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COMPARISON OF PELVIC FLOOR DISTRESS INVENTORY (PFDI) IN WOMEN WITH PELVIC ORGAN PROLAPSE UNDERGOING TOTAL VAGINAL HYSTERECTOMY AND PESSARY

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Abstract

Background and aim: Pelvic floor disorders encompass a wide variety of interrelated clinical conditions that can have a devastating impact on a woman's life. Several options for treating pelvic organ prolapse is either pessary or total vaginal hysterectomy. This study will see the differences between Pelvic Floor Distress Inventory (PFDI) scores in women with pelvic organ prolapse who underwent Total Vaginal Hysterectomy procedures and pessary

Method: The sample of this study were women with pelvic organ prolapse who went to the polyclinic at H. Adam Malik Hospital in Medan and Jejaring Hospital who met the inclusion criteria. The sample recruitment process was carried out then the research data was collected and then analyzed.

Results: From 34 patients, the majority of patients with pelvic organ prolapse were under 65 years of age, 25 cases (73.5%) with the highest parity groups being grand multiparas and multiparas with 9 cases (26.5%) and 25 cases respectively (73.5%). The mean POPDI score in patients with pessaries was 20.34 ± 16.06, and in patients with total vaginal hysterectomy was 7.10 ± 2.44. The mean CRADI score in patients with pessaries was 16.54±10.11, and patients with total vaginal hysterectomy was 5.14±3.30. The mean UDI score in patients with pessaries was 22.79±11.42, and patients with total vaginal hysterectomy was 7.35±3.13. The mean PFDI-20 score in patients with pessaries was 59.68±28.5, and in patients with total vaginal hysterectomy it was 19.60±4.99.

Conclusion: There are significant differences in the scores of PFDI, POPDI-6, CRADI-8 and UDI-6 between POP patients who undergo total vaginal hysterectomy and pessary

Keywords: Pelvic Organ Prolapse, PFDI score, Total Vaginal Hysterectomy, Pessary

Introduction

It is widely accepted that 50% of women will experience pelvic organ prolapse, but only 10 to 20% of those seek evaluation of their condition.[1] A regional study in the United States found that nearly 10% of women underwent surgery for urinary incontinence, pelvic organ prolapse, and urinary incontinence. or both during their lifetime, and 30% of them had 2 or more surgical procedures.[2]

Pelvic floor disorders encompass a wide variety of interrelated clinical conditions including urinary incontinence, anal incontinence, pelvic organ prolapse, voiding dysfunction, and defecation dysfunction that can have a devastating impact on a woman's life. This disorder rarely results in mortality or severe morbidity; The main impact is affecting the quality of life. Psychologically robust instruments to measure health-related quality of life (HRQOL) are essential for evaluating women with pelvic floor disorders. Although few such instruments exist for women with urinary incontinence, several condition-specific instruments have been developed to assess HRQOL in women with pelvic organ prolapse.

In 2001, two condition-specific HRQOL instruments were developed for women with pelvic floor disorders, the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ). [3,4] The PFDI instrument is based on the structure and content of a specifically used quality of life questionnaire. for women with lower urinary tract dysfunction, the Urinary Distress

Inventory (UDI) and Incontinence Impact Questionnaire (IIQ), originally described by Shumaker et al.[5] PFDI, are widely used and help researchers to evaluate the efficacy of specific therapies for POP or to compare severity symptoms between the patients and the normal group. These disease-specific instruments have been translated and validated in several different countries.[6] The PFDI can be used to measure the extent to which pelvic organ prolapse symptoms affect the quality of life of women with pelvic floor disorders. The aim of this study was to determine the Pelvic Floor Distress Inventory (PFDI) in women with pelvic organ prolapse who underwent Total Vaginal Hysterectomy and pessary placement.

Methods

This study was an observational analytic study with a cross-sectional study design which was conducted at H. Adam Malik Hospital Medan and Jejaring Hospital Medan from July 2022 to December 2022. The sample of this study were women with pelvic organ prolapse who went to the H. Adam Malik Medan Hospital polyclinic and Network of Hospital in Medan that meet the inclusion and exclusion criteria. The inclusion criteria were women who had grade III – grade IV pelvic organ prolapse, had undergone Total Vaginal Hysterectomy surgery as an operative management of pelvic organ prolapse within a maximum period of 3 years, had undergone a pessary placement as a management of pelvic organ prolapse within a maximum period of time 3 years, complete demographic data in the medical record, and willing to participate in the study and signed an informed consent. The exclusion criteria were had history of suffering from previous metabolic diseases, had history of smoking and alcohol, had undergone other operations in the field of gynecology, had a history of suffering from psychiatric disorders or other disorders which could make the subject unable to fill out the questionnaire, and the research subjects were not willing to be the research sample. . Data were collected and analyzed using the Fisher Extract Test for characteristics and bivariate analysis using the T-test. To simplify statistical calculations authors use SPSS software.

Results

This study is an observational descriptive study to determine the Pelvic Floor Distress Inventory (PFDI Score) in patients with pelvic organ prolapse who underwent total vaginal hysterectomy and pessary placement. Total samples in this study were 34 patients.

Table 1. Patients Characteristic

Characteristics	Pessary		Total Vaginal Histerectomy	
	n	%	n	%
Age :				
≤ 65 years	14	82.4	11	64.7
> 65 years	3	17.6	6	35.3
Parity :				
Primipara	0	0	0	0
Sekundipara	0	0	0	0
Multipara	6	35.3	3	17.6
Grandemultipara	11	64.7	14	82.4
BMI :				
Normoweight	5	29.4	4	23.6
Overweight	12	70.6	9	52.8
Obese	0	0	4	23.6
History of smoking :				
Yes	0	0	0	0
No	14	100	14	100
POP Grade :				
Grade III	13	76.4	5	29.5
Grade IV	4	23.6	12	70.5
PFDI Score:				
Mild	2	11.7	17	100
Moderate	8	47.1	0	0
Severe	7	41.2	0	0

The majority age of patients with pelvic organ prolapse were under 65 in 25 cases (73.5%). In the parity group, the most were cases with grandemultipara and multipara with 9 cases (26.5%) and 25 cases (73.5%) respectively. All sample of the study did not have a history of smoking. The majority of pelvic organ prolapse in this study was grade III in 19 cases (55.9%). PFDI scores were categorized into mild, moderate, severe categories. The majority of the PFDI scores in this study were in the mild category, 19 cases (55.9%).

Based on table 4.2, in pessary placement cases, the majority age were under 65 years, namely 14 cases (82.4%). The same thing happened in total vaginal hysterectomy cases, 11 cases were under 65 years old (64.7%). In this study, parity was divided into primiparas, secundiparas, multiparas and grandemultiparas. Both groups of patients with pelvic organ prolapse who underwent total vaginal hysterectomy and pessary placement had cases with a history of high parity. In the pessary group, 6 cases were multiparous (35.3%),

and 11 cases were grandemultiparous (64.7%). Meanwhile, the total vaginal hysterectomy group had 3 multiparous cases (17.6%) and 14 grand multiparous cases (82.4%). Body mass index in the pessary group was normoweight in 5 cases (29.4%), overweight in 12 cases (70.6%), when compared to total vaginal hysterectomy, 4 cases were normoweight (23.6%) and 9 cases were overweight (52.8%) and 4 cases of obesity (23.6%). No history of smoking was found in both cases of pelvic organ prolapse with pessary and total vaginal hysterectomy.

In calculating the PFDI score, there were 2 cases (11.7%) of patients with pelvic organ prolapse with a pessary in the mild category, 8 cases (47.1%) in the moderate category and 7 cases in the severe category (41.2%). While all cases of pelvic organ prolapse with total vaginal hysterectomy were found in the mild category (100%).

Table 2. The average of PFDI score based on Total Vaginal Hysterectomy and Pessary

PFDI score	Pessary			Total Vaginal Histerectomy			P value
	Mean±SD	Min	Max	Mean±SD	Min	Max	
POPDI-6	20.34±16.06	4.17	50	7.10±2.44	4.17	12.50	0.002
CRADI-8	16.54±10.11	3.13	40.63	5.14±3.30	3.13	15.63	0.000
UDI-6	22.79±11.42	8.33	50	7.35±3.13	4.17	12.50	0.000
PFDI score	59.68±28.5	19.79	140.63	19.60±4.99	11.46	28.13	0.000

The PFDI-20 questionnaire is a combination of 3 parameters from symptoms of pelvic complaints, voiding complaints and defecation complaints. This study measured the PFDI score on each parameter. The mean score of POPDI pelvic organ complaints in patients with pessary placement was 20.34 ± 16.06. Whereas in cases with total vaginal hysterectomy, the mean score was 7.10 ± 2.44. Based on the statistical analysis of the independent T-test, $p < 0.05$ was obtained. In the parameters of CRADI defecation complaints in patients with pessary placement, the average score was 16.54 ± 10.11 compared to the parameters of defecation complaints in cases with total vaginal hysterectomy which was found with an average of 5.14 ± 3.30. Regarding the urinary complaints parameter, an average score of 22.79 ± 11.42 was obtained in patients with pelvic organ prolapse with pessary placement, and an average score of 7.35 ± 3.13 in patients with pelvic organ prolapse with total vaginal hysterectomy.

The overall mean score of PFDI-20 in patients with pessary was 59.68±28.5, and 19.60±4.99 in patients with total vaginal hysterectomy. Based on the statistical analysis of the independent T-test, $p < 0.05$ was obtained.

Discussion

Based on the characteristics of the subjects in this study, the majority age of patients with pelvic organ prolapse were under 65 in 25 cases (73.5%). In the parity group, the most cases were grandemultipara and multipara with 9 cases (26.5%) and 25 cases (73.5%) respectively. All sample of this study did not have a history of smoking. The majority of pelvic organ prolapse in this study was grade III in 19 cases (55.9%). Dhital et al demonstrated a higher mean age of women with POP than women without POP (52.0 and 40.6 years, respectively; $p < 0.001$). Illiteracy was more common among women with POP (N = 226, 89.7%) than women without POP (N = 45, 31.7%; $p < 0.001$). Women with POP also had higher parity (mean = 5.3, SD 2.17) than women without POP (mean = 2.7, SD 1.71; $p < 0.001$). Women with POP also had higher depression scores (mean = 23.7, SD 8.7) than women without POP (mean = 8.6, SD 8.6, $p < 0.001$).[7]

In this study, the mean PFDI score of patients who underwent total vaginal hysterectomy was 19.60 ± 4.99, the mean POPDI-6 score was 7.10 ± 2.44, the CRADI-8 score was 5.14 ± 3.30, the UDI-6 score was 7.35 ± 3.13. A pessary is an intravaginal device made of hypoallergenic plastic or silicone that is inserted into the vagina for the purpose of supporting the pelvic organs. Currently the pessary is a conservative alternative for surgical repair of pelvic organ prolapse (POP).[8] Vermeulen et al analyzed the three subcategories separately, the median POPDI-6 scores being 0, 4, and 8 points for laparoscopic hysteroscopy (LH), and vaginal hysterectomy (VH) which differed significantly ($p = 0.005$). However the mean CRADI-8 score showed no significant difference between groups (VH-2 versus LH, $p = 0.076$). The median UDI-6 score was the same in all groups.[9]

The mean scores across quality-of-life domains improved from baseline to 3 months after surgery. Initial scores for the physical domain increased from 11.2 to 12.8 at six weeks and 13.5 at three months postoperatively ($p < 0.001$); the psychological domain score increased from 11.6 to 13.1 at six weeks and 13.8 at three months postoperatively ($p<0.001$); social relationship domain scores increased from 13.6 to 14.4 at six weeks and 15.0 at three months postoperatively ($p<0.001$); and the environmental domain score increased from 12.9 to 13.9 at six weeks and 14.0 at three months postoperatively ($p < 0.001$). There was increase in quality of life among women who underwent surgery.[7]

Preoperative staging was higher than three and six months after surgery ($p < 0.001$), and there was no difference in staging between the two postoperative time points ($p > 0.05$). Surgery with fascial repair for management of pelvic organ prolapse improves health-related quality of life, as assessed by P-QoL and ICIQ-VS, and urinary, vaginal, and bowel symptoms.[10]

Okcu compared the effectivity of vaginal hysterectomy with sacrospinous ligament fixation, laparoscopic hysterectomy with sacrocolpopexy or abdominal hysterectomy with sacrocolpopexy with follow-up at 36 months. They found that the abdominal hysterectomy group had a better prognosis (p = 0.047), whereas sexual function for the three groups was almost the same.[11]

Surgical management is generally considered for women with symptomatic prolapse, who are medically fit for surgery, and willing to undergo surgery. A vaginal hysterectomy is one of several surgical procedures to treat advanced POP. In addition, it is also an advanced stage of POP is the most common reason for hysterectomy in women over the age of 55 years.[11]

In this study it was found that in POP patients using a pessary, the average PFDI score was 59.68 ± 28.5, the mean POPDI-6 score was 20.34 ± 16.06, the CRADI-8 score was 16.54 ± 10.11, the UDI-6 score was 59.68 ± 28.5. In Tenfelde study, it was found that women overall reported high levels of QOL. Health-related QoL scores were negatively correlated with PFDI-20 scores (p = -0.55, p = 0.001). Women with a higher QoL reported fewer symptoms of POP for each of the subscales (urinary, colorectal, and prolapse).[16]

Nebel et al showed a significant improvement in global symptom scores of PFDI-20 after pessary placement, with mean scores of 105.22 at inclusion, 56.91 at 1 month, and 57.48 at 6 months ($p < 0.001$ for global difference, $p < 0.001$ for the M0-M1 difference, and $p = 0.62$ for the M1–M6 difference). In addition, significant improvements were also found in the POPDI-6, UDI-6, and CRADI-8 subscores from PFDI-20 with a similar profile. The POPDI-6 score was 45.62 + 23.29 at baseline, 18.10 + 21.82 at the first month of pessary placement and 18.23 + 20.63 at 6 months after installation. The CRADI-8 score was 23.98 + 20.52 at baseline, 18.08 + 18.56 at the first month of pessary placement and 17.15 + 16.61 at 6 months after insertion. The UDI-6 score was 36.38 + 24.79 at baseline, 22.19 + 23.77 in the first month of pessary placement and 21.97 + 21.46 at 6 months after insertion.[12]

The most commonly used validated questionnaires on hip symptoms are the PFDI-20 and PFIQ7 scores. In a 2019 study of 84 women, Mao et al. found that the PFDI-20 score fell from a mean of 98.4 to 46.6, and a PFIQ-7 score fell from a mean of 77.3 to 13.2 after 23 months of follow-up. 12 Sixty-one patients discontinued use pessary, and almost all (55/61, 90.2%) stopped using the pessary within the first 12 months after successful pessary insertion. Total vaginal length (TVL) < 7.5 cm (odds ratio [OR], 0.181; 95% confidence interval [CI], 0.062–0.524; p = 0.002) and an initial Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) lower score (OR, 0.974; 95% CI, 0.954–0.994; p = 0.013) was an independent factor associated with discontinuation of the pessary. TVL ≥ 7.5 cm and higher baseline POPDI-6 score are independent factors associated with long-term pessary use after successful insertion in women with symptomatic POP.[17]

Evolution of the PFDI-20 score over 24 months was found in patients with pessary placement, which can be seen by a decrease in the PFDI-20 score from baseline to follow-up at 3 months. Improvement in pelvic floor symptoms in the pessary group continued to the end of the study, with a difference of 9.3 points (16%) between baseline and 24 months. Analysis by Panman et al showed significant differences in prolapse symptoms (POPDI-6) between the pessary wearing group over 24 months (3.2; 95% CI, 6.3 to 0.0; P¼0.047). In the pessary group, the POPDI-6 score increased by 4.2 points (24%) between baseline and 3 months, and the increase persisted to the end of the study. 18 In the pessary group, the CRADI-8 score at study entry was 15.7+ 13.8, then to 12.4 + 10.5 at 3 months, 14.2 + 12.3 at 12 months and 13.6 + 13.4 at 24 months after insertion. Meanwhile, for the UDI-6 score found an average of 27.2 +17.5 at baseline, then 23.7 + 16.3 at 3 months, 22.3 + 17.9 at 12 months and 24.4 + 16.0 at 24 months post-insertion.[18]

When asked about the major disadvantages of pessaries, the most common answer was 'None' (26.4% and 35.4% at 1 and 6 months, respectively). Within 1 month, patients complained of vaginal discharge (16.5%), vaginal discomfort (16.5%), need for manipulation (23.1%), or problems with sexual intercourse (2.2%).[12]

Vaginal pessaries are a conservative treatment for pelvic organ prolapse and can be offered as first-line treatment in the majority of patients. Non-surgical modalities such as a pessary are the best option for older women with some type of cardiovascular disease or diabetes mellitus. Among the various vaginal pessaries, pessary rings are the most common type because they are convenient to insert and remove and have acceptable continuation rates and tolerable side effects. Additionally, a pessary-supported ring is a safe and effective conservative treatment for POP; it not only reduces prolapse and bothersome urinary symptoms but also significantly reduces their impact on health-related quality of life.[13]

After statistical tests were carried out using the independent T-test, p-value <0.05 was found which indicated that there were significant differences in the scores of PFDI, POPDI-6, CRADI-8 and UDI-6 between POP patients who used a pessary and underwent total vaginal hysterectomy. Currently, treatment modalities include pelvic floor muscle exercises, vaginal pessaries, and surgery. Surgical treatment displays a high rate of recurrence and reoperation is required in 30-56% of cases in certain populations, increasing treatment costs. [13] Although not life-threatening, POP negatively impacts quality of life through urinary and bowel symptoms, vaginal swelling and sexual disorders.[14]

Changes in PFDI-20 scores between baseline and 24-month follow-up indicated that both the pessary and surgery groups experienced statistically significant improvement on all subscales and total scores. Looking at the PFDI-20 subscale,: improvement on the POPDI-6 scale has high clinical relevance (ES > 0.8) for both interventions. With respect to the CRADI-8 scale, ES in both interventions showed little clinical relevance (ES < 0.5). The UDI-6 scale for the pessary group showed weak clinical relevance (ES < 0.3), in contrast to the surgery group, which showed moderate clinical relevance (ES > 0.6) The UDI-6 consisted of three subscales, involved SUI, obstructive symptoms and irritation. At 24 months the difference in mean improvement in scores between the groups on the SUI scale was 2.5 points (95% CI 2.7 to 7.8, P = 0.3). Regarding obstructive symptoms the mean score difference was 6.0 points (95% CI 0.6-11.4, P = 0.03), and for irritative symptoms the mean score difference was 7.5 points (95% CI 1.9–13.1, P < 0.01), surgery was prefered. Significantly more women in the surgery group reported subjective improvement after 24 months. Both therapies showed clinically significant improvement in prolapse symptoms.[14]

Conclusions

Based on the results of the study, the overall average of PFDI-20 score in patients with a pessary was 59.68 ± 28.5, and 19.60 ± 4.99 in patients with a total vaginal hysterectomy. Based on the statistical analysis of the independent T-test, $p < 0.05$ indicated that there were significant differences in the scores of PFDI, POPDI-6, CRADI-8 and UDI-6 between POP patients who underwent total vaginal hysterectomy and pessary placement.

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