



## Epidemiology Analysis of Pelvic Floor Medicine Center in Southern Israel Using PFDI-20 and PISQ-12 Quality of Life Questionnaires

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### Abstract

**Aim:** In the process of opening a new Pelvic Floor Medicine Unit, we aimed to map the pelvic floor dysfunction and sexual issues using validated quality of life (QOL) questionnaires.

**Material and Methods:** All the patients who attended the Pelvic Floor Medicine Unit clinic in Assuta University Medical Center in Ashdod, Israel, were given a validated Pelvic Floor Distress Inventory 20 (PFDI-20) and Prolapse Urinary Incontinence Sexual Questionnaire 12 (PISQ-12) questionnaires prior to meeting the physician. The patient's age, parity, and route of delivery were collected from the medical record. All data has been statistically analyzed using Kruskal Wallis Test and Mann-Whitney U Test.

**Results:** 647 patients were included in the study, of them 462 filled out the PFDI-20 questionnaires and 221 completed the PISQ-12 questionnaire filling.

In the PFDI-20 results, POPDI-6 higher scores were found to be associated with higher parity ( $p=0.043$ ) and with higher age ( $p=0.03$ ). CARD-8 scores were found to be significantly associated with cesarean delivery only in patients' history ( $p=0.023$ ) and with higher age ( $p=0.05$ ). UDI-6 scores were found significantly associated with older age ( $p<0.01$ ). PISQ-12 scores were found associated with age ( $p=0.002$ ), but not with either parity or route of delivery.

**Conclusions:** Using validated questionnaires, we could demonstrate a correlation between parity and age, an association between aging and higher rates of bowel and sexual dysfunction, an association between higher parity and pelvic organ prolapse complaints, and an association between previous cesarean deliveries only and higher rates of bowel dysfunction. The use of validated QoL questionnaires for describing the population suffering from PFDs presents an important tool in understanding the epidemiology of PFD in different communities.

### Keywords

Pelvic Floor Disorders, Southern Israel, Sexual Issues, Epidemiology, Surveys and Questionnaires, Women's Health

## Abbreviations

PFD: Pelvic Floor Disorders, QOL: Quality of Life, PFDI: Pelvic Floor Distress Inventory, PFIQ: Pelvic Floor Impact Questionnaire, PISQ: Prolapse Urinary Incontinence Sexual Questionnaire, POPDI: Pelvic Organ Prolapse Distress Inventory, UDI: Urinary Distress Inventory, CRAD: Colorectal-Anal Distress Inventory, AUMC: Assuta University Medical Center

## Introduction

Pelvic floor disorders (PFD) which include urinary incontinence, colorectal dysfunction, and pelvic organ prolapse, affect a substantial proportion of women and involve a significant influence on their quality of life (QoL) [1,2]. PFD are associated with psychosocial effects which negatively affect patients' self-esteem and sexual function [3], requiring a surgical solution in up to 20% of women [4,5], in order to achieve a normal lifestyle [5]. Thus, PFD carries considerable expense and personal suffering [6].

Ethnic and cultural variations of PFD perception [7], along with differences in PFD definitions, studies' design, methodology, and subgroups studied influence the reported prevalence of PFD<sup>1</sup>. An accurate estimation of the prevalence and distribution of PFD in a specific population is valuable for tailoring preventive interventions for high-risk patients and for research design in order to determine sample sizes.

Since PFD are usually not life-threatening conditions, but disorders of patients' well-being, a relevant tool for measuring their prevalence and their effects on QoL and on sexual function is the assessment of patients' complaints [8]. This has been facilitated by the development of disease-specific questionnaires for women with PFD. Some examples are the Pelvic Floor Distress Inventory (PFDI) - for symptom distress assessment, The Pelvic Floor Impact Questionnaire (PFIQ) for the assessment of symptoms' life impact [9], and the Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ) which is focused on sexual function [10]. Shorter versions of these questionnaires that are valid, reliable, and responsive to changes were developed for facilitating their use in the clinical and research settings [9,11].

The PFDI-20 [12] is a 20 item questionnaire divided into 6 items evaluating Pelvic Organ prolapse Distress

Inventory 6 (POPDI-6), 8 items evaluating Colorectal-Anal distress Inventory 8 (CRAD-8) and 6 items evaluating Urinary distress Inventory 6 (UDI-6) [12]. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) is a validated condition-specific quality of life questionnaire and is considered as the instrument of choice for the assessment of sexual function in women with urinary symptoms according to the International Continence Society recommends (with grade A) [11].

Nevertheless, Pelvic dysfunction QOL questionnaires are commonly used for comparison of patients' status before and after specific therapy and not as an epidemiological tool. Some previous studies investigated the prevalence of PFD using validated questionnaires, for the characterization of specific populations [13-16], but data is limited.

The Assuta University Medical Center (AUMC) was established in 2017 in order to provide medical services to the underserved population of Ashdod city and its suburbs. Ashdod is a southern city in Israel, counted 250,314 citizens as of 2017 (2.85% of the Israeli population), characterized by its ethnical heterogeneity: 63% of inhabitants were born in Israel. 33% were offspring of an Israeli born father. Of the others, 30% were American or European in origin, 17.5% of North African origin, 5% of Asian origin, and 2% of Ethiopian origin [17]. The Pelvic Floor Medicine outpatients' clinic opened in AUMC aimed to provide consultations to the community family physicians and gynecologists for their female patients with PFD complaints. In the process of opening the new Pelvic Floor Medicine Unit in AUMC, we aimed to map the pelvic floor dysfunction issues in this community using validated QOL questionnaires.

## Materials and Methods

This is a prospective cohort study conducted in AUMC, since the foundation of the department of

Obstetrics and Gynecology on August 2017 until July 2019. The study was approved by the hospital Helsinki committee.

#### Study Population and Data Collection:

All women who referred to the Pelvic Floor outpatient clinic in AUMC during the study period were included in the study. All patients were asked to fill out a validated PFDI-20 and the PISQ-12 questionnaires in their language (Hebrew, Russian or English) at their admission to the clinic, before encountering the physician. PFDI-20 results were calculated according to the original questionnaire's instructions: the total score was a summation of the 3 scales together (range 0 to 300), and each scale scores was calculated by obtaining the mean value of the answered items within the corresponding scale (possible value 0 to 4) and then multiplying by 25 to obtain the scale score (range 0 to 100). Missing items were dealt with by using the mean from answered items only [18]. PISQ-12 results were calculated as a summation of the items' scores. Missing items are dealt with by using the mean from answered items only. Questionnaires with more than 2 missing items were excluded [11]. The patient's age, parity, and route of delivery were collected from the medical record.

#### Statistical Analysis:

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, software version 21). All data has been statistically analyzed using the Kruskal Wallis test for multiple groups comparison, and Mann-Whitney U Test for determining differences between two study groups. P values for all hypothesis testing were two-sided, and  $P < 0.05$  was interpreted as statistically significant.

#### Results

647 patients attended the Pelvic Floor clinic during the study period, of them, 462 (71%) filled out the PFDI-20 questionnaires and were included in the study. Twenty-nine women were lacking obstetrical history in their medical records. 221 (48%) completed also the PISQ-12 questionnaire filling. The average age of patients was 56.5 (18-92) years old and the average parity of 3.29 (0-14) deliveries per patient. Eighty-six percent of the patients (n=370) had vaginal deliveries

(VD) only, 2% had undergone cesarean delivery (CD) only (n=7), and 10% had VD and CD in their past (n=44). 2% were nulliparous (n=10).

Mean study cohort questionnaires' scores are presented in **Table-1**. Mean PFDI-20 scores for the study cohort were: 35.58±22.54 for the POPDI-6, 29.26±20.62 for the CRAD-8, 50.24±25.80 for UDI-6 and 115.08±45.3 for the total PFDI-20 score. THE mean PISQ-12 score was 14.0±6.6. A correlation between patients' age and parity ( $p=0.005$ ) was found, and a correlation between PISQ-12 scores and PFDI-20 scores for each domain separately and for the total score ( $p$  value for Pearson correlation  $< 0.001$ ). POPDI-6 was shown to be associated with parity ( $p=0.043$ ).

**Table-1: Study cohort Questionnaires' Mean Scores**

	Study cohort scores (mean±)
n / mean score	462
POPDI-6 scale	35.6±22.5
CRAD-8 scale	29.3±20.6
UDI-6 scale	50.2±25.8
Total PFDI-20 score	115.1±45.3
n for PISQ-12	221
Total PISQ-12 score	14.0±6.6

Questionnaires' scores according to patients' parity are presented in **Table-2**. Significant differences were found in POPDI-6 scores which were higher with higher parity. A direct comparison between the different parity groups revealed a significant difference between the nulliparous and the group with the previous 3 deliveries or more. No other significant differences were demonstrated.

Results according to the route of previous deliveries are presented in **Table-3**. Differences between groups were significant in the CRAD-8 domain only. Women who had delivered by CS only had the highest and significant average total PFDI-20 score.

The questionnaires' results according to patients' age are presented in **Table-4a** to **Table-4c**.

Number of previous deliveries	0	1	2	3+	p value
n / mean score±SD	10	53	112	236	
POPDI-6 scale	23.3±20.6	29.0±21.1	36.3±23.9	37.5±22.2	0.043
CRAD-8 scale	29.7±16.0	25.6±20.3	28.60±18.8	30.35±22.0	0.499
UDI-6 scale	46.5±20.6	43.2±25.2	51.73±24.9	51.41±26.8	0.179
Total PFDI-20 score	99.3±32/7	97.9±44.8	116.6±45.1	119.2±46.4	0.149
n for PISQ-12	3	23	60	135	
Total PISQ-12 score	17.0±7.2	14.3±5.2	13.0±6.5	14.3±7.0	0.415

Previous route of deliveries	Previous VD only	Previous CS and VD	Previous CS only	Nuliparity	p value
n / mean score	370	44	7	10	
POPDI-6 scale	36.3±22.9	34.0±21.2	37.5±17.0	23.3±20.6	0.358
CRAD-8 scale	28.2±20.5	34.3±21.9	52.7±26.7	29.7±16.0	0.023
UDI-6 scale	50.3±26.0	48.7±27.9	67.9±20.2	46.3±20.6	0.281
Total PFDI-20 score	114.90±45.7	116.97±46.6	158.04±48.4	99.27±32.7	0.202
n for PISQ-12	194	23	1	3	
Total PISQ-12 score	14.1±6.7	11.8±5.9	21	17.0±7.2	0.172

Patient age	<45	45.01-60	60.01-70	>70.01	p value
n / mean score±SD	109	142	133	78	
POPDI-6 scale	30.5±22.6	37.9±23.5	34.7±20.3	40.0±24.5	0.03
CRAD-8 scale	27.2±17.9	31.1±22.1	26.7±21.0	33.2±20.1	0.05
UDI-6 scale	45.6±27.6	56.0±24.0	46.7±26.4	52.3±26.3	<0.001
Total PFDI-20 score	103.27±44.3	124.95±44.3	108.11±44.85	125.4±48.68	0.01

The cohort was divided into 4 age groups (<45, 45.01-60, 60.01-70, >70) and the results of PFDI-20 were compared. Data is presented in **Table-4a**. Significant differences between groups were found for each PFDI-20 category, and for the total PFDI-20 score. Significance was more pronounced when this comparison was made only between patients who delivered vaginally only in their past (not presented). A direct comparison between the different specific age groups is presented in **Table-4b**. All PFDI-20 scores were significantly different in the comparison of

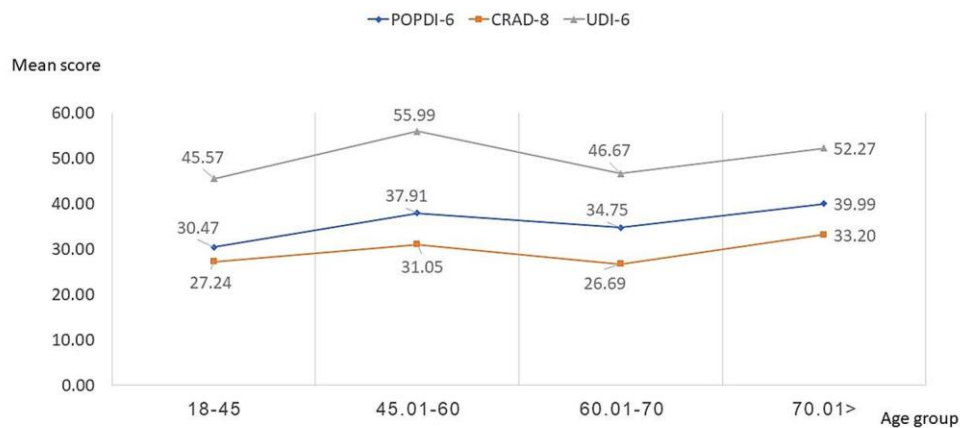
youngest to oldest patients. A higher score of the CRAD-8 was found beyond the age of 60. When the cohort was divided into 3 different age groups (<50, 50.01-70,>70), and a comparison of PISQ-12 scores was made the results were different. The results are presented in **Table-4c**. A significantly higher mean score was found in the group of patients older than 70. PFDI's scores' trends according to patients' age groups are presented in **Fig-1**. Similar differences between groups were found when patients who had VD only in their past were included.

**Table-4b: Specific comparison between different age groups in the four groups division**

Age groups compared	<45 vs >70			<45 vs 45-60			45-60 vs 60-70			60-70 vs >70		
	<45	>70	p value	<45	45-60	p value	45-60	60-70	p value	60-70	>70	p value
POPDI-6 scale	30.47	39.99	0.01	30.47	37.91	0.05	37.91	34.75	0.52	34.75	39.99	0.06
CRAD-8 scale	27.24	33.2	0.03	27.24	31.05	0.3	31.05	26.69	0.07	26.69	33.2	0.01
UDI-6 scale	45.57	52.27	0.06	45.57	55.99	0.01	55.99	46.67	0	46.67	52.27	0.05
Total PFDI-20 score	103.27 ±44.3	125.4±48.68	0.028	103.27 ±44.3	124.95 ±44.3	0.02	124.95 ±44.3	108.11±44.85	0.007	108.11±44.85	125.4±48.68	0.015

**Table-4c: Mean PISQ's scores according to age - a three categories division**

Patient age	<50	50.01-70	<70.01	p value
n / mean score	109	142	78	
PISQ-12 scale	12.0±5.8	15.3±7.0	15.3±7.4	0.002



**Fig-1: Questionnaires mean scores in four age groups division**

## Discussion

There is a real challenge in the epidemiological research of PFD. Only a few studies described its prevalence in the general population [16,19-21], but most of them were limited by measurement issues: the use of objective tools for PFD measurement, or the use of direct (face to face) questions for evaluating symptoms - with the inherent limitation of patients' embarrassment. Most data reported in other studies

usually reflected the minority of the patients who refer to specialist centers [21]. Variations in definitions and measurement issues are fundamental and lead to problems with assessing the findings in these studies [21]. These obstacles challenged the analysis of data, for determining risk factors for PFD.

Hence, the International Continence Society committee raised the need for studies done only with

recommended and validated questionnaires, for assessing the absolute and relative importance of several risk factors [21]. Nevertheless, the use of QOL questionnaires has been mostly comparative for specific intervention and their use for descriptive goals is limited.

In this study, we describe the PFD distribution and the sexual profile of an underserved, heterogeneous urban population, referred to a Urogynecology unit. We evaluated patients PFD, QOL, and sexual profile by validated questionnaires. Firstly, we could find a correlation between the total PFDI-20 mean score to PISQ-12 mean score, similar to earlier reports [22,23]. Next, we were able to find some trends in this cohort in 4 different aspects: prolapse symptoms, urinary complaints, fecal – anal disorders, and sexual dysfunction (SD). We analyzed their distribution in regard with patients' age, parity, and route of previous deliveries:

#### *Prolapse Symptoms:*

In the POPDI-6, we found a worsening in POP complaints with the increase in parity and with aging, as already described [24,25]. The significant difference between different parity groups, however, was found only between nulliparous and patients who had previous 3 or more deliveries. The role of multiparity as a risk factor for POP was already described [16,26]. On one hand, the damage of the levator ani muscles and the external anal sphincter, as studied sonographically, occurs during the first vaginal delivery, with no additional harm in subsequent deliveries [27,28]. On the other hand, however, the pathogenesis of POP is likely to be multifactorial, and other factors may have a role in POP formation: it was demonstrated lately that multiparity in ovine is associated with diminished vaginal muscularis, increased elastic fibers and vaginal wall weakness [29].

We found no association between the route of previous deliveries and POPDI-6 scores. A similar finding was reported by a Czech study [30] used the PFDI-20 for primiparous 5-10 years after delivery. However, a recent meta- analysis [31] analyzed subjective reports for POP, and a recent Chinese study

[16], used the PFDI-20, reported a higher risk for POP among patients who delivered vaginally. The ICS committee found a mode of delivery as a debatable risk factor for POP, and argue that the pelvic floor damage may be the result of previous pregnancies rather than previous deliveries [21].

#### *Fecal Incontinence:*

We could find in the literature studies which used questionnaires to investigate the long-term effect of patients' obstetrical history on FI and AI, some are not specific to long term impact of obstetric anal sphincter trauma [32-35]. In our study, we found the CARD-8 section a significantly higher mean score for women who had delivered by CS only ( $p=0.023$ ). Hence, in our cohort women who had delivered by cesarean section only, were found to suffer more from bowel disorders than nulliparous and patients who underwent VD. Some previous studies found a protective role for CS in the pathogenesis of FI and described lower rates of long term anal insufficiency and fecal incontinence among patients who delivered by CS only [35,36]. Nevertheless, other studies could not demonstrate this protective rule of CS, and argued that FI is not only a result of anal sphincter obstetrical trauma, but may also be a consequence of the pregnancy itself, and of an intra-abdominal nerves injury happening during CS, which results in bowel dysfunction [21,37-39]. These theories, however, may not suffice for explaining our findings, in which the scores of patients who had VD and CS in their past were not significantly different compared to patients who underwent VD only. It may be, however, that the limited number of patients in this group ( $n=7$ ) biased the results.

Age was found as associated with CARD-8 results, with significantly higher scores for older than 70-year-old when compared to the 60-70-year-old group. This finding is consistent with the literature, as age is one of the most important risk factors to anal insufficiency and fecal incontinence [21,38], most probably due to higher rates of comorbidities and pelvic floor degenerative processes among older patients [21,32]. We found no association between parity and CARD-8 results, as was already reported [32-40].

### *Urinary Incontinence:*

In the UDI-6 section, we found significant differences in scores between different age groups. We could demonstrate the differences when we followed females' physiology and compared 4 different life-periods (<45, 45-60, 60-70, 70<), (**Table-4a**, **Table-4b**, and **Fig-1**). Higher scores were found in the comparison between the 45-60-year-old group, and a 45-year-old young group. A later mild but significant improvement in scores was shown in the comparison of patients in the 70-60-year-old group to patients in the 45-60-year-old group, and later a significant worsening (higher scores) was found with aging. A similar pattern was described [21] in the ICS's committee paper of PFDs' epidemiology. This paper suggests that the pattern may reflect an increase in the prevalence of stress UI during middle age, followed by a later decline or even mild increase after the age of 50, integrated with an opposite trend in urge and mixed UI which continue to rise after age 50.

We found no association between UDI-6 scores and parity or route of delivery. Previous meta-analyses and a large study use a postal- and an internet-based questionnaire with validated questions that investigated the association of parity and UI did find higher parity as associated with higher rates of UI [41,42], and vaginal delivery as a risk for associated with higher rates of UI compared to CS or nulliparity [43]. These earlier studies are debatable, since it could be that these associations are a result of selection bias [21,44].

### *Sexual Disturbances:*

The use of questionnaires for the description of populations in the field of SD is much more common than their use in the fields of PFDs. Data regarding the rates of SDs in women suffering from PFD in comparison to the general population is heterogenous, while different studies that used the PISQ-12 published conflicting evidence: some found higher rates of SD among these women [45,46], and others found no difference in questionnaires' scores [47,48]. In our cohort, fewer patients were included in the PISQ-12 analysis than in the PFDI-20 analysis, due to the different questionnaire's instructions [11]. Patient's age was found as significantly associated with PISQ-12

higher scores (i.e higher rates of sexual dysfunctions in the older group), while parity and route of delivery were not found as associated with PISQ-12 scores. The association between aging and higher rates of sexual dysfunction is well established. Using PISQ-12, age was described as a risk factor for sexual dysfunction [49,50] and was reported as such among women who suffer from PFDs [51]. These studies, however, reported about patients' urinary and/or POP complaints but data regarding colorectal dysfunction is missing. As for parity, one study which used the PISQ-12 found nulliparous to have superior sexual satisfaction scores compared to parous women [52]. In our cohort, there were 3 nulliparous, who had higher but not significant mean score. It may be that the low number of patients in this group biased the results. Mode of delivery was found to have no long-term impact on sexual function in some studies used PISQ-12, similar to our findings.

### **Study's limitations**

The most significant limitation of this study is its inherent selection bias, which results from the study's design: only patients referred to our clinic were included in the study, and we could not describe the epidemiology of the general local population. However, the use of validated questionnaires for characterizing patients who were included enabled finding associations reliably.

Another limitation is the lack of validated criteria for defining the cutoff for significant differences when comparing between different groups, and not between the same patient's scores as for the evaluation of exposure or interventions. Nevertheless, we could demonstrate trends and patterns, and statistically significant differences between study groups.

Study cohort size is another limitation: in some case study groups were too small for drawing conclusions, and may only suggest a trend or association that would have to be studied in larger populations.

However, the use of validated questionnaires which were already proved as a reliable tool for evaluating clinically significant PFDs [18,53] reflects our cohort's PFDs well.

## Summery

Using validates questionnaires, we could demonstrate in this study a correlation between parity and age, and some interesting associations regarding risk factors for PDFs:

- An association between aging and higher rates of bowel and sexual dysfunction.
- An association between higher parity and pelvic organ prolapse complaints.
- An association between previous cesarean deliveries only and higher rates of bowel disfunction.

These results raise some questions regarding current conceptions, that are based on different research methodologies. We do believe that the field of PFDs should be farther investigated using the same method, in larger cohorts, different populations, and as a tool for describing the general population's epidemiology properly.

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## Conflict of Interest

All authors have read and approved the final version of the manuscript. The authors have no conflicts of interest to declare.

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