemde herhangi bir yan etki görülmedi. Başarı oranı laparoskopik cerrahi uygulanan hastalarda% 95.45 iken TVM cerrahisi grubunda% 98.10 idi.
Sonuç: Transvajinal meş cerrahisinin, yüksek başarı oranı ve minimal komplikasyon oranları nedeniyle pelvik organ prolaps cerrahisinde başarılı bir teknik olduğu gösterilmiştir.

Anahtar kelimeler: Pelvik prolapsus, laparoskopik cerrahi, transvajinal mesh cerrahisi

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INTRODUCTION

Pelvic organ prolapse (POP) is a type of pelvic floor disorder seen in about one third of the women. The term "prolapse" refers to the slipping forward or down of organs. Pelvic organ prolapse refers to outflow or sagging of bladder, uterus, vagina, small intestine, or rectum of pelvic floor organs, down vaginal canal or anus as a result of prolapse. More than 50% of women over the age of 50 have visible POPs, with a lifetime risk amounts to 30-50% [1,2]. Up to the age of 80, 11% of women underwent surgery for life-long POP and about one-third of women are required to undergo a surgical procedure[3,4].

POP is generally seen in post-menopausal period and it is more common in later years; however, it can still be seen in reproductive-age women suffering fertility problems. The cause of the prolapse could be multifactorial. Such as conditions associated with sections and those associated with increased intraabdominal pressure including pelvic organ prolapse, pregnancy, multiple births, hysterectomy, pelvic surgery and obesity besides chronic cough, constipation and repetitive heavy lift also contribute to prolapse. Most patients with pelvic organ prolapse are observed to be asymptomatic. The treatment of POP diversifies according to the severity and degree of POP, patient's symptoms, expectations from treatment, age of patient, request of pregnancy, medical diseases, previous surgery and the experience of the surgeon are the other factors playing role [5]. Hysterectomy is performed on some patients on those the conservative approaches or surgical methods such as pesser were not proved to be completely successful. In case where there is concurrent urinary stress incontinence with POP, correction with surgical treatment should be considered [6].

Although reconstructive surgery is an option for POP, it should also be noted that there is a 30% recurrence rate for women choosing this option. Prolapse repair can be performed through transvaginal, abdominal, laparoscopic and/or robotic ways. Abdominal repairs in POP treatment are believed to have the highest success rates, while increased morbidity makes this a risky option. Vaginal grafts (made of synthetic and biological materials) are considered to be long-term solutions for POP treatment. In POP, transvaginal surgeries have a very high success rates nearly 100% and they are generally preferred for elderly patients with other multiple medical problems [7].

Transvaginal mesh (TVM) surgery is one of the most popular methods of our time. Today, TVM proved to be an attractive option supporting minimally invasive surgery to reduce morbidity and hospitalization costs. In the USA, surgeries are preferred in one third of pelvic organ prolapses. In 75% of these surgeries vaginally applied mesh method was adopted. One of the advantages of transvaginal mesh surgery is its ability to protect uterus [8,9]. Similarly, Laparoscopic surgery is another method which is highly popular and frequently preferred in POP treatment in these days [10].

In this study, we aimed to conduct an in-depth research on some utero conservative surgery cases preferred to protect uterus in reproductive-age women (no menopause) with pelvic prolapse with POP-Q grade 2 and above. So, we compared the laparoscopic operations with the transvaginal mesh operations and evaluated the efficiency of these approaches in terms of their clinical outcomes. The gold standard method in POP is considered to be abdominal mesh surgery. Newly in this study, the following was determined: TVM has less operation time and a similar success rate.

MATERIALS AND METHODS

Sample

Between 2011-2019, 127 reproductive-age women were admitted to a private clinic named Sukgen Gynecology and Obstetrics Clinic (Adana, Turkey) and Derince Research and Training Hospital (Kocaeli, Turkey) diagnosed with pelvic organ prolapse at POP-Q stage 2 and above. The approval of the local ethics committee (no:2019-6, 25.04.2019, Derince Research and Training Hospital, Ethic Committee) Informed consent forms were obtained from all participants. These patients were divided into two groups according to the uterus protective surgery operations performed. According to that 22 women who underwent laparoscopic surgery (Group 1) while 105 of them underwent transvaginal mesh surgery (Group 2).

Procedure

All patients were evaluated with anamnesis and vaginal examination in post-operative period. The examination was carried out with Sims speculum, as the Valsalva maneuver in the left-hand position. The anamnesis were taken from the patients on POP

symptoms: the following symptoms were detected, pelvic or vaginal pressure sensation, low back pain or pelvic pain, urinary or fecal incontinence, chronic discharge or bleeding due to ulceration in the prolapsed tissue, and hand mass.

Patients< 45 years of age, with no polypropylene susceptibility and those who were informed about the outcomes of the mesh surgery and consent of whom were taken were included in the study. In the present study, patients with a chronic disease (e.g., hypertension, diabetes mellitus, and rheumatologic, nephrological, and hematological diseases), the presence of active infection, corticosteroid use, acetylsalicylic acid, and anticoagulant use were not included in the present study. Eighteen patients were not operated due to drug use and uncontrolled chronic diseases. Therefore, it was not included in the study.

Grading

Urogenital prolapse Pelvic Organ was graded using Pelvic Organ Prolapse Quantification System (POP-Q) [11]. In this examination system, prolapsed points are compared with reference points. It is aimed to standardize the degree of pelvic organ prolapse. In POP-Q1, the most distal part of the prolapsed area is 1 cm above the hymen (<-1 cm). In POP-Q2, the most distal part of the prolapsed area is in the interval 1 cm above and below the hymen (+1 cm and -1 cm). In POP-Q3, the most distal part of the prolapsed area is 1 cm below the hymen, but TVL is less than -2 cm prolapsed area. In POP-Q4, the most distal part of the prolapsed area prolapsed at least TVL -2 cm or more from the hymen (≥ TVL -2 cm)[11]. All operations, postoperative evaluations were performed by the authors. Betamix four-arm mesh (Betatech TR) was used as the current TVM surgical kits.

Transvaginal mesh (with sacrospinous fixation) surgery technique

Patients were operated under general or spinal anesthesia in lithotomy position following the required field cleaning and sterile coverage. During the procedure, a linear incision was made 2.5 cm below the urethra on the vaginal anterior wall and the bladder was dissected within uterus through vaginal mucosa. The vesicovaginal ligaments were withdrawn and the bladder was completely separated from the vaginal fascia. The two proximal arms of the web were passed from the outside by means of a guide, using the six-arm net, the two distal parts were passed through the obturator foramen and were placed in a way that totally covering the bladder wall. After the rectovaginal space was opened to the vaginal apex, the right side pararectal space was entered by blunt dissection, the ischial spine was palpated, and the reference point was fixed. Pararectomy was punctured and the range was expanded by blunt dissection. According to the Capioslim Boston Scientific Suture Guide, the posterior extensions were fixed to both the cardinals and the sacro-uterine ligaments to the bilateral sacrospinous ligament. Six arm anterior mesh implant and sacro-utero-ligamentopexy were performed thereafter. Posterior mesh arms were fixed applying traction to the skin. The vaginal mucosa was planted by way of putting stitches with 2/0 polyglactin to the base of the bladder. In the same session, rectovaginal fascia dissection was performed on the posterior vagina, and a large grade IV posterior prolapse was dissected to the apical region. The facial defect was repaired with 2/0 polyglactin sutures and the purche suture was inserted, then excised with a large lambda after repair. A horizontal dissection was performed on the perineum, levator ani muscle was obtained from the bilateral pararectal region and perineoplasty was performed by strengthening the fixation of center piece of pubecal muscle's (levator). After the cleaning and hemostasis were checked, the operation was completed by placing two bumpers on the vagina.

Laparoscopic operation technique

The operation was performed under general anesthesia. The patients were first placed in supine and 30° Trendelenburg position. The legs were placed in semi lithotomy position with the help of the assistant. Urethral catheter was placed in the bladder before the operation. Six trocars were used, being four were at the bottom of the belly (10mm), one at the middle of the umbilical line (5mm) and one at the medial (10mm-5mm) of the right and left anterior superior iliac crest. The vagina was retracted with a retractor placed inside. The peritoneum was opened to the right of the sigmoid column, and the dissection was completed by staying in the medial planar posterior wall. The same procedure was repeated at the vesico-vaginal distance by exclusion of the vagina posteriorly. Then, the promontorium was prepared and anterior longitudinal ligament was seen in the iliac and sacral medial arteries. 2 x 10 cm prolene patches were taken from the camera port into the abdomen. First vesico was entered into the vaginal distance and the patch was fixed to the vaginal

anterior wall by two sutures on both sides of the patch. The same procedure was then repeated on the rear wall. The two patches were atraumatically fixed by promormuria using 2/0 nonabsorbable synthetic (prolene) sutures sewed with 26 mm needles. Peritoneum was permanently closed with 3/0 absorbable synthetic (polyglactin) sutures sewed with 30mm needles.

Statistical analysis

SPSS 23.0 statistical program was used for statistical analysis of data. Descriptive statistical methods such as (means, standard deviation) were adopted and quantitative data were compared as well, in addition normal, distribution, indicating, parameters were compared between the groups. Student's t test was used for comparison. Mann Whitney U test was used to compare the parameters that did not show normal distribution. Chi-square test was used to compare qualitative data. The results were evaluated at 95% confidence interval and significance level (P) of 0.05.

RESULTS

The average age of the patients who underwent laparoscopy was 42.2 ± 11.4 years, while of the patients who underwent transvaginal mesh operation was 38.3 ± 12.8 years. The patients who were performed TVM surgery were 4 years younger and this was statistically significant (p <0.001).For the patients in Group 1, the mean gravida was 4.7±1.5, the average parity was 3.1±1.3, and the average operation time was 140 minutes (range: 100-180 minutes)and the average hospitalization time was 2 to3 days (1-4 days) (Table1).

For the patients in Group 2, the mean gravida was 5.1±1.2; the mean parity was 2.9±1.4; the average operation time was 97 minutes (range: 65-130 minutes); and the average hospitalization time was 3 days (range: 2-4 days) (Table1). While there was a statistically significant difference between the two groups in terms of gravida, parity and BMI values (P <0.05), there was no significant difference in POP-Q staging (P par0.05).

For patients underwent laparoscopy and TVM operation, the average duration of hospitalization were 2 to3 days (range: 1-4 days) and 3 (2-4 days), respectively; however, the average duration of operation was 140 and 97 minutes, respectively. However, these results were not statistically significant (P > 0.05).

Table 1. Preoperative data of patients

Preoperative data		Laparoscopy (n:22)	Transvaginal Mesh (n:105)	P
Age *		42.2±11,4	38.3±12.8	<0.001
Gravida *		4.7±1.5	5.1±1.2	0.036
Parity *		3.1±1.3	2.9±1.4	0.022
BMI (kg/m²) *		22.7±2.6	23.1±3.1	<0.001
POP-Q staging	22	40.9% (n:9)	34.3% (n:36)	0.063
	33	36.4% (n:8)	54.4% (n:57)	
	54	22.7% (n:5)	11.3% (n:12)	

BMI: Body mass index; kg:kilogram; m: meter; n: number; POP-Q: Pelvic organ prolapse stage
*Results are presented as mean ± SD.

None of our patients had any adverse reactions neither in early nor late period. None of the patients developed ureter or bowel injury. No post-operative bowel obstruction or wound problems were detected. Only one patient underwent laparoscopy and had intra-operative bladder injury. That patient underwent primary suture and catheterization. In all 5 patients who were diagnosed with pre-operative chronic constipation, were controlled by medical treatment. No vaginal mesh erosion or incisional hernia development was observed in any of the patients.

Some minimal complications were observed after surgeries. These complications are classified as Grade 1 according to Classification of Surgical Complications[12]. While hemorrhage was not observed in the laparoscopic operations, it was observed in 6 patients with TVM, but not amounted to the level that blood transfusion was required. In only one patient underwent laparoscopic operations,

bladder injury was observed, not any such problem was observed on patients underwent TVM (Table 2).

In our study, the complication in the transvaginal mesh group was extrusion in the vaginal procedure. Primary excised and treated with estrogen creams for 3 weeks. According to Table 2, the pain complaint in this operation was found 33.33% and 36.36%, and a statistically significant difference was observed between them (P = 0.022 <0.05). The most common complication of transvaginal mesh was groin pain. These were treated by physical exercise and anti-inflammatory therapy. There was no significant difference in urinary dysfunction (urge and dysuria).

Table 2. Complications in patients

Complications	Laparoscopy (n:22)	Transvaginal Mesh (n:105)	P
Bladder Injury	4.54% (n:1)	-	-
Hemorrhage	-	5.71% (n:6)	-
Mesh extrusion	4.54% (n:1)	4.76% (n:5)	0.247
Pain	36.36% (n:8)	33.33% (n:35)	0.022
Dyspareunia	22.73% (n:5)	21.90% (n:23)	-
Adverse reactions	-	-	-
Ureter injury	-	-	-
Bowel injury	-	-	-
Mesh erosion	-	-	-
Incisional hernia	-	-	-

Table 3. Postoperative data of patients

Postoperative data	Laparoscopy (n:22)	Transvaginal Mesh (n:105)	P
Operation time (min)	140 min (100-180)	97min (65-130)	0.547
Hospitalization time (days)	2.3 (1-4 day)	3 (2-4 day)	0.354
Success rate (%)	95.45% (n:21)	98.10% (n:103)	-
Recurrence rate (%)	4.55% (n:1)	1.90% (n:2)	-
SUI	9.09% (n:2)	1.90% (n:2)	0.042
UUI	13.64% (n:2)	7.62% (n:8)	-
PVR	9.09% (n:2)	5.71% (n:6)	0.034

Min:minute; PVR: Postoperative Post Voiding Residual; UUI: Postoperative Urge Urinary Incontinence; SUI: Postoperative stress urinary incontinence

One year after the operations, patients were re-examined and in patients receiving treatment, the recurrence rate of the disease was determined POP-Q Classification System (ICS POP-Q ≥ Stage 2). The success rate of the patients underwent laparoscopic surgery and transvaginal mesh surgery was 4.55% (only one recurrence at 22 operation) and 4.76% (only five recurrences at 105 operations). At the end of the first year, a minimal degree of cysto-rectocele was observed in 1 patient. Dyspareunia in patients who underwent Laparoscopic surgery and transvaginal mesh surgery was determined as 22.73% (n:5) and 21.90% (n:23), respectively.

In our study, postoperative stress urinary incontinence (SUI) formation was 9.09% in patients who underwent Laparoscopic surgery. This rate was 1.90% in patients undergoing transvaginal mesh surgery (Table 3) and the P value determined 0.021 for the post-operative SUI formation between these two operations. Pre-operatively, the incidence of SUI was 50% (n:11) in group 1and 64.7% (n:68) in group 2. No additional operations were ever conducted to the patients in both groups for SUI complaints. In both groups, there was a statistically significant improvement in resolving the complaints. Particularly in the transvaginal mesh group, there was a statistically significant decrease in the SUI complaint rate. It is thought that mid urethral support for better anatomical support of SUI complaints in the transvaginal mesh group is beneficial. Besides post-operative Urge Urinary Incontinence (UUI) values and post-operative Post Voiding Residual

(PVR) values were higher after laparoscopy operations in comparison with TVM operations.

In addition, post-operative PVR results was better in TVM operations in proportion to laparoscopic operations (P=0.034<0.05). PVR (residual urine post-voiding) was considered significant at 50 mL and above. The post-operative residual urine in POP was also significantly lesser in the mesh surgeon than in PVR (post voiding residual urine). This may be owing to the better anatomic support.

DISCUSSION

Pelvic organ prolapse can be seen at any age; however, it is a common problem among women at reproductive-age. So, the most appropriate uterine protective prolapse surgery method should be adopted for the reproductive-age patients who want to protect their fertility. Transvaginal mesh surgery and laparoscopic surgery are among the most frequently performed operations. The unique advantage of this vaginal surgery that it includes no incision in the abdominal wall.

The laparoscopic method offers quick recovery, short hospitalization and cosmetic advantages in proportion to open surgery. Laparoscopy also provides important technical facilities for the identification of the relationship of the vagina with the pelvic organs and the association of the sacral promontorium with the iliac veins and ureters However, the operation time and the surgeon's learning periods are longer than the other methods [13]. In our study, the average duration of hospitalization for patients underwent laparoscopy was shorter, but the average duration of operation was longer (Table 2); however, the results were not statistically significant.

Transvaginal mesh (with sacrospinous fixation) and POP repair techniques require special surgical skills; no standard technique for surgical approach was described. The purpose of sacrospinous fixation is to bring the uterus to anatomic position and provide vaginal support. Technical; dissection, material type, size of material, lateral and apical connection points may vary. Wide surgical dissection is required for mesh use. This increases the risk of morbidity, blood loss, bladder and bowel perforation. In our study, transvaginal mesh operation was performed on total 105 patients. In our study, the rate of success was 98.10% (the rate of recurrent prolapse at the end of 1 year was found 1.90%). The results were relatively high for laparoscopy surgery with rate of success95.45% (Table 2). So, transvaginal mesh was evaluated as relatively successful. Dietz et al. found a higher rate of recurrences after one year in patients with sacrospinous fixation (27% versus 3% recurrence in patients with vaginal hysterectomy) and they reported that the sacrospinous hysteropexy for uterine descent has some advantages such as faster recovery and more recurrent apical prolapses; however, but it offers no differences in functional outcomes, and quality of life [14]. Gutman and Maher observed that TVM was more successful; they note that: the evidence on safety and efficiency is currently lacking, although surgical operations is a viable option at uterine prolapse [15,16]. Gamble et al. reported that recurrence rates were reported as 2.6% for uterine prolapse, 4% for cystocele, and 4.3% for rectocele after 1-year follow-up with bilateral sacrospinous hysteropexy using polypropylene mesh in treatment of stage II prolapse[17].

Besides Detollenaere et al. and Maher et al. although there are small differences in the two methods, they generally considered equivalent [16,18]. Detollenaere et al. reported that sacrospinous hysteropexy was as effective as vaginal hysterectomy and similar in overall surgical failure rate (recurrent prolapse, pessary use, or repeat surgery) (P=0.81); however, it was observed shorter operating time, less blood loss, faster recovery, and fewer complications [18]. Maher et al. compared vaginal hysterectomy with sacrospinous fixation and found no significant difference in objective and subjective results [16].

The mean age of the patients who underwent transvaginal mesh operation was 38.3 ± 12.8 years, while the mean age of patients underwent laparoscopy was 42.2 ± 11.4 years. Contrary to the results of our study, wide age ranges are studied, and the general average age is 60s. For example, Detollenaere et al. was evaluated patients between 33 and 82 [18]. Similarly, study of Dietz et al. were presented the results of the patients at age of 62 in average [14].

Although the morbidity of vaginal surgery seems lower, serious hip pain may be observed due to compression of sciatic nerve branches up to 15% of patients [19]. In our study, however, no such complication was ever observed in any of the patients.

One of the important findings in our study is the significant relationship between BMI and POP.

According to the studies, the risk of high BMI POP increased 4.1 times; stage ≥2 the risk of POP increases 7.6 times. Gyhagen et al. similar to our study, BMI was found to be an independent risk factor for POP and shown that POP risk for each unit increases when BMI increased by 3% [20]. Miedel et al. reported similar rates of increase in POP risk for BMI [21].

Sexual function after surgery is recognized as a surgical success in POP [22]. Especially after the both surgical methods, hysterectomy is performed, there is no negative uterine contractions. Also deteriorates the psychology of women due to the losses [23]. It has been proved that preservation of the uterus positively contributes to the patient's self-esteem, body shape, confidence and sexiness in POP surgery [24]. In our study, complaint of dyspareunia in patients with sexual life was similar it was approximately 22% for both groups. Lopes et al. found that sexual dysfunction was significantly more likely for the mesh group [25]; however, Ağaçayak et al.in compliance with the results of our study, didn't find significant difference between the two groups in sexual dysfunction [26].

The limitations of our study include its retrospective design. The number of cases was too small to compare morbidity. In addition, there was no data on long-term outcomes.

In conclusion; despite many successful applications, such surgical operations are not eliminated POP recurrence or re-operation, complications, or emergence of new pelvic floor symptoms. However; in the study, owing to the high success rate and minimal complication transvaginal mesh surgery was found to be a relatively successful method in pelvic organ prolapse surgery. The primary goal at POP treatment is to determine the most appropriate methods without disturbing fertility. Therefore, it is of paramount importance the surgeon's experience and success for treating prolapse and surgeon's guidance to patients on the possible outcomes and risks.

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