Sexual Function and Quality of Life in Women with Urinary Incontinence Treated by a Complete Pelvic Floor Rehabilitation Program (Biofeedback, Functional Electrical Stimulation, Pelvic Floor Muscles Exercises, and Vaginal Cones)

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ABSTRACT

Introduction. Urinary incontinence (UI) is a debilitating condition that can cause discomfort, embarrassment, loss of confidence; it can lead to withdrawal from social life, and adversely affects physical and mental health, sexual function and quality of life (QoL) in women.
Aim. The aim is to determine the impact of combined pelvic floor rehabilitation (PFR) on UI, female sexual dysfunction, and QoL.
Main Outcome Measures. Female Sexual Function Index questionnaire (FSFI) and King's Health Questionnaire (KHQ).
Methods. Sixteen patients with UI were selected and underwent a complete PFR program (biofeedback, functional electrical stimulation, pelvic floor muscles exercises, and vaginal cones). Patient filled out the FSFI questionnaire and the KHQ at the baseline and at follow-up.
Results. After PFR none of the patients reported urine leakage during sexual activity. Resolution of incontinence was achieved in 13 (81.25%) women. Only three (18.75%) patients had positive 1-hour pad test after the treatment. There was significant difference between pad test leakage before and after the PFR ($P < 0.001$).

The mean Stamey incontinence score was 1.37 ± 0.5 at the baseline vs. 0.25 ± 0.57 at the follow up ($P < 0.001$). Before PFR, FSFI total score ranged from 25.8 to 2 (mean 14.65 ± 6.88), after treatment the FSFI total score ranged from 36 to 2 (mean 22.65 ± 9.5) ($P < 0.001$). The improvement of the scores in the six FSFI domains, 5 months after the conclusion of PFR, was statistically significant (desire, arousal, lubrication, orgasm, satisfaction, and pain). All the nine domains in the KHQ presented a low average score after treatment and the improvements were statistically significant.
Conclusions. PFR led to a significant difference in the daily use of pads, 1-hour pad test, and Stamey incontinence scores. The treatment caused an improvement in patient's QoL index and sexual function. **Rivalta M, Sighinolfi MC, Micali S, De Stefani S, and Bianchi G. Sexual function and quality of life in women with urinary incontinence treated by a complete pelvic floor rehabilitation program (biofeedback, functional electrical stimulation, pelvic floor muscles exercises, and vaginal cones). J Sex Med **;**:**–**.**

Key Words. Urinary Incontinence; Pelvic Floor Rehabilitation; Sexual Function; Quality of Life

Pelvic floor rehabilitation should be considered as first-line-therapy, as it is a minimally invasive procedure and effective, without precluding surgery in case of failure. A complete rehabilitation program can provide a beneficial effect on sexual function and quality of life.

Introduction

Urinary incontinence (UI) is a very common condition, especially in women, and affects almost all aspects of everyday life, influencing not only affected individuals but also their families.

The prevalence of UI increases with age, with a typical rate in young adults ranging from 20% to 30%, reaching from 30% to 40% around middle age, with a further steady increase in older age (prevalence: 30–50%) [1]. Stress urinary incontinence (SUI) is the most common type of UI and it is defined as any involuntary leakage of urine related to any abdominal effort such as coughing or sneezing [2]. It is estimated that 49% of the women with symptoms of incontinence present SUI [3]. Increased life expectancy, particularly in women, has led to an increasing incidence of UI. UI interferes in social, physical, psychological, and sexual aspects, adversely affecting self-esteem and quality of life (QoL). Health problems, bad sleep, economic impair, sexual dysfunction, uncomfortable interpersonal relationships, and decreased self-confidence can cause social exclusion and psychological problems [4,5].

Conservative treatment based on pelvic floor muscle exercises to restore the support of the pelvic organs and the urethral closing mechanism is becoming an important therapeutic option for the treatment of SUI. Pelvic floor rehabilitation (PFR) should be considered as first-line therapy (according to U.S. Department of Health and Social Services Clinical Guidelines Panel and according to European Association of Urology [EAU] Urological Guidelines), as it is a minimally invasive as well as effective procedure, which does not preclude surgery in case of failure [6].

A complete PFR treatment program usually includes the following: biofeedback (BFB), functional electrical stimulation (FES), pelvic floor muscle exercises (PFME), and PFME using vaginal cones (VC) [6,7].

Female UI is frequently associated with sexual dysfunction, and as a consequence, lower Female Sexual Function Index (FSFI) scores in clinical trials [8,9].

An evaluation of sexual health among women who were affected by overactive bladder (OAB) was recently carried out by Coyne and co-workers: whether associated or not with incontinence, OAB results in an impairment of sexual function, desire, and ability to achieve orgasm [10]. Urinary stress incontinence has been found to have a negative impact on the quality of the patient's sexual life, the patient experiencing frequent pain, and coital incontinence during intercourse [5,11].

We previously presented a therapeutic approach to this emerging aspect of incontinence: a preliminary experience with the use of combined PFR techniques (BFB–FES–PFME–VC) in just three female patients affected by sexual dysfunction [7].

Table 1 Inclusion and exclusion criteria

Inclusion criteria
Women older than 18 years of age
No associated neurological disease
Stress urinary incontinence
Exclusion criteria
Detrusor overactivity
Reduced cistometric capacity and/or bladder compliance
Previous surgical treatment for stress urinary incontinence
Cystocele, rectocele, uterine prolapse of degree II or higher
Current or recurrent vulvovaginitis
Current or recurrent urinary tract infections
Pregnancy
Pace Maker

The purpose of this study is to evaluate the effects of the combined and complete rehabilitative treatment of SUI, through 1-hour pad test, Stamey incontinence score, the FSFI, and the king's Health Questionnaire (KHQ).

Materials and Methods

This is a prospective study conducted from December 2007 to March 2009. The treatment was offered to patients with clinical history of SUI during medical consultation. For a total of 30 patients that underwent consultation during this period, 12 did not meet the inclusion criteria (Table 1) and 2 refused the treatment modality because of difficulties to take part in the session at the hospital once a week.

The average age of the patients was 48.5 years (range from 29 to 70 years). Pads were used by all the patients (mean of 1.3 pads per day). In the 56.2% of the patients there had been a previous vaginal delivery, and mean parity was 1.33. The mean body mass index was 22.3 (range 17–30). Five women (31.2%) reported "a little" urine leakage during sexual activity or intercourse (KHQ has a specific section for urinary symptoms, which is not considered for global score, but allows the patient to express the degree of impact of each individual symptom on their life as "a little," "moderately," or "a lot").

SUI was indicated by a full clinical examination, including a complete history, standard urodynamic evaluation, urinalysis, urine culture, a complete gynecologic examination, and a cough provocation test in the supine and standing position with a comfortably full bladder. Participants in the study were free from any other gynecologic disease such as uterine myoma, ovarian cyst, or

advanced uterine or vaginal prolapsed. Only patients in grade 0 and grade 1 according to the Pelvic Organ Prolapsed-Quantification Scale (POP-Q) were included in the study. The POP-Q scale was used pretreatment as well as during every follow-up visit. Urodynamic studies were performed according to the International Continence Society standards. Leak-point pressure during Valsalva maneuver (VLPP) was measured. VLPP was determined at 180 mL of bladder filling. Intrinsic sphincter deficiency (ISD) was defined as VLPP of ≤60 cm H2O. Postvoid residual volume was measured after spontaneous micturition. The Stamey incontinence score (grade 0: continent; grade 1: loss of urine with sudden increases in abdominal pressure, coughing, sneezing, laughing; grade 2: leaks with lesser degrees of physical stress, such as walking, standing erect from a sitting position, or sitting up in bed; grade 3: total incontinence, urine is lost without any relation to physical activity or position) was used for grading the severity of SUI before and after the treatment [12].

A 1-hour pad weighing test, with standardized volume (200 mL of bladder filling), was performed in order to quantify the degree of UI and it was considered as positive when the weight was >2 *g* [13].

The patients underwent combined PFR (BFB–FES–PFME–VC) after signing an informed consent with prior verbal explanation of all the steps of the procedure.

The steps for a complete PFR program were carried out as follows [7,8]: (i) FES for 20 minutes once a week for a period of 3 months. Selected parameters included biphasic intermittent current with the frequency set at 50 Hz, pulse width of 300 ms, and an adjustable current intensity (0–100 mA) to reach the tolerable intensity of stimulation that did not cause pain in each individual patient. "On time" ranged from 0.5 to 10 seconds and "off time" ranged from 0 to 30 seconds. (ii) BFB was conducted for 15 minutes, once a week for a period of 3 months. (iii) PFME alone and (iv) PFME using VC were performed by the patient at home, after a preliminary training with the urologist, accordingly to the Kegel protocol; this procedure requires at least 300 contractions of the pelvic floor muscle (PFM) a day divided into six sessions, isolating PFM contractions and eliminating co-activation synergies, alternating isotonic, and isometric exercises. PFME were also performed using VC: three plastic cones with a metal interior identical in shape and volume but different in weight. Each patient began exercising with the lightest cone retainable in the vagina for 1 minute; once the cone can be retained easily for 10 minutes, the patient started exercising with the next heaviest cone. Before moving on to a heavier cone, it is advisable to check that the patient can retain the cone when coughing, ascending and descending stairs, and running.

The patients were assisted by the same urologist during the treatment. No patient (n 16) missed the follow up.

Patient filled out the FSFI questionnaire [14] and the KHQ [15] before the PFR and at follow-up (5 months after the conclusion of PFR). We evaluated each domain score.

The KHQ is a specific assessment instrument of the QoL for women with UI [15], which consists of 21 items distributed in nine dimensions: general health, incontinence impact, role limitations, personal limitations, social limitations, personal relationship, emotions, sleep/energy, severity measures. The score of each dimension ranges from 0 (lower UI impact and therefore better QoL) to 100 (higher impact, worse QoL).

FSFI is a brief, self-report measure of female sexual function that evaluates six different domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. It was first described by Rosen in 2000 [16] and is widely used for the assessment of female sexual function. The optimal cutoff between normal and pathological values is set at 26.55 [14], which means sexual life is considered normal in the patients who scored >26.55, and pathological in those who scored <26.55. The cutoff scores to determine the presence of difficulties on the six domains of the FSFI were obtained from published sources [14,17]; accordingly, scores smaller than: 4.28 on the desire domain, 5.08 on the arousal domain, 5.45 on the lubrication domain, 5.05 on the orgasm domain, 5.04 on the satisfaction domain, and 5.51 on the pain domain were used to classify participants as having difficulties on that domain.

The student's *t*-test was used for statistical analysis, to compare pretreatment and post-treatment data; statistical significance was set at the 5% level (P value < 0.05).

Results

All the patients completed the scheduled program, and their compliance was verified through a

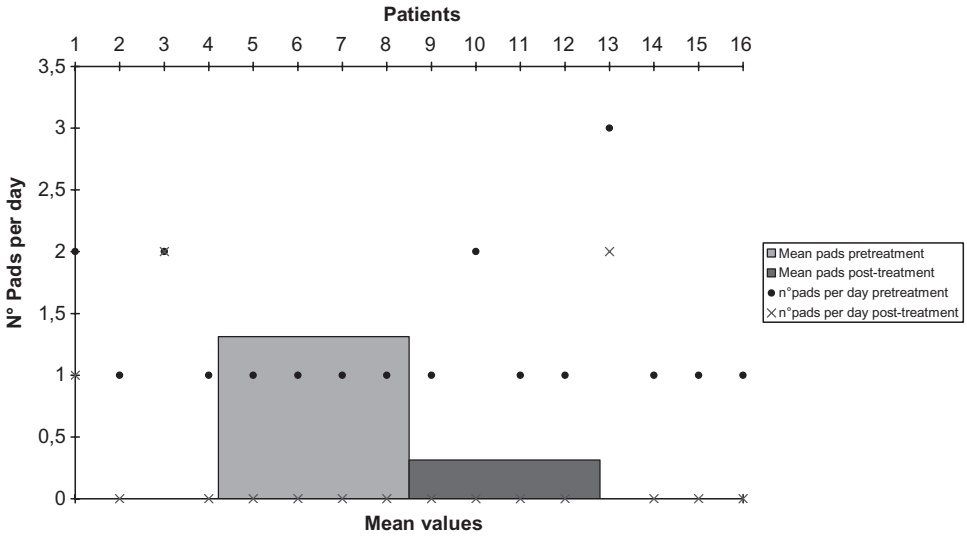

Figure 1 Pads usage per day before and after the treatment.

weekly visit. None of the patients reported side effects as a result of the treatment.

After the combined rehabilitation program none of them reported urine leakage during sexual activity, including intercourse.

Daily Use of Pads (Figure 1)

Resolution of incontinence was achieved in 13 (81.25%) women who were dry and did not require any use of pads; two (12.5%) patients improved (reduced their daily use of one pad), but had persistent stress incontinence. The mean pads per day utilize was 1.3 ± 0.6 in pretreatment vs. 0.3 ± 0.7 in post-treatment, at 5 months after the conclusion of PFR ($P < 0.001$) (Figure 1).

1-Hour Pad Test (Figure 2)

Mean urinary leakage at the 1-hour pad test before the rehabilitation was 19.93 *g* ± 14.29 *g*, ranging from 52 *g* to 10 *g*. At the follow up, the mean urinary leakage was 4.68 *g* ± 12.03, ranging from 45 *g* to 0 *g*; only three (18.75%) patients had positive 1-hour pad test (weight > 2 *g*) after the treatment (Figure 2). There was a significant difference between pad test leakage before and after the PFR ($P < 0.001$).

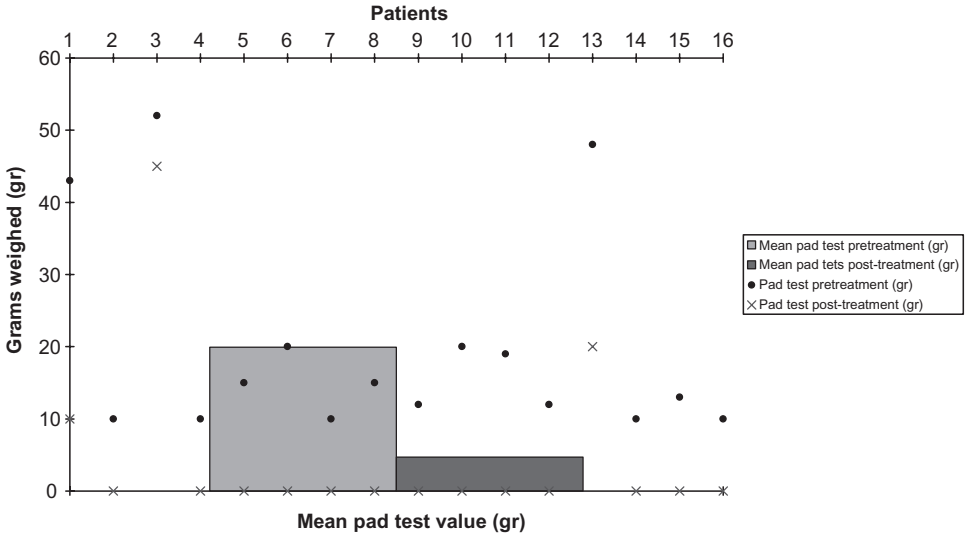

Figure 2 1-Hour pad test before and after the treatment.

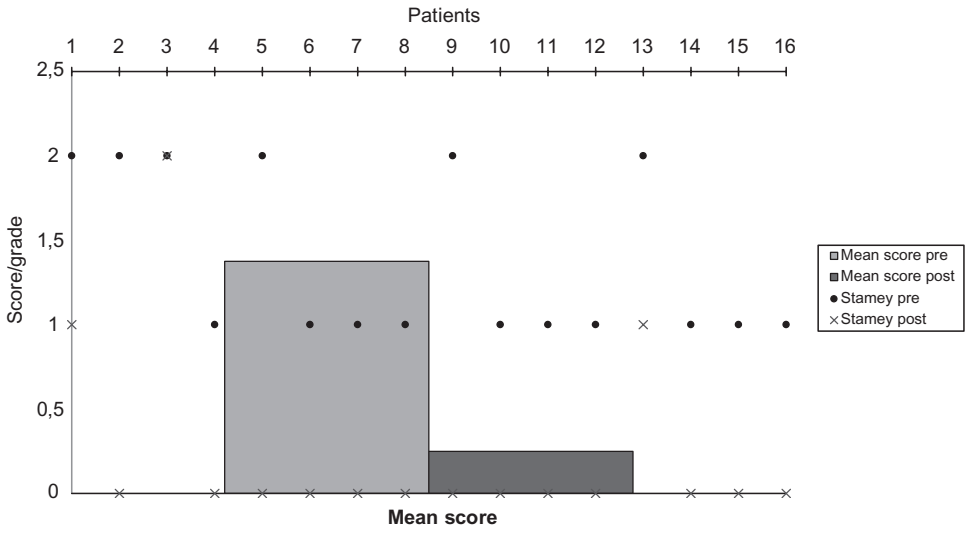

Figure 3 Stamey incontinence score before and after the treatment.

Stamey Score (Figure 3)

The Stamey incontinence score was used for grading the severity of SUI. The mean score was 1.37 ± 0.5 (range 1–2) at the baseline vs. 0.25 ± 0.57 (range 0–2) at the follow up ($P < 0.001$). Thirteen (81.25%) patients were cured (grade 0—"continent"), two (12.5%) improved (grade 1—"loss of urine with sudden increases in abdominal pressure"), and one (6.25%) patient had an unchanged incontinence score (grade 2—"leaks with lesser degrees of physical stress").

FSFI (Figure 4)

Before PFR, the FSFI total score ranged from 25.8 to 2 (mean 14.65 ± 6.88), after treatment the FSFI total score ranged from 36 to 2 (mean 22.65 ± 9.5) ($P < 0.001$).

The domain of desire improved significantly, from 2.36 ± 1.06 in the pretreatment to 3.86 ± 1.62 in the post-treatment ($P < 0.001$); arousal from 2.47 ± 1.25 to 3.82 ± 1.55 ($P < 0.001$); lubrication scores increased from 2.71 ± 1.09 to 3.91 ± 1.67 ($P < 0.001$); orgasm from 2.42 ± 1.24 to 3.8 ± 1.62 ($P < 0.001$); satisfaction from 2.35 ± 1.12 to 3.75 ± 1.53 ($P < 0.001$); and pain from 2.32 ± 1.22 to 3.5 ± 1.74 ($P < 0.001$) (values are mean values plus or minus standard error of the mean). Figure 4 shows the results of the FSFI questionnaire.

The improvement of the six domains FSFI scores 5 months after the conclusion of PFR were statistically significant.

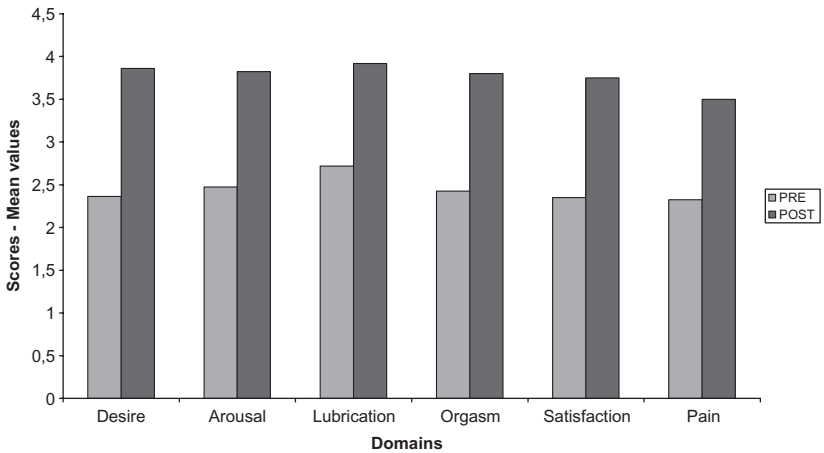

Figure 4 Female Sexual Function Index (FSFI) scores before and after the treatment.

Table 2 KHQ scores before and 5 months after the conclusion of pelvic floor rehabilitation

KHQ domains	Mean scores pre-treatment	Mean scores post-treatment	*P* value
1. General health perception	32.81 ± 15.05	21.87 ± 17.96	<0.005
2. Incontinence impact	62.50 ± 26.87	33.33 ± 27.21	<0.001
3. Role limitations	62.50 ± 19.72	30.20 ± 22.92	<0.001
4. Physical limitations	70.83 ± 16.66	34.37 ± 25.43	<0.001
5. Social limitations	59.37 ± 21.05	29.16 ± 21.80	<0.001
6. Personal relationships	74.44 ± 20.76	27.77 ± 24.93	<0.001
7. Emotions	47.22 ± 26.75	26.38 ± 28.36	<0.001
8. Sleep/Energy	33.33 ± 21.08	25.00 ± 21.08	<0.05
9. Severity measures	56.25 ± 27.32	23.33 ± 30.59	<0.001

KHQ = King's Health Questionnaire.

KHQ (Table 2; Figure 5)

Each KHQ domain obtained a score, and therefore there was no general or total score for this questionnaire (Table 2) (Figure 5). The scores range from 0 to 100 and the higher the score, the poorer the QoL. All the nine domains (general health, incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy, and severity measures) in the KHQ presented a lower average score after treatment and the improvements were statistically significant (Table 2).

Discussion

UI has a profound impact on patients' lives. This debilitating, chronic condition can cause discomfort, embarrassment, and loss of confidence that can lead to withdrawal from social life, affect physical and mental health, and disrupt interpersonal relationships. Patients often develop a variety of coping behaviors and strategies [18]. These strategies can include the avoidance of activities and social encounters, and preparations to minimize the potential for embarrassment from incontinence episodes by wearing protective garments, using pads, and carrying a change of clothing. Daily activities including hobbies, household chores, and physical recreation are often scheduled around the location of toilets to avoid potentially embarrassing situations. In spite of the impact SUI has on patients' lives, the condition often goes unreported. Many individuals do not seek medical help because they mistakenly believe that bladder control problems are an inevitable part of aging, that there is no treatment available, or they are too embarrassed to discuss their problems with their healthcare provider [18].

The treatment of UI pursues not just the disease's objective cure, but also an improvement in QoL and sexual function [4,5].

Female sexual dysfunction represents a common and multifaceted problem, associated with biological, sociocultural, medical, and interpersonal factors [19]. Its incidence increases with age, and according to the most recent statistics,

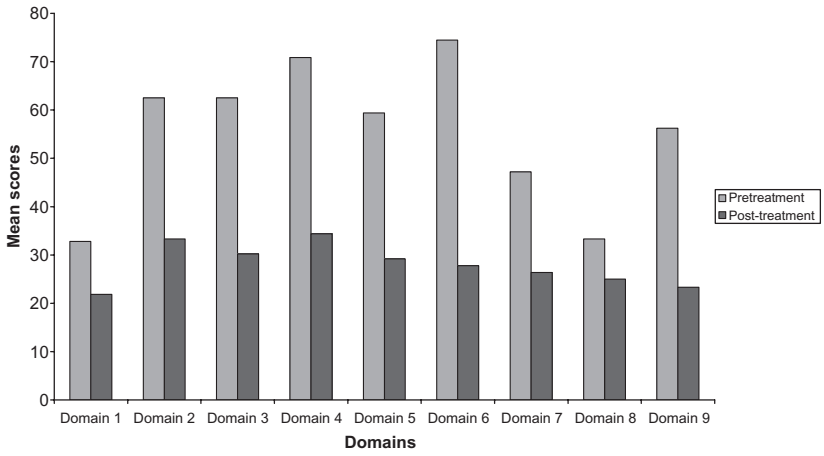

Figure 5 King's Health Questionnaire (KHQ) scores before and after the treatment.

affects 30–50% of women [8,9,19]. Female sexuality is adversely affected by UI in premenopausal, sexually active women: incontinent women report a higher prevalence of sexual dysfunction than those who do not suffer from incontinence [8]. Desire, lubrication, orgasm, and sexual satisfaction are the areas most affected by this problem [9].

This may be explained by the occurrence of dermatitis caused by urine leakage, depression, and decreased libido, as a result of embarrassment and fear of UI during sexual activity, including intercourse [8].

The role of FES in treating UI had been previously investigated with regard to sexual dysfunction [8]. The authors suggest that electrical stimulation represents an important part of PFR. However, according to Abrams [6], a complete rehabilitation program may include other components such as BFB, PFME, and VC. Previously, in a brief report, we had introduced a new approach to this problem that consists of a combination of different rehabilitative techniques for UI [7]. In the current study we confirm, on a more extended female population, that FSFI questionnaire is the best approach to assess all domains of female sexuality. It represents a valid instrument that can be applied to several diseases potentially affecting sexuality, such as chronic pelvic pain and painful bladder syndrome [20]. In Paradiso Galatioto's series, the FSFI, administered before and after FES, showed a significant improvement in desire, lubrication, sexual satisfaction, and pain, whereas arousal and orgasm domains were not significantly affected. Our outcomes are consistent with the ones previously noted, thus suggesting a remarkable enhancement in sexual health and satisfaction in all the FSFI domains. This statement is particularly evident for the desire, arousal, satisfaction, and orgasm domains.

The normalization of muscle tonus provided by PFR could be one of the possible explanations of these outcomes [21]. As a result, rehabilitation represents the basis for satisfying orgasmic sensation [22]. In fact, ischiocavernous attachment to the clitoral hood results in clitoral engorgement; the bulbocavernous muscle, when contracted, places pressure on the deep dorsal vein of the clitoris, preventing venous escape [22]. Additionally, BFB–PFME can improve arousal, reducing the inhibition caused by leakage during orgasm [23].

Complete PFR should consist in BFB, FES, PFME, and VC, as those steps act on multiple components of the pelvic floor. As reported in our study, a complete rehabilitation can provide a beneficial effect on sexual function.

The effectiveness of a complete scheme, together with the lack of side effects, makes it a suitable approach to sexual dysfunction associated with UI.

The KHQ was chosen to verify the impact of therapies on QoL, which is increasingly relevant and common in clinical research. International literature reveals a consensus regarding the fact that urinary incontinence can adversely affect QoL in many aspects. The International Continence Society has recommended that an assessment of QoL should be included in all clinical studies as a complement of objective data [24]. Robinson et al. [25] demonstrated that the impact on the QoL of patients with complaints of UI could be assessed using a questionnaire. The KHQ is a health-related QoL questionnaire that was originally developed and validated on women with urinary incontinence [15]. It has subsequently demonstrated consistent reliability, validity, and responsiveness among culturally diverse samples of men and women, mostly with either stress or urgency incontinence [18,26–29]. The KHQ has been translated to numerous languages, and these translations have generally been found to display good psychometric properties [26,29,30]. The KHQ has been used in numerous studies on a clinically and demographically diverse range of patients. Most commonly, it has been used to evaluate pharmacological or surgical treatments outcomes in patients with overactive bladder and urinary incontinence, and it has consistently demonstrated the ability to detect improvement in QoL [18,31–33]. It also been used as an anchor in studies designed to validate other instruments [34]. A six-item short form of the KHQ has been found to have good internal consistency reliability and sensitivity to change [35]. The KHQ was chosen for our study, particularly because of its extensive approach, easy comprehension, specificity, and applicability. To our knowledge, this study represents the first application of KHQ in the assessment of a stress urinary incontinence complete rehabilitative program (BFB–FES–PFME–VC). Previously Capelini MV et al. analyzed the influence of pelvic floor rehabilitation on KHQ domains, but simply with pelvic floor exercises and biofeedback for UI [4]. In this study the "General Health Perception" domain did not demonstrate a significant variation.

In our study, the complete treatment applied demonstrated a significant improvement in QoL

as shown by the reduced scores obtained in all the nine domains.

Conclusion

PFR according to the described protocol promoted important difference in the daily use of pads, 1-hour pad test, and Stamey incontinence score. The rehabilitative protocol led to improvements in QoL index scores and sexual function, as assessed by validated instruments. Moreover, after the combined rehabilitation program none of the women reported urine leakage during sexual activity, including intercourse.

The learning process offered by the biofeedback and training, followed by the stabilized of the exercises, even without supervision, may have maintained the good results observed 5 months after the supervised program of exercises were interrupted.

These positive results must be confirmed throughout further studies with a larger number of patients and a longer follow-up.

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Statement of Authorship

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