Journal of Women's Health Care
ISSN: 2167-0420

Fernandez-Cuadros et al., J Women's Health Care 2015, 4:6
DOI: 10.4172/2167-0420.1000273

Research Article Open Access

Associated Risk Factors in Female Urinary Incontinence and Effectiveness of Electromyography-Biofeedback on Quality of Life

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Abstract

The aim of this study is to determine the demographic characteristics and risk factors related to female Urinary Incontinence (UI), the frequency by age, sex, type and degree of incontinence; and to evaluate the effectiveness of a pelvic floor muscle training (PFMT) protocol with electromyography (EMG-BFB) with surface electrodes applied at the Pelvic Floor (PF) Unit of the Department of Rehabilitation at Salamanca's Healthcare University Complex: as well as the potential effect on the Quality of Life (QoL) of incontinent women through the ICIQ-SF/I-QOL scales/questionnaires.

We studied 311 female with different types of UI. They were all treated with 20 EMG-BFB sessions, twice a week. Superficial electrodes were used around the anus, and self administered ICIQ-SF and I-QOL questionnaires/scales were used.

The mean age was 55.76+/-14.95 years. There were 83.6% female and 16.4% male. The UI increases with age. We have found statistical significance ($p<0.05$) between UI and pregnancy, delivery, menopause and gynecological abdominal or urological surgery in women. The commonest UI type was the Stress Urinary Incontinence (SUI) (58.28%), and the 2º grade SUI (47.73%) the most common.

After EMG-BFB treatment, we have found a statistically significant improvement ($p<0.05$) in the mean values for both of the scales, in total UI female patients, for any of the UI types (included UUI) as well as in every I-QOL subscales.

After analyzing our data and the bibliography reviewed, EMG-BFB was effective as a training technique of the pelvic floor muscles in UI, and in improving the QoL of female patients. The risk factors for female UI are age, pregnancy, delivery, menopause, and gynecological, abdominal or urological surgery.

Keywords: Electromyography biofeedback; Urinary incontinence; Quality of life

Introduction

Since 2002, the International Continence Society (ICS) defines urinary incontinence (UI) as the manifestation of any involuntary leakage of urine, thus highlighting the true prevalence of the disease [1]. It differs from the previous definition where the voiding had to be demonstrable and in such a magnitude to cause a hygienic or social problem [2,3].

Clinically, UI can be classified as stress urinary incontinence (SUI), urgency urinary incontinence (UUI) and mixed urinary incontinence (MUI) [4,5]. SUI is also divided into three grades according to Obrink's Scale [6], and it is inversely related to the intensity of efforts that produces the leakage.

UI remains an underdiagnosed disease. It is attributed to age, embarrassment or lack of information [7]. It has a great economic, social and psychological impact (8). It is estimated that between 2 and 6 million people are incontinent in Spain, affecting nearly 4.3 million women, with prevalence between 10-50%. Variability can be explained by the difference in age of the sample (9). UI affects both sexes, but it is more prevalent in women [1,5,7,8-10].

The UI is obviously not a life-threatening process, but it impairs significantly the quality of life (QoL) of patients, limiting their autonomy and reducing their self-esteem [5]. The impact of UI in QoL can even be greater than the impact caused by certain chronic diseases such as diabetes or hypertension [10]. Thus, UI has a negative impact on many aspects of daily life [11]. Such is the involvement in the QoL that the ICS recommends that parameters of QoL should be included in assessing treatments for UI [11].

There are different questionnaires/specific scales to assess QOL in UI [6]. Among them are the Incontinence Quality-of-life Measure (I-QOL) and the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), both in Spanish, validated and frequently used. The King's Health Questionnaire (KHQ) is another scale.

The ICIQ-SF is a brief questionnaire which allows detecting not only UI, but also the severity, type and impact of UI on QoL. It is scored from 0-21; the higher the score, greater the severity [10].

The I-QOL specifically measures the QoL in UI. It is a scale of 22 items; each of them is assigned a value of 1 (very) to 5 (anything). It has a maximum value of 110 points, where higher scores, better the

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Received September 17, 2015; **Accepted** September 19, 2015; **Published** October 25, 2015

Citation: Fernández-Cuadros ME, Geanini-Yaguez A, Nieto-Blasco J, Miron-Canelo JA, Perez-Moro, OS, Lorenzo-Gomez MF (2015) Associated Risk Factors in Female Urinary Incontinence and Effectiveness of Electromyography-Biofeedback on Quality of Life. J Women's Health Care 4: 273. doi:10.4172/2167-0420.1000273

QoL. For a better interpretation, it is transformed into a scale from 0 to 100. I-QOL is divided into three subscales: limitation of activity or behavior (LB) 8 items, psychosocial impact (PI) 9 items, and social embarrassment (SE) 5 items [12-14].

Biofeedback (BFB) is considered within the conservative measures of treatment for UI. It is an instrumental technique for training the pelvic floor muscles (PFMT). There are two types: manometric and Electromyography-Biofeedback (EMG-BFB) [6]. The EMG-BFB is the most widely used and has shown efficacy in the treatment of SUI and MUI [15]. The most recent data available indicates that PMFT reduces episodes of UI in 54-72% and the rates of cure/improvement in randomized trials vary between 61-91% [10]. There is no data published nowadays about the efficacy of PFMT on UUI.

The aim of this study is to determine the demographic characteristics and risk factors related to female UI, the frequency by age, sex, type and degree of incontinence; and to evaluate the effectiveness of a PFMT protocol with EMG-BFB with surface electrodes applied at the Pelvic Floor (PF) Unit of the Department of Rehabilitation at Salamanca's Healthcare University Complex: as well as the potential effect on the QoL of incontinent women through the ICIQ-SF/I-QOL scales/questionnaires.

Material and Methods

A prospective, quasi-experimental, before-and-after study was performed in a sample of 311 women out of 372 patients referred to the PF Unit of the Department of Rehabilitation at Salamanca's Healthcare University Complex. The study period run from October 2005 to June 2012, and it was included in the action protocol carried out in our unit (Table 1).

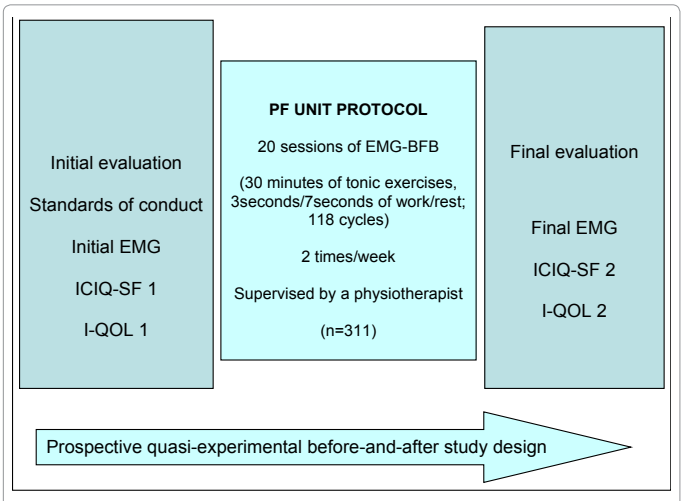
The exclusion criteria were lack of cooperation, failure to understand the treatment, neglect and/or failure to fulfill any of the two questionnaires/scales used.

Affiliation data, medical history, predisposing factors and type of incontinence (age, sex, pregnancy, childbirth and menopause, waiting time, gynecological, urological and abdominal surgery) were collected at the initial evaluation. The patients were given standards of conduct and the questionnaires/scales in order to be completed at the beginning and at the end of treatment (Table 2).

The questionnaires/scales used for this study were the ICIQ-SF (Table 3) and I-QOL (Table 4), specific for QoL in UI.

The used equipment was Myomed® 932, which allows EMG-BFB with two channels, emits auditory and visual signals, and is connected to a computer. Two semi frozen adhesive electrodes were placed around the anus at 3 and 9 h in order to record the electrical activity of the muscles of the pelvic floor. An indifferent third electrode was placed in a remote area of work (front of thigh) working as ground or reference electrode. The second channel is used to prevent contraction of the parasite musculature (abdominals, gluteus and adductors), isolating the exclusive work of the PF muscles.

The treatment consisted of 20 sessions of EMG-BFB supervised by a physiotherapist and performed biweekly, lasting approximately 30 minutes. In each session the patient was placed supine with legs half bent and facing the computer screen for visual control. The recorded



ICIQ-SF=International Consultation on Incontinence Questionnaire–Short Form. I-QOL=Incontinence Quality-of-Life; EMG-BFB=Electromyography-biofeedback. PF=pelvic floor.

Protocol applied at the Pelvic Floor Unit (PF) of the Department of Rehabilitation at Salamanca's Healthcare University Complex. The study runs from October 2005 to June 2012.

Table 1: Prospective quasi-experimental before-and-after study design.

Urinary Incontinence: Advices
• Avoid constipation (drink plenty of liquids, eat rich fiber meals, do exercise), avoid obesity, smoking and exhausting exercises.
• Do not stop urinating. Go to urinate every 2-3 hours.
• Do not push to finish empting the bladder.
• Do contract pelvic floor muscles while making efforts like coughing, loading, sneezing, and if you are in the imperious need of urinating.
• Repeat the Biofeedback pelvic floor learned exercises, six times a day, at different moments, cycles of 15 repetitions (3 seconds of contraction, 7 seconds of relaxation).

Table 2: Standards of conduct.

1. How often do you leak urine? (circle only one answer)	□ Never	0
	□ Once a week	1
	□ 2-3 times/week	2
	□ Once a day	3
	□ Several times a day	4
	□ All the time	5
2. How much urine do you think you leak?	□ None	0
	□ A small amount	2
That is, how much urine do you usually leak (whether you wear protection or not)?	□ A moderate amount	4
	□ A large amount	6
(circle only one answer)		
3. Overall, how much does leaking urine interfere with your everyday life?	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	Not at all
4. When do you leak urine? Please tick all that applies to you.	□ Never	
	□ Before you can get to the toilet	
	□ When you cough or sneeze	
	□ When you are asleep	
	□ When you are physically active/exercising	
	□ When you have finished urinating and are dressed	
	□ For no obvious reason	
	□ All the time	

ICIQ-SF=International Consultation on Incontinence Questionnaire–Short Form. ICIQ-SF score: Sum scores of 1+2+3 questions. Any score more than zero is considered as urinary incontinence diagnostic.

Table 3: Urinary Incontinence ICIQ-SF Questionnaire.

	1	2	3	4	5
1. I worry about not being able to get to the toilet on time.					
2. I worry about coughing or sneezing.					
3. I have to be standing after sitting down.					
4. I worry about where the toilets are in new places.					
5. I feel depressed.					
6. I don't feel free to leave my home for long periods of time.					
7. I feel frustrated because my incontinence prevents me from doing what I want.					
8. I worry about others smelling urine on me.					
9. My incontinence is always on my mind.					
10. It is important for me to take frequents trips to the toilet.					
11. Because of my incontinence, it is important to me to plan every detail in advance.					
12. I worry about my incontinence is getting worse as I get older.					
13. I have a hard time getting a good night sleep.					
14. I worry about being embarrassed or humiliated because of my incontinence.					
15. My incontinence makes me feel like I am not a healthy person.					
16. My incontinence makes me feel helpless.					
17. I get less enjoyment out of life because of my incontinence.					
18. I worry about wetting myself.					
19. I feel like I have no control over my bladder.					
20. I have to watch what or how much I have to drink.					
21 My incontinence limits my choice of clothing.					
22. I worry about having sex.					
The following scoring system is used for all the elements:1: Always; 2: Usually; 3: Sometimes; 4; Rarely; 5: Never Subscales structure: (LB), Items 1, 2, 3, 4, 10, 11, 13, and 20 (PI), Items 5, 6, 7, 9, 15, 16, 17, 21, and 22 (SE), Items 8, 12, 14, 18, and 19.					

I-QOL=Incontinence Quality-of-Life; LB=Limiting Behavior; PI=Psychosocial Impacts; SE=Social Embarrassment. Calculation of subscale score=(obtained sum by corresponding items/sum of maximum value of analyzed items) × 100%. Calculation of total score of the scale=(obtained sum by total items/110) × 100%.

Table 4: I-QOL of Urinary Incontinence Quality of Life Questionnaire.

signal of the muscle activity acted as a catalyst for motor learning. The patient performed 118 cycles of rest/work tonic exercises of the pelvic muscles, with duration of 3 seconds work and 7 rests, preceded by a minute of rest.

In the first 18 cycles, the intensity of the work to be performed for each patient was assessed according to their capabilities, using the mean value in micro-volts (uV) given by the equipment in order to perform the rest of the cycles, not exceeding 10uV in women.

SPSS version 14.0 was used for the statistical analysis. Means and standard deviations were used for the descriptive analysis of quantitative variables; frequencies and percentages were used for qualitative variables. The Chi-square test for qualitative variables contrasts was used. During the study of quantitative variables, it was found that the population did not meet the normal distribution, according to the Kolmogorov-Smirnov test, so a nonparametric test (Kruskal Wallis) was performed in order to examine whether the observations of each group were or were not independent.

Non-parametric tests were used for the comparative analysis because the variables were not distributed according to a normal distribution. To determine the difference between pairs of each scale (median), the Wilcoxon test for two related samples was used. In order to make comparisons between the medians of the surveys before and after the treatment, the nonparametric Mann-Whitney U test was used.

Results

Of 372 patients referred to the unit during the study period, a total of 311 were included as final sample. 62 patients were excluded: 40 by default, 21 for not filling any of the questionnaires/scales and one by death.Patients were referred from different services: 61% from Urology, 25.8% from Gynecology, 3.2% from Primary Care, 2.7% from Surgery and 1% from other services (Pediatrics, Radiation Therapy, Gastroenterology and Neurology) .

The average age was 55.76+/-14.95 years. 83.6% of patients (n=311) were women and 16.4% (n=61) men. A ratio female/male of 4:1 was observed.

Regarding the predisposing factors in women, 71% (n=221) had a history of pregnancy and childbirth, 63% (n=198) were postmenopausal, and 24.9% (n=93) had undergone gynecological surgery. In relation to other surgeries, 14.5% (n=45) underwent surgery for urological problems and 14.1% (n=44) underwent abdominal surgery (hernias, appendectomy or cholecystectomy). From the above, pregnancy, childbirth, menopause and gynecological, urological and abdominal surgery have demonstrated significant association ($p<0.05$) with female UI (Table 5).

Regarding the type of UI; SUI was the most common (58.28%), followed by MUI (29.14%) and IUU (12.58%) (Figure 1)

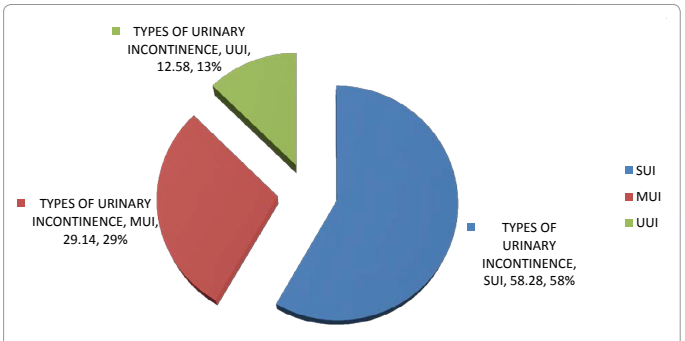
Characteristics		AV	SS_a
Age (years, average, *SD*)	55.76 +/-14.95	311	-
Women (n, %)	311 (84.6%)	372	-
Waiting time (days, SD)	94.62+/- 94.06	311	-
Pregnancy (n, %)	221 (71.0%)	311	0.00
Delivery (n, %)	221 (71.0%)	311	0.00
Menopause (n, %)	198 (63.0%)	311	0.00
Ginecological surgery (n, %)	93 (24.9%)	311	0.00
Urological surgery (n, %)	45 (14.5%)	311	0.00
Abdominal surgery (n, %)	44 (14.1%)	311	0.00

AV=analyzed value; SD=standard deviation; SS=statistical significance.

SS_a=Statistical analysis type: chi-square.

Pregnancy, delivery, gynecological, urological and abdominal surgery have demonstrated significant association with UI (p=0.00).

Table 5: Demographic Characteristics and History of Patients of the Studied Population (n=311).



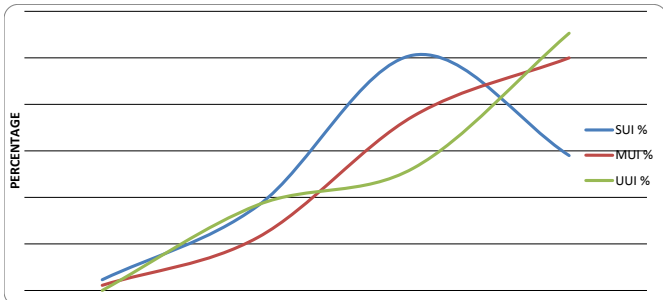
SUI=stress urinary incontinence; UUI=urge urinary incontinence; MUI=mixed urinary incontinence

Figure 1: Clinical types of female Urinary Incontinence.

In relation to age, MUI and UUI showed a progressive increase in cases with aging. On the other hand, SUI progresses to 40-60 years (peak) and then suffered a small decline (Figure 2).

According to Obrink's classification for SUI, 2º grade was the most frequent (47.73%) followed by 3º grade (27.27%) and finally, by 1º grade (25%) (Figure 3)

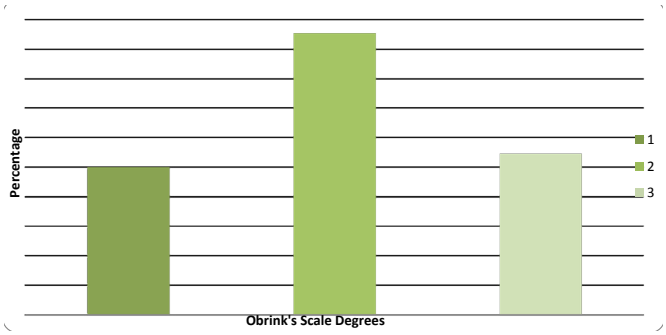
A significant improvement ($p<0.05$) in both ICIQ-SF and I-QOL questionnaires and its subscales was observed when compared the results before and after the EMG-BFB treatment protocol for UI (Table 6) in all of their types (Figures 4 and 5) and in all of the I-QOL subscales (Figure 6).



UI=urinary incontinence; SUI=stress urinary incontinence; UUI=urge urinary incontinence; MUI=mixed urinary incontinence.

Age is considered a risk factor for Urinary Incontinence in all of its types, as the prevalence increases with aging.

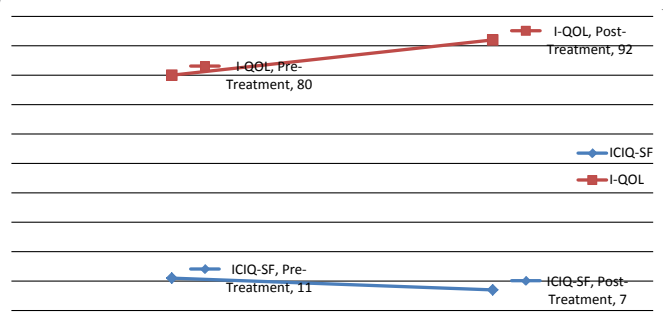
Figure 2: Urinary incontinence by age and type.



1=mild or SUI 1; 2=moderate or SUI 2; 3=severe or SUI 3.

According to Obrink's Scale, the most frequent type of Stress Urinary Incontinence was the moderate (SUI 2).

Figure 3: Stress Urinary Incontinence (SUI) according to Obrink's Scale.



ICIQ-SF = International Consultation on Incontinence Questionnaire–Short Form. I-QOL = Incontinence Quality-of-Life;

The medians of both ICIQ-SF and I-QOL improves after the EMG-BFB Protocol.

Figure 4: Medians of ICIQ-SF and I-QOL surveys at the beginning and at the end of the treatment, in global UI female patients.

UI		ICIQ-SF b-e	I-QOL b-e	LB b-e	PI b-e	SE b-e
GLOBAL	Median	11.0 – 7.0	80.0–92.0	29.0–33.0	36.0–39.0	17.0–19.5
	SS	0	0	0	0	0
SUI	Median	10.0 – 7.0	85.0–94.0	32.0–34.0	38.0–40.0	18.0–20.0
	SS	0	0	0	0	0
UUI	Median	12.0 – 9	72.0–84.0	26.0–28.0	33.0–37.0	14.0–16.0
	SS	0	0	0	0	0
MUI	Median	13.0 – 9.0	69.0–83.0	24.0–31.0	30.5–36.0	13.5–18.0
	SS	0	0	0	0	0

UI=urinary incontinence; SUI=stress urinary incontinence; UUI=urge urinary incontinence; MUI=mixed urinary incontinence; b-e=beginning to end; SS=statistical significance; LB=limiting behavior; PI=psychosocial impacts; SE =social embarrassment.

Type of statistical analysis: Mann–Whitney *U*.

Table 6: Results of Biofeedback on the Medians of the ICIQ-SF and I-QOL Scales Total and by Items (LB, PI, SE), at the Beginning (b) and the End (e) of the Intervention, in Global Urinary Incontinence (UI) and by Types (*n*=311).

Discussion

This is a prospective study that includes a large sample (n=311) and reflects 7 years of experience using the EMG-BFB protocol implanted since the creation of the PF Unit at Salamanca's Healthcare University Complex (2005-2012). There is only one study of the same characteristics and with a similar sample (n=390) published by Dannecker [15].

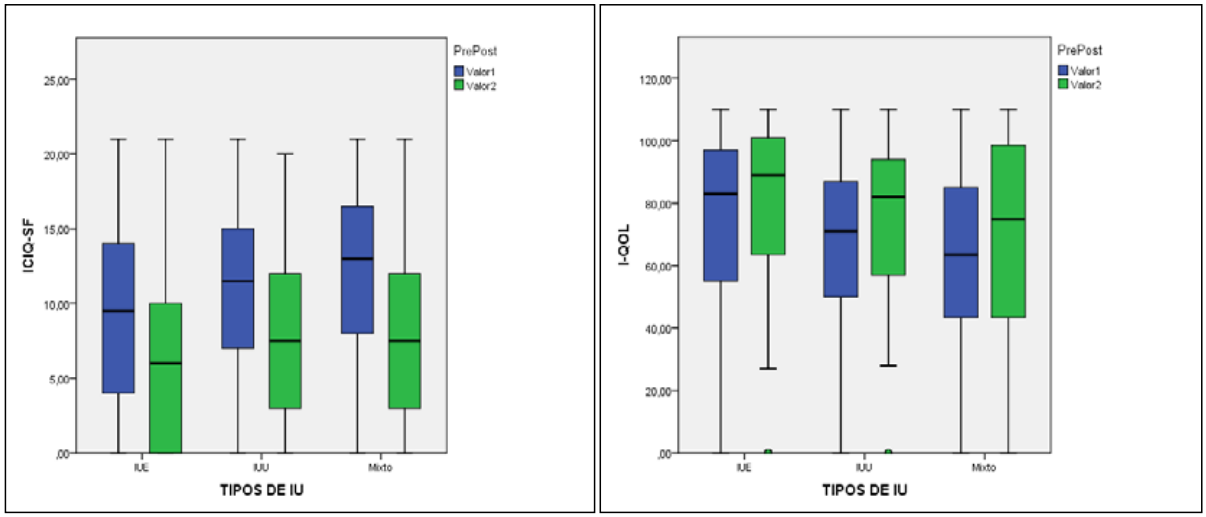
UI may occur in both sexes, although the literature shows that it is more common in women than in men, with different percentages for different authors 10, some of them up to 20:1. Cervera et al. sustain that this great difference would be because men are more reluctant to admit the problem [16]. In our study the relationship female:male was 4:1, 84.6%of the sample were women.

Among the predisposing factors associated with female UI are obstetric causes (pregnancy, childbirth), abdminal, urological and gynecological surgery and menopause [10,17]. In men the more prevalent and influent factor is prostate cancer and its treatments. UI and impotence are the more frequent secondary symptoms [18]. Prostatectomy is associated with SUI or MUI, while radiotherapy with UUI. MUI occurs in older patients with radiotherapy and/or hormonal treatment [19,20]. The cause of UI in the prostatectomy patients may be sphincter failure, detrusor overactivity or urinary obstruction [21]. In elderly patients, prostatic hyperplasia is a risk factor for UI [22].

In our study statistical association between female UI and factors such as age, obstetric history (pregnancy and childbirth), menopause and gynecological, urological and abdominal surgery is been found. This is in accordance with Robles and Peña Outetrino [10,17].

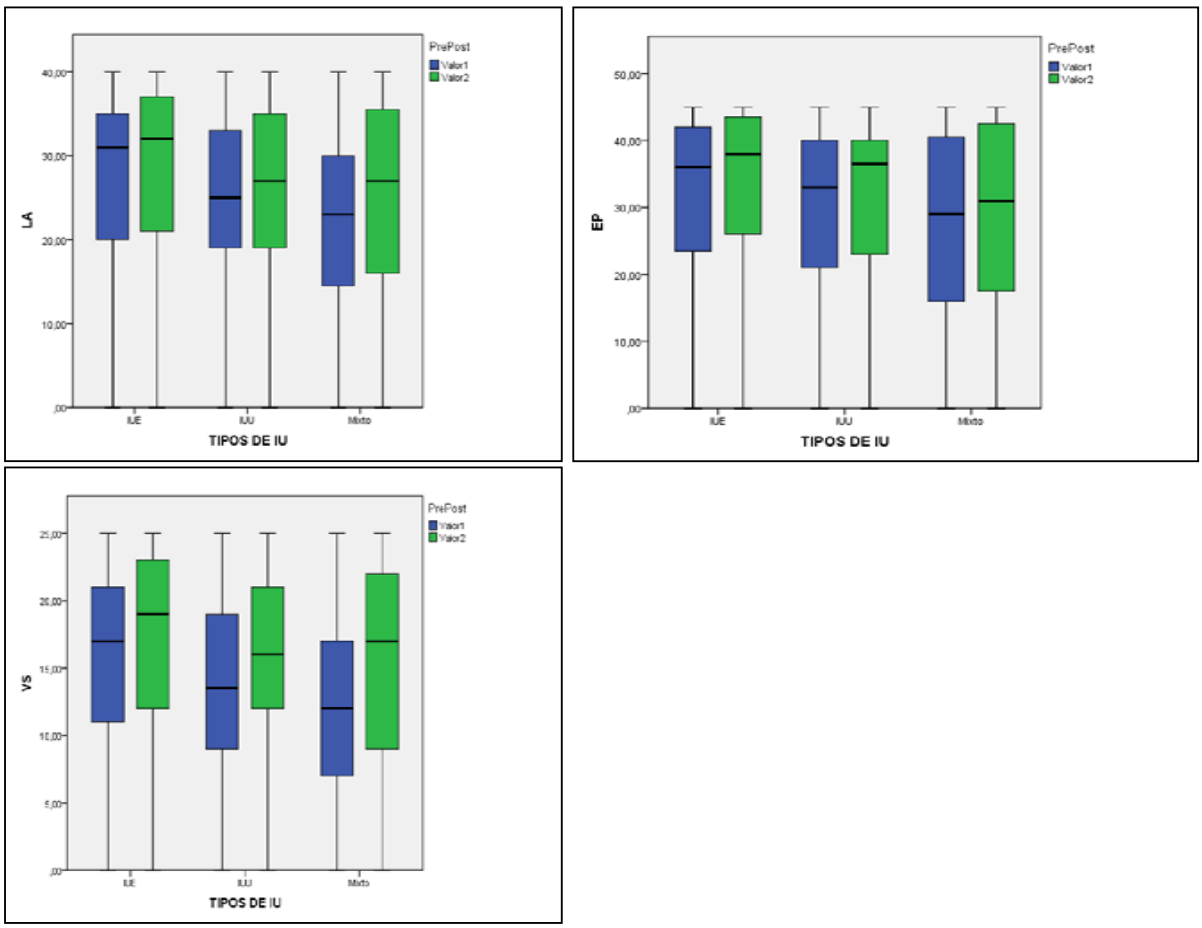
With respect to the most common clinical form of UI, as most of the studies sustain, SUI was the most common type, followed less frequently by MUI and UUI [10]. However, Garcia Bascones maintains that MUI can be underestimated [23]. In this point there is some controversy. Espuña Pons reports in her work that SUI is the most common type, but UUI exceeds MUI [5]. On the other hand, Sanchez Flores gives the higher prevalence to MUI, followed by UUI and finally SUI, in a population sample of working age females [24]. In this study the more prevalent UI type was SUI, as published by most of the authors, followed by MUI and finally UUI.

Aging is considered a risk factor for UI, and so is referenced by



ICIQ-SF=International Consultation on Incontinence Questionnaire–Short Form. I-QOL=Incontinence Quality-of-Life; IUE=SUI (stress urinary incontinence); IUU=UUI (urge urinary incontinence); IUM=MUI (mixed urinary incontinence); Pre=valor 1; Post=valor 2.
The medians of both ICIQ-SF and I-QOL improves after the EMG-BFB Protocol in all types of UI.

Figure 5: Medians of ICIQ-SF and I-QOL surveys at the beginning and at the end of the treatment in SUI, MUI and UUI female patients.



ICIQ-SF=International Consultation on Incontinence Questionnaire–Short Form. I-QOL=Incontinence Quality-of-Life; IUE=SUI (stress urinary incontinence); IUU=UUI (urge urinary incontinence); IUM=MUI (mixed urinary incontinence); Pre=valor 1; Post=valor 2.
LA=LB (Limiting Behavior, EP=PI (psicosocial impact); VS=SE (social embarrasment).
The medians of I-QOL subscales improve after the EMG-BFB Protocol in all types of UI.

Figure 6: Medians of I-QOL subscales survey at the beginning and at the end of the treatment in SUI, MUI and UUI female patients.

different authors [10,16,24,25]. In our study, this assertion is absolutely true for UUI and MUI, while SUI also increased progressively with age, showing a maximum peak between 40-60 years, afterwards the prevalence descended slightly, over 60 years.

Regarding the degree of SUI (Obrink's scale), our study shows that mild and moderate incontinence (1º and 2º grade) were more frequent than 3º grade (severe incontinence) coinciding with Robles (10) who maintains that only 27% are severe incontinence, while more than 50% are mild.

In the treatment of UI, there are conservative and surgical techniques. A mixed technique between the two is neuromodulation. The therapeutic modalities of conservative treatment include drug treatment, behavioral therapy, changing hygiene/dietary habits, active PFMT, BFB and electro stimulation, being more effective those therapies that produce active contractions [17,26].

PFMT activates the perineum-detrusor inhibitory reflex, acting on UUI episodes. PFMT also increases the tone of these muscles strengthening the resistance to efforts [17]. The PFMT maintains the correct position and mobility of the urethra, which is fundamental especially for female continence [26]. In PFMT the effective contraction compresses the urethra against the pubic symphysis increasing intraurethral pressure, thus giving resistance to voluntary voiding of urine. Urodynamic studies have demonstrated this fact [26].The passive containment elements and nerve structures exposed to stretch are also protected by PFMT [27].

PFMT is used in both mild and moderate female UI and male post-prostatectomy [18,20,26].

The BFB is a technique by which a normally unconscious physiological process is presented to the patient and the therapist with a visual or auditory signal or a combination of both. The signal is then used to teach and correct the physiological process achieving a therapeutic effect [17]. This PFMT technique facilitates learning, creates strong motivation and allows self-control and custom work. It is the most effective technique for perineal training and recovery [17].

Besides, the assessment of the physiotherapist and the visual/auditory signal of the EMG-BFB let the patients a correct execution of the tonic exercise protocol. This partnership between physiotherapist-patient increases patient satisfaction, and improves compliance of the treatment, considering that this protocol was 20 sessions duration [28].

In this work, the female UI patients treated with EMG-BFB showed statistical improvement (p=0.000) in both ICIQ-SF and the I-QOL questionnaires, the latter improving for the overall score and for all the subscales. All types of UI and all degrees of SUI improved after the protocol.

This is the first paper stating that EMG-BFB is effective in UUI and QoL, while the effectiveness of EMG-BFB for the other types of UI (SUI and MUI) is been already reported by Robles and Sari [10,29].

Regarding the literature, Sari found that an exercise of PFMT exercises improves 7% the I-QOL survey [29]. Bascones García et al. report that BFB reduces the ICIQ-SF score in women with UI [23]. Lorenzo Gómez reported that EMG- BFB treatment with surface electrodes in women with SUI improves ICIQ-SF questionnaire score [26]. Glazer and Lane revealed seven studies where BFB statistically improved the UI [19].

Conclusions

- Female urinary incontinence was significantly associated with obstetric history of pregnancy and childbirth, menopause, gynecological, urological and abdominal surgery.
- Urinary incontinence is more common in women and increases with age.
- The EMG-BFB protocol applied at our PF Unit improves the continence and the QoL in all of the three types of UI, including UUI.

Acknowledgements

To the physiotherapists Maria Nieves Hernández and Maria Luisa Alonso Herrero de Célis, without them the treatment could not have been carried out.

To Saturnino Díaz Trujillo, for the articles' search librarian at Santa Cristina's University Hospital.

In memory of Dr. Rafael Gonzalez Celador, Physician at the Epidemiology Department of Salamanca's Healthcare University Complex, for his unconditional support in the initial statistical analysis of this study.

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