Original Article

Responsiveness Of Pelvic Floor Distress Inventory (PFDI) And Pelvic Floor Impact Questionnaire (PFIQ) In Women With Pelvic Organ Prolapse, Undergoing Vaginal Reconstructive Surgery Versus Women With No Surgery

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ABSTRACT:

Objective: To determine the responsiveness of Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) in women with pelvic organ prolapse, undergoing vaginal reconstructive surgery versus women with no surgery.

Methodology: This study was a cross sectional comparative study carried out in the department of Obstetrics and Gynecology, Pakistan Air Force Hospital, Mianwali in a period from January 2011 to December 2015. Prolapsed women with stage II or more and with willingness for surgery were included in the surgery group. Those willing for conservative management (pelvic floor exercises) were included in the non-surgical group. All patients in both groups completed the PFDI and PFIQ at baseline and 6 month follow-up.

Results: Mean (±SD) age, weight, and parity of the patients were 51.42 (±9.07) years, 58.60 (±6.8) kg and 4.00 (±2.14) respectively. More than half of the patients (61%) belonged to low socio economic status, followed by middle class 34% and upper class 5%. Majority of the patients (61%) were post-menopausal. Most of the patients (72%) had stage II prolapse, followed by stage III (27%) and stage IV (1%). Among the associated symptoms, voiding dysfunction (81%) was most commonly observed symptom. At baseline all the scores were found to be significantly high in surgical group as compared to non-surgical group however at follow-up significantly low scores were observed in surgical group than non-surgical group. Also, significant decrease in mean scores was observed in both the groups from baseline to follow-up.

Conclusion: The PFDI and PFIQ both are responsive to change in women undergoing surgical and non-surgical treatment for pelvic organ prolapse. But PFDI and PFIQ are more responsive to change in the surgical group. It was also concluded that PFDI is more responsive than the PFIQ in women with pelvic organ relapse.

Key Words: Prolapse, PFDI, PFIQ, POPIQ, UDI, CRADI, POPDI, UIQ, CRAIQ

INTRODUCTION:

According to World Health Organization (WHO), one of the most leading causes of ill health of women is utero-vaginal prolapse with global prevalence estimated to be 2-20% in women under 45 years of age[1]. It has been reported that it affects up to 50 percent of the women over 50 years of age[2]. The common symptom of vaginal prolapse is the displacement of tissues outside the vagina. Majority of the women undergoing vaginal prolapse describe the sensation as "something coming out of vagina". The most common symptoms associated with utero-vaginal prolapse includes pressure in the vagina or pelvis, painful intercourse (dyspareunia) and recurrent urinary tract infections. It has been estimated that 50 percent of parous women have some degree of uterovaginal prolapse, but only 20 percent of these are symptomatic[2]. Utero-vaginal prolapse is responsible for more than 200,000 surgical repair procedures each year[3]. Whereas urinary incontinence contributes about 13.1% in Asian population. As reported by Asian Society for Female Urology, its prevalence in Pakistan is about 11%[4]. Incontinence, either urine, faeces or flatus, is a distressing condition which affects all aspects of a woman's quality of life[5-7].

Surgical procedures are the mainstay in the treatment of female stress incontinence, pelvic organ prolapse or fecal incontinence[8-11]. The most important outcome of a surgical procedure is the relief of symptoms and improvement in quality of life[12-15]. The lifetime risk for a woman to undergo a single operation for prolapse or urinary incontinence has been estimated at 11 percent. Outcome measures for pelvic floor dysfunction procedures in the literature include the presence or absence of subjective symptoms, pad testing, urodynamic parameters and physical examination findings[16-18]. Over

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Received: 26-10-17
Revised: 15-12-17
Accepted: 24-03-18

the past decade, several quality of life questionnaires have been introduced for assessment of outcome measures in pelvic floor dysfuntion[19]. The pelvic floor Distress Inventory (PFDI) and pelvic floor impact questionnaire (PFIQ) are two questionnaires intended for women with all forms of pelvic floor disorders including pelvic organ prolapse, urinary incontinence and fecal incontinence[12]. The use of these questionnaires serves as the dual purpose of screening for and assessment of severity of disease. Their use has been recommended by the international continence initiative[20, 21].

This study conducted to determine the responsiveness of Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) in women with pelvic organ prolapse, undergoing vaginal reconstructive surgery versus women with no surgery.

MATERIALS AND METHODS:

This study was a cross sectional comparative study conducted in the department of Obstetrics and Gynaecology at Pakistan Air Force Hospital, Mianwali in a period from January 2011 to December 2015. A total of 120 patients were included in the study with 60 patients in Group A i.e. the surgical group and 60 patients in Group B i.e. the non-surgical group. Prolapsed patients with stage II or more, willing for surgery or conservative treatment were included in the study. Patients with mental illness (unable to answer the questionnaire) or with any pelvic pathology like fibroid uterus, malignancy etc. were excluded from the study.

Patients attending the gynecology OPD clinic, with complaints of something coming out of vagina or some associated symptoms, like voiding dysfunction, urinary incontinence or constipation were shortlisted and enrolled after the confirmation of prolapse through pelvic examination. Pelvic examination was performed in the lithotomy position and staging of prolapse was assessed according to the standards recorded by International Continence Society (ICS) with stage 0 – IV (POPQ). Per speculum examination was performed by inserting a Sim's speculum into the vagina and anterior and posterior walls were examined. After the decision for the type of vaginal surgery by a consultant, patient was referred to pre-operative room where informed consent was taken to participate in the study. Responsiveness of PFDI and PFIQ was assessed in two independent groups, one undergoing vaginal reconstructive surgery (group A) and the other (group B) with no surgical intervention, but was treated by pelvic floor exercises.

The two questionnaires PFDI and PFIQ were filled for all patients in both groups at baseline and 6 month follow-up. Patients in the group B were called for follow up after six months of the baseline visit and scores were calculated.

The PFDI and PFIQ assess the impact of pelvic floor disorders on health related quality of life. The PFDI contains 20 questions while PFIQ consists of 21 (7 in each scale) that assess the degree to which a subject's bowel, bladder, or pelvic symptoms impacts different activities of daily living, social relationships, or emotions. Each questionnaires further is divided into 3 scales i.e PFDI (POPDI, UDI, CRADI) and PFIQ (POPIQ, UIQ, CRAIQ). For the scales of both PFDI and PFIQ, a higher score indicates worse health status or poorer quality of life.

Data was analyzed using SPSS version 21.0. Mean ± SD were calculated for quantitative variables such as age, weight, and parity. Percentages/frequencies were calculated for qualitative variables such as socioeconomic status, menopausal status, previous pelvic procedure, stage of prolapse and associated symptoms like voiding dysfunction, urinary incontinence, fecal incontinence, and constipation. A paired T-test was used to compare pre and post treatment scores of PFDI and PFIQ for both Group A and Group B. Independent T- test was used to compare the scores of PFDI and PFIQ between the both groups. A repeated measure ANCOVA was applied to assess differences in PFDI and PFIQ scores between the groups adjusting for variables that were found to be significant in univariate analysis. P-value of < 0.05 was considered as significant.

RESULT:

Total number of patients enrolled in the study were 120 with equal allocation in both the groups out of which 9 were lost to follow-up (5 patients from surgical group and 4 from non-surgical group). Analysis was done on 111 patients i.e. 55 from surgical group and 56 from non surgical group. In the surgical group, 48 patients underwent vaginal hysterectomy with anterior repair(out of these 48 patients, 33 patients had posterior repair too). While 7 patients out of 55, had both anterior and posterior repair without hysterectomy.

There was significant difference in mean age between surgical and non-surgical patients. Mean (±SD) age of patients in surgical and non-surgical group was 51.42 (±9.07) years and 44.65 (±9.2) years respectively (p-value<0.0001, Table 1). Mean (±SD) weight of patients in group A and B was 58.6 (±6.8) kg and 59.93 (±7.10) kg respectively (p-value=0.295, Table 1). Mean (±SD) for parity was 4.5 (±2.14) in surgical group and 4.6 (±2.29) in non-surgical group (p-value=0.652, Table 1). Minimum parity was 0 and maximum parity was 13 in both groups. Majority of the patients (61%) belonged to low socio-economic class, followed by middle class 34% and upper class 5% (p-value=0.819, Table 1).

75% patients from the surgical group and 47% patients from non-surgical group were post-menopausal (p-value=0.001, Table 1). A significantly higher proportion of patients in non-surgical group had stage II prolapse as

compared to surgical group (85% vs 60%) whereas stage III and IV prolapse was found more in surgical group patients as compared to non-surgical group (38% vs 15%, 2% vs 0% respectively, p-value=0.004, Table 1).

Among associated symptoms; patients in surgical group were more likely to have voiding dysfunction (88.3%), followed by constipation (33.3%), urinary incontinence (26.7%), and fecal incontinence (5%). In non-surgical group voiding dysfunction (73.3%) was more prevalent followed by constipation (46.7%), urinary incontinence (20%) and fecal incontinence (1.7%, Table 1).

Significant decrease were found in mean pelvic floor distress inventory (PFDI) and pelvic floor impact Questionnaire (PFIQ) scores of both surgical and non-surgical patients from baseline to follow-up (Table 2). In PFDI, no significant differences in mean POPDI scores at baseline were found between surgical and non-surgical group (92.29 vs 91.25, p-value=0.223, Table 2) however, on average POPDI score was significantly low in surgical group as compared to non-surgical group at follow up visit (52.09 vs 74.54 p-value<0.0001, Table 2). Whereas, significant differences were observed in mean baseline and follow-up in UDI and CRADI score between surgical and non-surgical group (Table 2). In PFIQ, no significant differences in mean CRAIQ scores at baseline were found between surgical and non-surgical group (83.44 vs 83.27, p-value=0.850, Table 2) however, on average CRAIQ score was significantly low in surgical group as compared to non-surgical groupat follow up visit (58.76vs 67.36 p-value<0.0001, Table 2). Whereas, significant differences were observed in mean baseline and follow-up in POPIQ and UIQ score between surgical and non-surgical group (Table 2).

Also, adjusting for age, menopausal status, and prolapse stage significantly low PFDI and PFIQ scores were observed in surgical group as compared to non-surgical group, however in PFIQ no significant difference was observed in adjusted mean PFIQ score between surgical and non-surgical group (Table 3)

	Surgical group; n=60	Non-surgical group; n=60	Total	P-value
Age in years; Mean ± SD	51.42±9.07	44.65± 9.204	48.0±9.71	0.000*#
Weight in kg; Mean ± SD	58.60±6.8	59.93±7.10	59.27±6.95	0.295#
Parity; Mean ± SD	4.47 ± 2.14	4.65± 2.29	4.56±2.21	0.652#
Menopausal status; n (%)				
Pre-menopausal	15 (25)	32 (53)	47 (39)	
Post-menopausal	45 (75)	28 (47)	75 (61)	0.001*†
Socio-economic status; n (%)				
Low	37 (62)	36 (60)	73 (61)	
Middle	21 (35)	20 (33)	41 (34)	0.819 ~
High	2 (3)	4 (7)	6 (5)	
Prolapse stage; n (%)				
Stage II	36 (60)	51 (85)	87 (72)	
Stage III	23 (38)	9 (15)	32 (27)	0.004*~
Stage IV	1 (2)	0 (0)	1 (1)	
Symptoms				
Urinary Incontinence	16 (26.7)	12 (20)	28 (23)	0.388†
Voiding Dysfunction	53 (88.3)	44 (73.3)	97 (81)	0.037*†
Fecal Incontinence	3 (5)	1 (1.7)	4 (3)	0.619 ~
Constipation	20 (33.3)	28 (46.7)	48 (40)	0.136~
*P-value<0.05, **P-value<0.0001, # Independent Sample T-test, † Chi-square test, ~ Fisher-Exact test				

Table 1: Characteristics of study participants

	Surgical group		Non-surgical group		Between group
	Mean ± SD	P-value†	Baseline	P-value†	P-value#
PELVIC FLOOR DISTRESS INVENTORY (PFDI) SCORES					
Pelvic organ prolapse distress inventory (POPDI)					
Baseline	92.29 ± 5.45	0.000**	91.25 ± 4.44	0.000**	0.272
Follow-up	52.09 ± 3.9		74.54 ± 3.94		0.000**
Urinary Distress Inventory (UDI)					
Baseline	91.4 ± 4.49	0.000**	84.75 ± 4.24	0.000**	0.000**
Follow-up	52.22 ± 6.75		64.93 ± 4.73		0.000**
Colorectal anal Distress Inventory (CRADI)					
Baseline	87.2 ± 4.23	0.000**	80.98 ± 4.45	0.000**	0.000**
Follow-up	57.69 ± 4.7		70.64 ± 3.83		0.000**
PELVIC FLOOR IMPACT QUESTIONNAIRE (PFIQ) SCORES Pelvic Organ Prolapse Impact Questionnaire (POPIQ)					
Baseline	88.98 ± 3.88	0.000**	75.85 ± 4.32	0.000**	0.000**
Follow-up	53.29 ± 4.32		62.84 ± 2.84		0.000**
Urinary impact questionnaire (UIQ)					
Baseline	89.56 ± 3.57	0.000**	82.45 ± 4.03	0.000**	0.000**
Follow-up	53.09 ± 4.68		69.80 ± 3.75		0.000**
Colorectal anal impact questionnaire (CRAIQ)					
Baseline	83.44 ± 5.61	0.000**	83.27 ± 3.52	0.000**	0.850
Follow-up	58.76 ± 5.17		67.4 ± 3.39		0.000**
*P-value<0.05, **P-value<0.005, † Paired T-test, # Independent Sample T-test					

Table 2: Comparison of baseline and follow-up scores

	Surgical group	Non-surgical group	P-value
	Mean ± SE	Mean ± SE	
PELVIC FLOOR DISTRESS INVENTORY (PFDI) SCORES			
POPDI	74.25 ± 0.78	84.17 ± 0.71	0.000**
UDI	72.71 ± 0.91	75.29 ± 0.83	0.041*
CRADI	72.64 ± 0.80	76.98 ± 0.73	0.000**
PELVIC FLOOR IMPACT QUESTIONNAIRE (PFIQ) SCORES			
POPIQ	71.08 ± 0.65	69.86 ± 0.59	0.174
UIQ	73.38 ± 0.69	76.19 ± 0.63	0.000**
CRAIQ	71.61 ± 0.81	75.30 ± 0.73	0.001*
*P-value <0.05, **P-value<0.0001, Repeated measures ANCOVA (adjusting for age, menopausal status and prolapse stage)			

Table 3: Estimated marginal means

DISCUSSION:

The PFDI and PFIQ questionnaires were designed to provide a comprehensive evaluation of the extent to which lower urinary tract, lower gastrointestinal tract and pelvic organ prolapse symptoms affect the quality of life of women who have disorders of the pelvic floor[12].

This study showed that PFDI and PFIQ are responsive to change and are reliable to detect improvement in scores of patients undergoing surgical and non-surgical treatment for pelvic organ prolapse. Significant better improvement in the scores of all the 3 scales of PFDI as well PFIQ was found, in both study groups (P-value<0.0001). It was also concluded that patients in the surgery group showed significant improvement in the scores of PFDI and PFIQ, than the patients of non-surgical group (P-value<0.0001). This study also showed that PFDI is more responsive to change than PFIQ, except the CRADI which was significantly less responsive than PFIQ, in the non-surgical group (P-value<0.0001).

A study conducted by Barber et al. concluded that the PFDI and the PFIQ are reliable, valid, condition specific quality of life instruments for women with pelvic floor disorders[22]. They found each scale of the PFDI and PFIQ proved to be internally consistent and reproducible. The POPDI and the POPIQ correlated significantly with the stage of prolapse (P value<0.01) and the CRADI and CRAIQ significantly correlated with the number of fecal incontinence episodes per month and diagnosis of defecatory dysfunction (P value < 0.01). The mean age in their study was SD 56±15years; median parity was 2 range (0-5) and mean weight SD 78±21kg. The results of mean age and weight were similar to this study whereas median parity was quite different[22].

Wren conducted a study, and they also found that the condition-specific health-related quality-of-life measures i.e. PFDI and PFIQ are valid and reliable in women after surgical procedures for pelvic organ prolapse[23].

A similar study was conducted in which validation of telephone administration of 2 condition-specific quality-of-life instruments i.e. PFDI and PFDI, was confirmed. Study period was 9 months with a study population of 55 women, and they were recruited at their 6 weeks post-partum visit. They found PFDI and PFIQ reliable and accurate measure of the impact of pelvic floor disorders and may facilitate clinical and epidemiologic research by decreasing cost and improving access to research participants. Their findings also strengthen the results for validation of these instruments[24].

Barber et al. conducted a study in which they developed the short forms of these 2 condition-specific quality-of-life questionnaires for women with pelvic floor disorders from the previously used long forms of both questionnaires i.e Urinary Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ). They studied data on 100 women, and observed the pre and postoperative scores at 6 months after surgery. They concluded that PFDI-20 and PFIQ-7 are valid, reliable and responsive short forms of 2 condition-specific quality-of-life questionnaires for women with pelvic floor disorders that matches the results of our study[25].

In this study it was found that both PFDI and PFIQ are valid and reliable questionnaires which are responsive to change in patients both with surgery and conservative management. These questionnaires should be used routinely in gynaecological outpatient clinic for subjective assessment of patients with pelvic organ prolapse.

CONCLUSION:

The PFDI and PFIQ both are responsive to change in women undergoing surgical and non-surgical treatment for pelvic organ prolapse but PFDI and PFIQ are more responsive to change in surgery group. It was also concluded that PFDI is more responsive than the PFIQ in women with pelvic organ relapse.

Our study has been done on a good strength of patients and follow-up period. However post-operative complications of surgery for POP, take much longer time to appear, at least 1 year. So studies require to be done with longer follow-up period to see the responsiveness of PFDI and PFIQ. As we have found both PFDI and PFIQ as valid and reliable questionnaires which are responsive to change in patients both with surgery and conservative management. So we think that they should be used as a routine in gynaecological outpatient clinic for subjective assessment of patients with pelvic organ prolapse.

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