Prospective Follow-up of Women Undergoing Uterine-Preserving Surgery for Symptomatic Pelvic Organ Prolapse

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Abstract

Objectives: Approximately 25% of all women will suffer from pelvic organ prolapse, its incidence increases with age. Treatment includes pelvic floor physical rehabilitation, and pelvic floor surgical reconstruction. The aim of this study is to evaluate the post-surgical anatomical and functional status of the patients when presenting up to 6 months after uterine-preserving reconstructive surgeries.

Methods: This prospective study included women, above the age of 30, suffering from symptomatic Pelvic Organ Prolapse who underwent uterine-preserving vaginal approach surgery with Mesh. PFIQ-7 questionnaire was used to assess women’s subjective perception regarding urinary, bowel and psycho-sexual function. The questionnaire was undertaken 6 months after surgery via telephone interview. Positive effect rate, representing improvement of quality of life following surgery, was defined as 80% of the cohort ranking “0” or “1” (reflecting “not at all” to “somewhat” effect at the questionnaire) regarding a specific question about the symptomatic Pelvic Organ Prolapse.

Results: The study cohort included 41 women at the average age of 66.87 ± 10.61 years old. In 87.8% (35/41) of the patient’s, a posterior repair was made using a PROLIFT® mesh. In 7.5% (5/41) a posterior PROLIFT and anterior PROSIMA® were used. One patient – (1/41) had an anterior and posterior repair using PROLIFT mesh. Vaginal uterine-preserving surgery improved: urinary (58% to 70%); bowel (82.6% to 92.7%); and vaginal and pelvic (82.9% to 87.8%) symptoms. Success rate was higher above the age of 60. The age of the patient had a small-moderate positive correlation with urinary symptoms (p=0.416), small positive correlation with vaginal-pelvic symptoms (p=0.367) and no correlation with bowel symptoms (p=0.149).

Conclusion: Uterine-preserving surgical interventions are an effective method for treating symptomatic POP. Women undergoing reconstructive pelvic surgery reported high post-operative resolution rate of intestinal and vaginal symptoms. Urinary symptoms are more challenging to overcome by surgical interventions.

Keywords: Pelvic organ prolapse; Uteri-preserving surgery; PFIQ-7 questionnaire; Hysterectomy

Introduction

Pelvic Organ Prolapse (POP) is a condition of growing medical importance and its occurrence increases as the world population age. The lifetime risk for POP is estimated to reach to about 50% among women in the western society [1], while the lifetime risk for surgical intervention due POP and incontinence is around 11% to 19% [2]. POP is a leading cause for gynecological surgery in general and particularly for hysterectomy in women over the age of 50 years [3]. The importance of an appropriate treatment for symptomatic POP cannot be overemphasized. The spectrum of symptoms includes urinary [4] and fecal [5] incontinence, reduce sexual satisfaction [6,7] and psychological value of reproductive system as well as desire to preserve fertility. Hysterectomy has been long considered as the treatment of choice for symptomatic POP [8]. However, its necessity at the time of prolapse surgery is being questioned, with the progress of novel surgical techniques and the understanding that hysterectomy might be an independent risk factor for POP [9,10], its use as a “gold standard” procedure for treatment of symptomatic POP has declined [11].
need for recurrent surgical intervention in women who undergone hysterectomy, and developed post-operative POP symptoms played a key in the efforts for the trend to preserve the uterus. However, no clear guidelines exist concerning the trend to preserve the uterus with POP repair, and the operative approach is primarily made according to the experience and preference of the surgeon and the patient [12,13]. Uterine-preserving procedures for the treatment of POP had, comparable long-term follow-up outcome in terms of recurrence of POP symptoms to those reported following hysterectomy. The Aim of this study was to evaluate the post-surgical anatomical and functional status of the patients when presenting up to 6 months after uterine-preserving POP reconstructive surgeries.

**Material and Methods**

This study was a cohort prospective descriptive study. Patient’s data was collected from medical records. The study population included women who had uterine-preserving POP reconstructive surgeries at the participating medical centers during 2016. The inclusion criteria consisted of women above the age of 30 with full medical record available including obstetric history. Previous Caesarean section or pelvic surgical interventions not due to POP causes were included. All women underwent urodynamic/stress cough test with prolapse reduction for the diagnosis of urinary stress incontinence. The diagnosis was made if the patient had at least stage 2 prolapse. Exclusion criteria were previous pelvic procedures due to POP and insufficient medical record. The study was approved by our institutional IRB committee, and patients who met the inclusion criteria signed informed consent prior to participation in the study. Data was collected by phone interview and from the patient’s medical record. On the first post-operative day, the patients were interviewed for any post-operative complication. Physical examination was conducted one month after surgery, including POP-Q evaluation. The information collected from patient’s medical records included anamnesis and patients physical examination. The mined data included age, parity, BMI, general health, length and nature of complaints, personal and familial medical history, previous surgical procedures, and pre-surgical physical examination – including POP-Q system status, full medical history and the performed surgery. All women underwent post-operative follow up with in 3 to 6 months post operatively to assess recurrent prolapse or mesh exposure or other potential complications of the surgery. A telephone interview 6 months after surgery was made by an OBGYN resident. In this interview, the patients were requested to answer a PFIQ-7 questionnaire [14]. The (PFIQ-7) questionnaire was previously tested and validated in Hebrew and used in resembling setting and for patients with pelvic floor disturbances [14,15]. The interview was held in Hebrew after translating the PFIQ-7 questionnaire (Supplementary Files 1 and 2). The patients graded the success of their surgery in term of level of the urinary, bowel and vaginal/pelvic symptoms. Each of the system received a specific score of 0–100 the lowest the better) and a total score that summarizes all the symptoms was calculated for each patient. The data collected at the 6th month interview included the followings: The patient's ability to perform house chores. Suffering from urinary/fecal incontinence. Success for every examined parameter in the questionnaire was defined as 80% improvement rate. This success rate included the patient's rating 0 which reflects “no effect at all” or mild effect for each given aspect of the questionnaire.

**Statistical analysis**

Continuous variables are described by mean and standard deviation, median and range, and compared by student’s t-test of Mann Whitney tests as appropriate. Dichotomy variables are presented as frequencies and percentages and compared by Chi square test or Fisher's exact test, as appropriate. The correlation between the age and the effect on the different systems was calculated using spearman’s correlation coefficient test. The results reliability for every system examined (i.e. urinary, intestinal and vaginal) was calculated with Cronbach’s alpha. The calculation was made prior to calculating the mean. Value greater than 0.7 stands for reliable results – which allows the collected date to be further averaged. Statistical significance is determined as P value <0.05. Data was analyzed using SPSS, V.21. Reliability value was calculated using the Cronbach’s Alpha.

**Results**

A cohort of 63 patients who met the inclusion criteria was recruited. Of them, 13 patients could not be reached using the listed phone number in the medical file. A 50 patients were reached, among them 41 questionnaires were obtained (compliance ratio of 82%) comprising the cohort for analysis. Demographic data: The mean women’s age of the study cohort was 66.87 years old (± 10.61). All the patients underwent anterior and posterior colporrhaphy and mesh kit surgery for apical suspension. In 87.8% (35/41) of the patient’s, a posterior repair was made using a PROLIFT mesh. In 7.5% (5/41) a posterior PROLIFT and anterior PROSIMA were used. One patient – (1/41) had an anterior and posterior repair using Prolift mesh. There were no intra and post-operative mesh complications. Six months after surgery, 92.6% of the patients stated that intestinal symptoms and 83% stated that pelvic/vaginal symptoms do not limit their ability to perform physical activity, while 58.5% stated that urinary symptoms do not limit their ability to perform physical activity. Among the parameters examined with the PFIQ-7, urinary symptoms during physical activity had the lowest success rate (Figure 1a). Similar success rates were also reported regarding outdoor activity. 90.2% and 82.9% of the patients were able to enjoy movies and concerts without any significant intestinal and pelvic bothering symptoms, respectively (Figure 1b). Similar rates of intestinal and vaginal symptoms were reported for driving time of up to 30 min.
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from patient’s residence (Figure 2a) and for social outdoor gathering (Figure 2b). As for urinary symptoms, 61% of the patients felt comfortable enough to enjoy a concert or a movie (Figure 1a), and similar rate felt so to go for a drive (Figure 2a). Higher rate of 68.7% stated up to mild disturbance at a social gathering (Figure 2b). The last two questions of the PFHQ-7 questionnaire relate to the mental effect of the POP symptoms. Urinary symptoms had the highest effect on the mental health status of the patients, 66.8% of the cohort stated minimal mental influence due to urinary symptoms (Figure 3a), and following surgery there was a reduction of 73% in frustration levels. More than 90% of the patients stated that intestinal symptoms had none to minimal effect of their mental health (Figure 3b) and even higher rate felt almost no frustration at all (Figure 3b). The negative effect of vaginal/pelvic symptoms was found to be lower than that of bowel symptoms and above the desired 80% success rate - around 83% of patients stated none to minimal effect on mental health or feeling frustrated from it. The reliability calculated was 0.97, 0.993, and 0.981 for the urinary, intestinal and vaginal system, respectively. Following uterine preserving procedure the level of: 1) urinary symptoms was scored as a median of 33.33 (range 0 to 100); 2) bowel symptoms were scored as a median of 0.00 (range 0 to 100); 3) vaginal/pelvic symptoms were scored as a median of 0 (range: 0 to 100); and the total score of the symptoms had a median of 42.86 (range: 0 to 300). Subsequently we tested the association between women’s age and the level of the symptoms following surgery according to their grading by the patients. There was a significant association between women’s age and the level of: 1) urinary symptoms ($r^2=0.326$, $p=0.019$); 2) vaginal/pelvic symptoms ($r^2=0.266$, $p=0.046$); and 3) total score ($r^2=0.367$, $p=0.009$). Women’s age was not associated with the level of bowel symptoms following surgery.

**Discussion**

The principle finding of this study was that uterine-preserving surgery significantly improves intestinal and pelvic/vaginal functional status and daily activity of patients with POP, suggesting that the preservation of the natural anatomical structure while repairing the damaged connective tissues and using surgical mesh as a support is a key role in this improvement. Our study demonstrated that uterine sparing surgery resulted in an impressive improvement in the urinary symptoms of such patients. Nevertheless, the beneficial effect of surgery did not reach our desired level of 80%. This is in accord with previous reports [1,2,7,16,17] and may require continuation of treatment – whether conservative or surgical. The resolution of Urinary symptoms are more challenging, due to the proximity of the prolapsed uterus and the urinary bladder, especially in women with impaired supporting connective tissue. We found correlation between women’s age and symptoms. Younger patients gain higher level of benefit from the surgery. A possible explanation for this observation is that due to their younger age these patients connective tissue more functional than that of older patients, which contributes to the higher success rate. Older patients in spite of the relatively high success rates demonstrated variable results, suggesting that a single surgical intervention for prolonged prolapse at those women might not be sufficient. Our results are compatible to the results found in medical literature regarding uterine-conserving surgery for POP [1,2,7,16,17] where a significant percentage of the operated patients experience recurrence of stress urinary incontinence and prolapse-recurrence. The data and results collected in this study can serve as a reference for future follow-up on the same cohort, with the same tool – PFHQ-7. This might shed some insights regarding the long turn post-operative progression and change in functional status, including prolapse recurrence rates. Including the questionnaire in future, studies containing different surgical technique for POP repair will allow objective and valid comparison between the techniques. This study has a several limitations. The follow up period is 6 months after the surgery. Longer follow up is required in order to evaluate functional status for long term. This study though, as mentioned can be the initial reference point for this future follow up. On the other hand, 6 months after surgery is a conventional period to assess POP uterine-preserving surgeries and previous studies have shown high symptoms recurrence during the first year after surgery [17]. Although mesh kit were removed from further clinical utilization in most part of the world, our study present important information regarding the success of uterine preserving pelvic organ prolapse reconstructive surgery. From the 64 women who met the inclusion criteria, 41 women agreed to participate in the study (82% compliance rate while considering
the women contacted). A relatively small cohort (although many of the studies in the field have a similar sample size). Since POP has a profound effect on both physical and emotional state of the patients, we presume some refused to precipitate due to inconvenience and reluctance to address to their experience while answering personal questions. Patient’s satisfaction and her perception of quality of life improvement is the major key point in the assessment of the success of POP surgeries. Given the fact the POP repair surgeries are quality of life interventions the subjective perception of the patient matters even more than the object POP Q score/measurements.

Conclusion

Uterine-preserving surgery is an effective interventional method for treating symptomatic POP. High post-operative success rate was found for intestinal and vaginal symptoms. Urinary symptoms are more challenging to overcome, with a lower success rate for those symptoms.

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