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Biofeedback with Pelvic Floor Electromyography as Complementary Treatment in Chronic Disorders of the Inferior Urinary Tract

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1. Introduction

Chronic inflammatory disorders of the female urinary tract are common and often impact negatively on the quality of life of the affected individual. The management of these disorders, which encompass infectious and non-infectious conditions presenting with pain, is evolving as a result of current research. These changes are reflected in recent changes in the commonly used management guidelines.

Pelvic floor biofeedback with electromyography is used as a primary or adjuvant treatment for these disorders. In this chapter we present the experience gathered in our unit with this treatment modality.

1.1. Definitions

The Association for Applied Psychophysiology and Biofeedback, Inc. (<http://www.aapb.org>) defines biofeedback as: “the process of gaining greater awareness of many physiological functions primarily using instruments that provide information on those same systems, with a goal of being able to manipulate them at will.” In their website it is further stated that: “Biofeedback is a process that enables an individual to learn how to change physiological activity for the purposes of improving health and performance”. Precise instruments measure physiological activity such as brainwaves, heart function, breathing, muscle activity, and skin

temperature. These instruments rapidly and accurately "feed back" information to the user. The presentation of this information — often in conjunction with changes in thinking, emotions, and behavior— supports desired physiological changes. Over time, these changes can endure without continued use of an instrument.

Also, biofeedback techniques have been defined as the use of instrumentation to help a person to instantly and better perceive the information of a specific physiological process which is under the control of the nervous system control but that is not correctly perceived (Miller 1974). Many physiological responses which are purely anatomical can be modified under voluntary control. The mechanisms for many of these responses include the relaxation of smooth or striated muscles or both (Repariz and Salinas 1995).

Programs for bladder re-education in women with bladder instability have opened new therapeutic perspectives for the various micturition dysfunctions (Frewen 1972 ; Cardozo, Abrams et al. 1978; Jarvis and Millar 1981; Cardozo and Stanton 1984)

Bladder sphincter re-education using surface electrodes was described for adults and children in 1979 and has since been widely applied (Maizels, King et al. 1979; Wear, Wear et al. 1979).

Electronic instrumentation allows the translation of normal or abnormal physiological processes (often unconscious) to visual or auditory signals. The method involves the manipulation of unconscious or involuntary events modifying these signals. Thus the technique is at the same time behavioural therapy and a learning process which aims at creating awareness of an unconscious function that is incorrectly performed, and to correct it. Biofeedback has allowed going from subjectivity to objectivity.

Individuals know little about their perineal region, and therefore control its functions (bladder, anorectal and sexual functions) poorly. Biofeedback permits a progressive and active awareness of these functions, creating a "ring" or "communication cycle" between patient and computer. The instructor serves as a guide in this Learning process.

Biofeedback with electromyography (BFB-EMG) was approved by the Food and Drug Administration in the USA in 1991. It has been effectively used since 1992 without secondary effects or complications (Perry 1994).

For biofeedback to be successful, it is important to have a single instructor conducting the sessions with a given patient. The following are also important for success: 1) A friendly attitude of the instructor; 2) A receptive and confident patient with sufficient cognitive ability; 3) Effective teaching technique 4) Patient's willingness to reproduce at home what was learned during the sessions; 5) A relaxed working atmosphere free of interruptions; 6) Patient friendly equipment 7) Adequate length and frequency of the sessions 8) A system of rewards to encourage the patient, 9) Confidence in success of the treatment.

The conditions listed below can benefit from biofeedback with EMG:

- Cauda equina syndrome with neurogenic bladder.
- Anal sphincter spasm.
- Atonic bladder.

- Extrinsic urethral sphincter's deficiency.
- Urethral instability.
- Muscle atrophy or weakness due to disuse.
- Fecal incontinence.
- Specific and non-specific acute urinary retention.
- Incomplete bladder emptying.
- Urgency urinary incontinence..
- Female stress urinary incontinence.
- Female and male mixed urinary incontinence.
- Urinary incontinence without voiding desire.
- Post-micturition dribbling.
- Nocturnal enuresis.
- Continuous leakage and urinary frequency.

1.1.1. Existing protocols for perineal electromyography

Many protocols have been used to treat pelvic floor dysfunction. No single protocol is applicable to all patients given individual variations. We favour a personalized approach or "therapist guided method" in which one therapist carries out the entire treatment (Lorenzo Gómez, Silva Abuín et al. 2008).

Variations in described protocols include frequency and duration of the sessions. For example: Three 20-minutes sessions per week over a seven-week period (Amaro, Gameiro et al. 2006); twice weekly for 8 weeks (Voorham-van, Pelger et al. 2006); stimulator is activated on demand only by a sudden increase in intra-abdominal pressure (Nissenkorn, Shalev et al. 2004); 30 minutes per session, twice a week for 6 weeks ; 12 weeks training (Di-Gangi-Herms, Veit et al. 2006);and six weeks, two training sessions per week (Seo, Yoon et al. 2004).

1.1.2. Scientific evidence supporting the use of biofeedback with electromyography (BFB-EMG)

The main component of the pelvic floor musculature is the levator ani. The contraction of the levator compresses the urethra and helps continence (DeLancey 1990). The aim of pelvic floor re-education is to improve muscle function, which can significantly reduce stress incontinence. Success rates vary between 21 and 84%, but the subjective improvement is always greater than the objective results.

Several studies have demonstrated the efficacy of BFB-EMG for the treatment of pelvic floor dysfunction in women with stress urinary incontinence (Burgio, C et al. 1986; Aukee, Immonen et al. 2002).

In the elderly, pelvic exercises with biofeedback in the office is more effective than pelvic floor exercises alone (Burns, Pranikoff et al. 1990).

The first study using rehabilitation assisted with pelvic floor muscles EMG for the treatment of vulvovaginal pain was published in 1995 by Glazer et al. These authors reported a cure rate greater than 50% with an average subjective improvement of 83%. Only changes in the electromyographic signal at rest preceded improvement of pain. These findings confirmed that the efficacy of the treatment depended on muscle stabilization (Glazer, Rodke et al. 1995).

1.2. Chronic inflammatory disorders of the lower urinary tract in females

In the following section we shall discuss common conditions, both infectious and non-infectious that can benefit from biofeedback.

1.2.1. Recurrent urinary tract infections

Urinary tract infections (UTIs) are the second most common infections in humans (Foxman 2002). A UTI is the presence of microorganisms in the urine (not due to contamination) which can invade the urinary tract or adjacent structures. It is well established the route of infection is ascending in most cases of infections with enteric bacteria which explains why UTIs are more common in females. The development of a UTI is determined by the balance between bacterial virulence, size of the inoculum, local defence mechanisms and anatomical or functional alterations of the urinary tract (Andreu, Cacho et al. 2011).

It is estimated that the prevalence of UTIs in sexually active young women is 0.5-0.7 episodes per year. One fourth of these will recur. Eighteen out 10000 of these women will develop pyelonephritis and 7% will require hospitalization (Andreu, Cacho et al. 2011). This is despite the fact that most young women with UTI have normal urinary tracts (Hooton 2001). The development of infection is determined by the balance between bacterial virulence, size of the inoculum, local defence mechanisms and anatomical or functional alterations of the urinary tract.

Recurrent UTIs are defined as 3 or more culture-documented infections in 1 year or 2 or more in 6 months in women without structural or functional abnormalities. (Grabe, Bjerklund-Johansen et al. 2011).

Risk factors that predispose to UTIs abnormalities of the urinary tract (such as urinary incontinence or obstruction), sexual behaviour, use of contraceptives, postmenopausal hormonal deficiency, asymptomatic bacteriuria and past urinary tract surgery (Grabe, Bjerklund-Johansen et al. 2011). Risk factors for recurrent UTIs in postmenopausal institutionalised women include atrophic vaginitis, incontinence, cystocele and post-voiding residual urine and a history of UTI before menopause (Nicolle 1997). Collagen diseases represent another extra-urogenital risk factor.

Systemic diseases, mainly diabetes mellitus and chronic renal failure are also important risk factors (Sharifi, Geckler et al. 1996). Women with diabetes mellitus are prone to UTIs. UTI in both diabetic men and women is more likely to progress to pyelonephritis. Patients with type

1 diabetes and UTIs can develop renal damage with time. This is more likely in the presence of proteinuria and peripheral neuropathy. Risk factors for renal damage in women with type 2 diabetes mellitus and recurrent UTIs include old age, proteinuria and low body mass index (Geerlings, Stolck et al. 2000). In addition, autonomic neuropathy may cause bladder dysfunction (Korzeniowski 1991).

In the presence of risk factors, bacterial strains of low virulence can cause UTIs. These risk factors predispose to recurrence but do not affect outcome.

Prevention of recurrent UTIs should avoid the use antibiotics given the alarming rise in antibiotic resistance observed worldwide (Fihn 2003; Grabe, Bjerklund-Johansen et al. 2011). Antibiotic prophylaxis should only be used after counselling and behaviour modification has been attempted (Grabe, Bjerklund-Johansen et al. 2011). Other measures to prevent recurrences include immune active prophylaxis (Lorenzo-Gómez, MF et al. 2013), probiotics and cranberry juice.

1.2.2. Non-infectious chronic cystitis — Painful bladder syndrome

Over the years much of the focus for chronic pelvic pain has been on peripheral-end-organ mechanisms, such as inflammatory or infective conditions (Engeler, Baranowski et al. 2012).

A peripheral stimulus such as infection may initiate the beginning of chronic pelvic pain, and the illness may become self-perpetuating as a result of modulation of the central nervous system, independent of the original cause (Engeler, Baranowski et al. 2012).

Chronic pelvic pain mechanisms may involve on-going acute pain mechanisms, such as those associated with inflammation or infection, which may involve somatic or visceral tissues (Linley, Rose et al.). Nevertheless in most cases, inflammation or infection is not present (van de Merwe, Nordling et al. 2008). However, conditions that produce recurrent trauma, infection or inflammation may result in chronic pelvic pain in a small proportion of cases (van de Merwe, Nordling et al. 2008). Therefore such factors should be ruled out early.

Central sensitisation is responsible for a decrease in threshold and increase in response duration and magnitude of dorsal horn neurons. For instance, with central sensitisation, stimuli that are normally below the threshold may result in a sensation of fullness and a need to void (Nazif, Teichman et al. 2007) and other non-painful stimuli may be interpreted as pain and noxious stimuli may be magnified with an increased perception of pain. Also, somatic tissue hyperaesthesia is associated with recurrent bladder infection.

The increased perception of stimuli in the viscera is known as visceral hyperalgesia, and the underlying mechanisms are thought to be responsible, among, others for bladder pain syndrome and dysmenorrhoea.

Chronic bladder pain may be associated with the presence of Hunner's ulcers and glomerulation on cystoscopy, whereas other bladder pain conditions may have normal cystoscopic findings. Recent reports about prevalence of bladder pain syndrome show higher figures than earlier ones, ranging from 0.06% to 30% (Parsons and Tatsis 2004).

The conditions associated with the painful bladder include interstitial cystitis, bladder pain syndrome or BPS. The European Urological Association (EUA), the International Society for the study of BPS (ESSIC), the International Association for the Study of Pain (IASP) and several other groups now prefer the term bladder pain syndrome (BPS). Terms that end in “itis” in particular should be avoided unless infection and/or inflammation is proven and considered to be the cause of the pain (Abrams, Baranowski et al. 2006). Chronic pelvic pain may be subdivided into conditions with well-defined classical pathology, such as infection, and those with no obvious pathology.

BPS is the occurrence of persistent or recurrent pain perceived in the urinary bladder region, accompanied by at least one other symptom, such as pain worsening with bladder filling and day-time and/or night-time urinary frequency. There is no proven infection or other obvious local pathology. BPS is believed to represent a heterogeneous spectrum of disorders. There may be specific types of inflammation as a feature in subsets of patients (Engeler, Baranowski et al. 2012).

Pelvic floor muscle pain syndrome is the occurrence of persistent or recurrent episodic pelvic floor pain. It is often associated with symptoms suggestive of lower urinary tract dysfunction (Engeler, Baranowski et al. 2012).

BPS should be diagnosed on the basis of pain, pressure or discomfort associated with the urinary bladder, accompanied by at least one other symptom, such as daytime and/or night-time increased urinary frequency, the exclusion of confounding diseases as the cause of symptoms, and if indicated, cystoscopy with hydrodistension and biopsy (van de Merwe, Nordling et al. 2008). Hunner’s lesion and inflammation is referred to as BPS type 3. Current thought implicates an initial unidentified insult to the bladder, triggering inflammatory, endocrine and neural phenomena (Warren, Wesselmann et al.).

No infection aetiology has been implicated since BPS patients and controls have equal UTI frequency (Nickel, Shoskes et al. ; Warren, Brown et al. 2008). Of interest however is the fact that UTI and urgency are significantly more frequent during childhood and adolescence in patients who later develop BPS in adulthood (Peters, Killinger et al. 2009).

Cystoscopic and biopsy findings in both ulcer and non-ulcer BPS are consistent with defects in the urothelial glycosaminoglycan (GAG) layer. Urinary uronate, and sulphated GAG levels are increased in patients with severe BPS (Lokeshwar, Selzer et al. 2005).

The physiopathologic relationship between interstitial cystitis and rheumatic, autoimmune, and chronic inflammatory diseases has been investigated. (Lorenzo Gomez and Gomez Castro 2004).

Biological markers have been explored as an attractive idea to support or, even better, to confirm the clinical diagnosis and prognosis (Lokeshwar, Selzer et al. 2005).

The therapeutic modalities currently available for BPS include the following:

Medical management: Analgesics, corticosteroids, anti-allergic medications, Amitriptyline, Pentosan polysulphate sodium. Immunosuppressants such as Azathioprine, Cyclosporin A,

Methotrexate, Gabapentin, Pregabalin, Suplatast tosilate (IPD-1151T), Quercetin. Antibiotics have a limited role in the treatment of BPS. Cimetidine, prostaglandins, L-Arginine, anticholinergic drugs have also been used (Engeler, Baranowski et al. 2012).

Intravesical therapy: Local anaesthetic (lidocaine), Pentosan polysulphate sodium, intravesical heparin, hyaluronic acid (hyaluronan, chondroitin sulphate, dimethyl sulphoxide (DMSO), bacillus Calmette Guérin (BCG) and vanilloids which disrupt sensory neurons such as Resiniferatoxin (Engeler, Baranowski et al. 2012).

Interventional management: Bladder distension with or without electromotive drug administration, transurethral resection (TUR) coagulation and laser, Botulinum toxin A (BTX-A), Hyperbaric oxygen (HBO), neuromodulation (Engeler, Baranowski et al. 2012).

Non-pharmacological: Behavioural bladder training techniques (Parsons and Koprowski 1991), physiotherapy (Karper 2004), electrical stimulation (de-Oliveira-Bernardes and Bahamondes 2005). Physiotherapy with pelvic floor biofeedback (Borrego-Jiménez, Lorenzo-Gómez et al. 2009 Jan).

Surgical: When all efforts fail to relieve disabling symptoms, surgical removal of the diseased bladder is the ultimate option (Loch and Stein 2004).

1.2.2.1. Urethral pain syndrome

Urethral pain syndrome is the occurrence of chronic or recurrent episodic pain perceived in the urethra, in the absence of proven infection or other obvious local pathology (Parsons 2011). The pathogenesis of urethral pain syndrome is unknown but it may be part of the spectrum of BPS. Some have postulated that neuropathic hypersensitivity can develop following urinary a UTI (Kaur and Arunkalaivanan 2007). The same authors suggested that behavioural therapy including biofeedback and bladder training can be helpful (Kaur and Arunkalaivanan 2007).

1.2.2.2. Other causes of chronic pelvic pain

Pelvic organ prolapse is often an asymptomatic condition, unless it is so marked that it causes back strain, vaginal pain and skin excoriation (Roovers, van der Vaart et al. 2004).

In the past few years, non-absorbable mesh has been used in the pelvic organ prolapse surgery. Although they may have a role in supporting the vagina, they are also associated with several complications including bladder, bowel and vaginal trauma (Niro, Philippe et al. 2010). A subset of these patients may develop chronic pain because mesh insertion causes nerve and muscle irritation (Daniels, Gray et al. 2009).

Most patients can be treated by surgical removal of the mesh (Margulies, Lewicky-Gaupp et al. 2008). If appropriate, multidisciplinary pain management strategies can be applied. Another cause of pain is previous surgery for incontinence with transoburator tapes. Chronic perineal pain at 12 months after surgery was reported by 21 trials and meta-analysis of these data showed strong evidence of a higher rate in women undergoing

transobturator insertion (7%) compared to retropubic insertion (3%)(Barber, Kleeman et al. 2008; Lorenzo-Gómez, B et al. 2013).

Vulvovaginal pain can developed after bacterial vaginal infections or bacterial vaginosis. Infections change the vaginal ecosystem. Oestrogen deficiency in peri- and post-menopausal women can also lead to vulvar tissue atrophy and a subsequent irritation. Contact with irritating agents such as soaps, detergents and topical preparations as well as vulvar trauma associated with accidents or surgery can lead to vulvar irritation and the development of vulvovaginal pain (White, Jantos et al. 1997 Mar).

1.3. Urinary incontinence

Urinary incontinence is an extremely common complaint worldwide. It causes a great deal of distress and embarrassment, as well as significant costs, to both individuals and societies (Lucas, Bosch et al. 2012). The standardization committee of the International Continence Society (ICS) has defined the female urinary incontinence as the involuntary urine loss, objectively demonstrable, which represents a social or hygienic problem (Abrahams, Blaivas et al. 1988).

At least one out of four women in Europe suffers from a disorder associate with incontinence which often has been present for several years before consultation (Thomas, Plymat et al. 1980). In geriatric hospitals, the incidence of urinary incontinence I in women is 43% and as high as n 91% in psychogeriatric patients.

Patients with 'complicated incontinence' are those with co-morbidities, a history of previous pelvic surgery, past surgery for incontinence, radiotherapy and associated genitourinary prolapse (Lucas, Bosch et al. 2012). Urinary incontinence is more common in women with UTIs and is also more likely in the first few days following an acute infection (Moore, Jackson et al. 2008).

In women with incontinence, diagnosis of a UTI by positive leucocytes or nitrites using urine test strips had low sensitivity but high specificity (Semeniuk and Church 1999; Buchsbaum, Albushies et al. 2004).

Incontinent women with symptoms of lower urinary tract or pelvic floor dysfunction and pelvic organ prolapse have a higher risk of of incomplete bladder emptying (elevated post void residual urine volume) compared to asymptomatic patients. Therefore it is suggested that the presence of post void residual should be ruled out in this patients (Fowler, Panicker et al. 2009).

In the elderly incontinence can be caused or worsened by underlying diseases including diabetes (Lee, Cigolle et al. 2009). A higher prevalence of incontinence was associated with higher age and body mass index (Sarma, Kanaya et al. 2009). A recent meta-analysis showed that systemic oestrogen therapy for post-menopausal women was associated with the development and worsening of urinary incontinence (Cody, Richardson et al. 2009). Obesity appears to confer a four-fold increased risk of UI (Chen, Gatmaitan et al. 2009).

1.3.1. Physical therapies for the urinary incontinence

The treatment of lower urinary tract's disorders with pelvic floor exercises with or without biofeedback represents a risk-free option which can be applied in a great number of women. The correct function of the female pelvic floor depends on the position and mobility of the urethra and the urethrovesical junction. Pelvic floor muscle training increases urethral closure pressure and stabilises the urethra, preventing downward movement during moments of increased physical activity. There is evidence that increasing pelvic floor strength may help to inhibit bladder contraction in patients with an overactive bladder. This training may be augmented with biofeedback (Bidmead 2002).

The evidence published in the guidelines regarding urinary incontinence suggests that UTI treatment does not correct the UI. It is unclear if improving the incontinence helps decrease recurrence rate of UTI.

Valid methods to evaluate the morphologic and electromyographic abnormalities of the levator ani muscle are necessary in order to better select women or the treatment with pelvic floor training and biofeedback (Bo, Larsen et al. 1988; Espuña-Pons 2002).

The most recently published systematic review in 2010 found that medication was less effective than behavioural therapy in a comparative effectiveness trial (81% vs. 69% reduction in UI episodes) (Goode, Burgio et al. 2010), therefore pelvic floor physiotherapy must always be the first line of treatment for stress incontinence and overactive bladder. Drugs must be prescribed if pelvic floor physiotherapy fails (Bidmead 2002).

1.3.1.1. RTUI after surgical correction of UI or pelvic organs prolapses

In 1995 the tension-free transvaginal tape (TVT) was introduced to treat UI (Ulmsten and Petros 1995). In 2001 another technique, the suburethral transobturator tape (TOT), was introduced (Delorme 2001). The main advantages were that the tape lays at a more anatomic position than in TVT, the needle does not cross the retropubic space, no abdominal incisions are made, there is a lower risk of vesical or intestinal injury and no cystoscopy is required (Sola Dalenz, Pardo Schanz et al. 2006; Delorme and Hermieu 2010).

The simplicity of these techniques and their reproducibility has dramatically increased their use, by both Urologists and Gynaecologists (Castiñeiras-Fernández 2005).

When surgical treatment is indicated, the TOT procedure is the procedure of choice, absent contraindications. This recommendation is supported by the establishment of TVT as a worldwide validated and proven procedure for the surgical correction of urinary stress incontinence.

2. Our experience with the treatment of bladder pain syndrome

In the following sections we describe the experience with biofeedback and electromyography obtained at our academic unit.

2.1. Method and tools used

We conducted a retrospective study of 548 women diagnosed with inflammatory, infectious and non-infectious disorders of the lower urinary tract treated between March 2003 and May 2012.

Patients were divided into 2 groups according to whether or not they had UTIs. Each group received conventional treatment and were further divided into 2 subgroups, one receiving biofeedback with electromyography and the other not.

Group A consisted of 270 patients with repeated urinary tract infections managed with prophylactic Sulfamethoxazole/Trimethoprim 40/200mg/day for a period of 6 months versus sublingual bacterial vaccine Uromune® for a period of 3 months.

Subgroup A1 (n=112) no biofeedback.

Subgroup A2 (n=158) treatment was supplemented with biofeedback and electromyography.

Group B consisted of 278 patients with non-infectious chronic inflammatory diseases of the inferior urinary tract who were managed with Perphenazine 2mg/ Amitriptyline 25 mg orally daily and intravesical Hyaluronic acid weekly for 4 weeks.

Subgroup B1 (n= 99) received no biofeedback.

Subgroup B2 (N=179) treatment was supplemented with biofeedback and electromyography.

Age, secondary diagnoses, concomitant treatments, medical and surgical background, response to treatment, answers to the King's Health Questionnaire (Kelleher, Cardozo et al. 1997 Dec) and SF-36 QoL Questionnaire Spanish Version (Vilagut, Ferrer et al. 2005 Mar-Apr) were recorded. The interpretation of results of the questionnaires was as follows: for of Kings Health questionnaire the range varied between 25 points (normal status, healthy) to 97 points (critical illness perception). For the SF-36 questionnaire the range varied from 149 points (normal status, healthy) to 36 points (critical illness perception).

For subgroups A2 and B2, the program of biofeedback with electromyography (BFB-EMG) consisted of 20 sessions of therapy. Two surface electrodes were placed on the perineum over the pelvic floor musculature and a neutral or ground electrode was placed on the inner aspect of the thigh.

In the first 3 sessions the electrodes were placed near anal external sphincter. In the subsequent sessions the electrodes were placed closer and closer to the urethra. We considered the correct position of the electrodes very important (Figure 1).

The contractions lasted 3-5 seconds followed by a relaxation period of 8-10 seconds Patients were trained to manage the signal in the screen by using the appropriate perineal muscles. The goal was to bring the two perineal electrodes closer together. The weekly session lasted 20 minutes.

Sessions took place at the urodynamics office with Medicina y Mercado™ equipment. The patient lay supine, with light flexion of the hips and protection of the lumbar lordosis in order

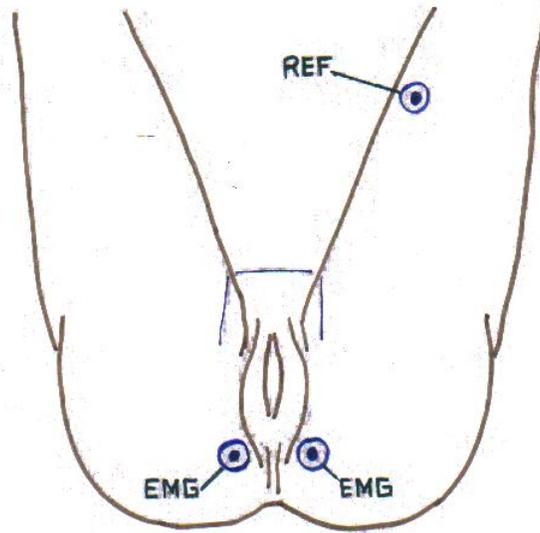


Figure 1. Position of electrodes for BFB-EMG session.

to avoid fatigue (figure 2). In this position the patient could see the screen of the biofeedback equipment (figures 3 and 4). The electrodes used were paediatric pre-gelled electrodes. After explaining the anatomy and physiology of the pelvic floor, the patient was instructed to contract the perineal musculature during 3-5 seconds and relaxing to relax it during 6-8 seconds. Each signal was recorded continuously with a polygraph the power, muscle tone and the duration were recorded in the perineal electromyography (figures 2-4).



Figure 2. BFB session.



Figure 3. Screens showing several scenes for BFB-EMG.



Figure 4. Screens showing several scenes for BFB-EMG.

Figure 5 shows fragments of the graphics obtained from the EMG activity registry at a biofeedback session.

Statistical analysis was as follows: Results from the answers in Kings' Health and SF-36 QoL questionnaires yielded qualitative and quantitative variables which were analysed by NCSS-2000™ statistic program. Descriptive and inferential studies included analysis of cross tabulation, Fisher exact test, Chi-square, Student's t-test, Pearson correlation test. $p < 0.05$ was accepted as statistically significant.



Figure 5. EMG registry at BFB session.

2.2. Results

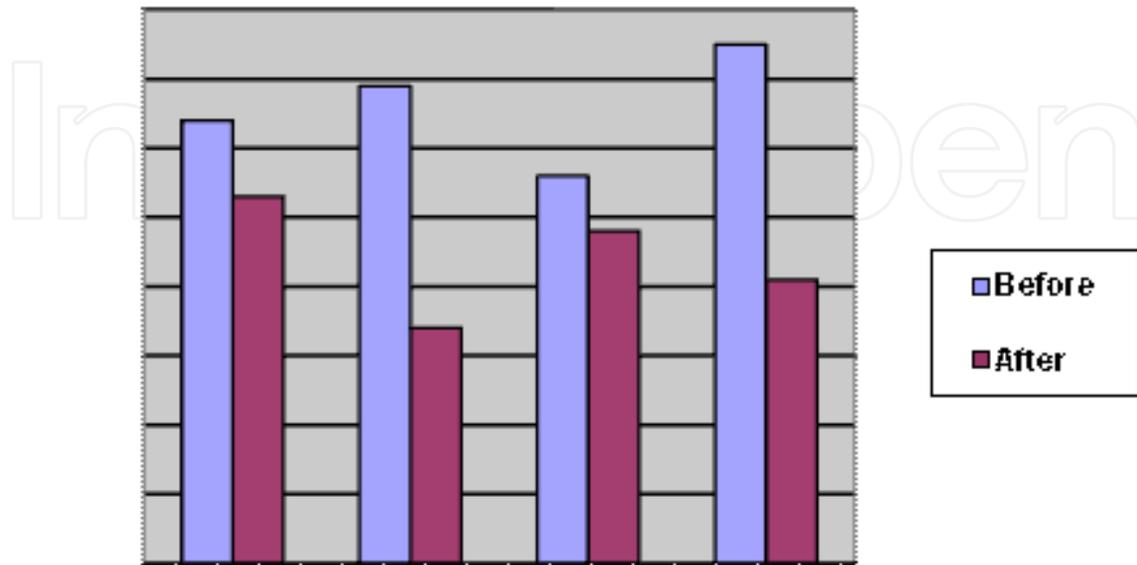
There were no difference in the age ($p=0.2615$), medical history of diabetes ($p=0.2365$), arterial hypertension ($p=0.1629$), smoking, alcohol and caffeine consumption ($p=0.8317$), obesity ($p=0.6732$), occupation ($p=0.4319$) and marital status ($p=0.0729$) between the four groups. Median age were Group A

Table 1 shows the prevalence of urinary incontinence (UI) grade 1, 2 and 3, cystocele >2 , cystocele >2 +rectocele, colpocele, cystocele >2 +UI, rectocele in the 4 groups:

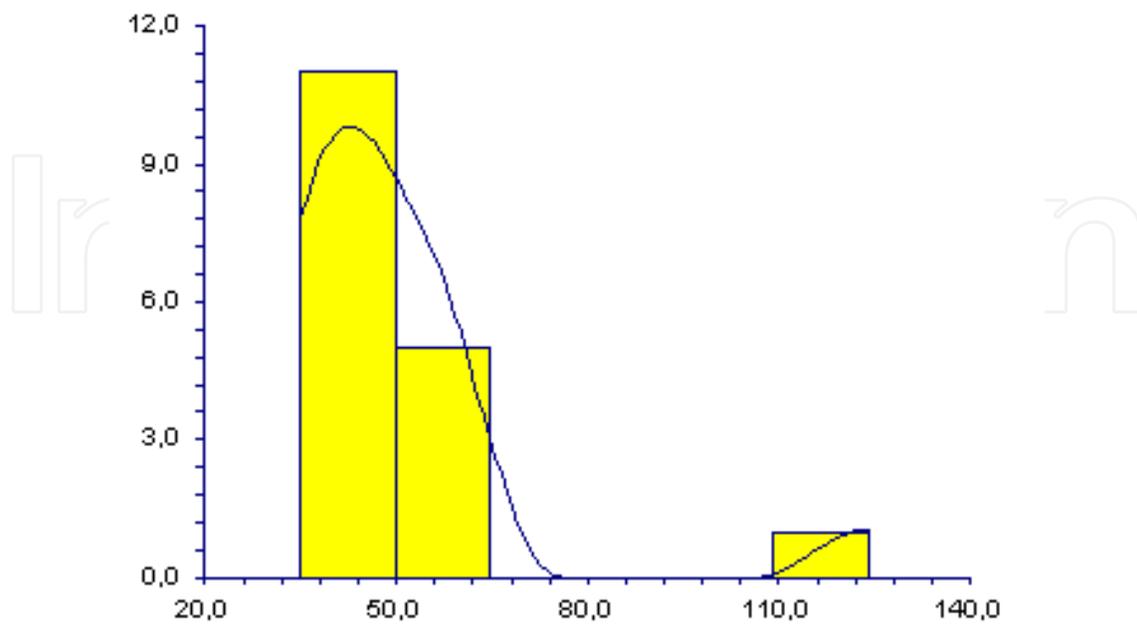
Pelvic floor condition	Subgroup A1 (n= 112)	Subgroup A2 (n= 158)	Subgroup B1 (n= 99)	Subgroup B2 (n= 179)
Incontinence grade 1	4	6	10	6
Incontinence grade 2	11	8	2	3
Incontinence grade 3	8	13	1	2
Cystocele >2	11	20	11	10
Rectocele and cystocele	9	15	1	2
Colpocele	7	11	3	15
Cystocele and Incontinence	8	10	3	12
Rectocele	6	5	1	5
SIGNIFICANCE	$p=0.4507$		$p=0.7886$	

Table 1. Pelvic floor conditions in the inferior urinary tract chronic inflammations (Incontinence grade 1: uncontrollable urine leakage, dripping (< 50 cc); grade 2: uncontrollable leakage of moderate urine quantities (50-120 cc); grade 3: uncontrollable leakage of big urine quantities (> 200 cc).

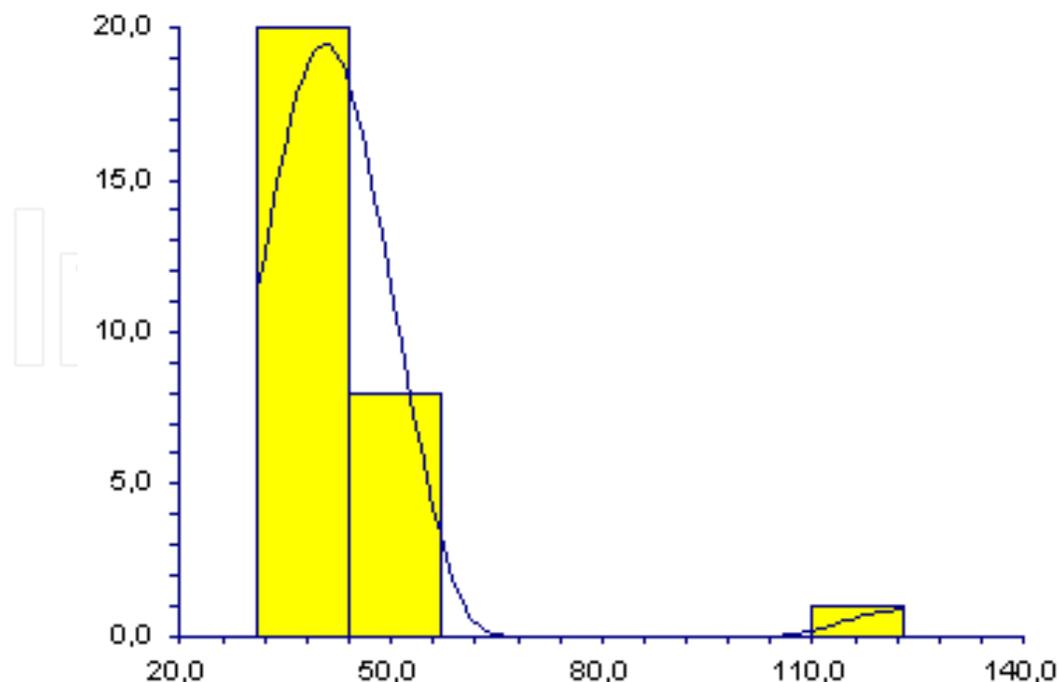
The results of the questionnaires before and after treatment are shown in the figures below.



Graphic 1. King's Health Test before and after treatment.



Graphic 2. Histogram showing Group B1 King's score after treatment.



Graphic 3. Histogram showing Group B2 King 's score after treatment.

In the King's Health Questionnaire, Group B2 shows better results compared with Group B1 ($p < 0.0003$). Group A2 shows better results than group A1 ($p < 0.0042$). Group B2 shows the best results. We found similar findings in the SF-36 questionnaire.

3. Discussion

Pelvic floor dysfunction can lead to urinary incontinence and to other lower urinary tract symptoms (LUTS). A neuromuscular disorder has been found in women with incontinence or traumatic delivery, with a good response to the functional treatment of the pelvic floor (Gunnarsson, Ahlmann et al. 1999).

In our unit, we decided to combine the BFB-EMG program for patients with LUTS who were refractory to conventional treatments. We have not found any adverse effects caused by the treatment, but we have recorded surprisingly good results with the quality of life tests we systematically performed.

Regarding the patient allocation between antibiotic treatment and immunological modulators (bacterial vaccines), there was an homogeneous distribution of treated recurrent UTIs between both groups, but patients treated with bacterial vaccine showed a better response than those treated with suppressive antibiotic protocol ($p < 0.001$).

Pelvic floor exercises are an essential part of the bladder-sphincter re-education. Pelvic floor's functional treatment with or without BFB has been used to treat stress urinary incontinence

with an efficacy ranging between 17 and 84% (Cammu, van Nylén et al. 1991 Oct; Workman, Cassisi et al. 1993 Jan; Lorenzo-Gómez, Silva-Abuín et al. 2008).

We wish to emphasize the benefit that the BFB-EMG gives to patients with chronic lower urinary tracts disorders, whether of an infectious nature or not. Several explanations can be offered. There is a demonstrated benefit in the collagen type changes that the pelvic floor's muscles after BFB-EMG, which increases the contractile capability of the levator ani and strengthen the type I (slow contraction, high resistance) and type II fibres (quick contraction, quick fatigue) (Arlandis-Guzmán and Martínez-Agulló 2002). In addition the detrusor activity is inhibited by the voluntary perineal contraction (activating the Mahony's reflex #3 or perineal-detrusor reflex (Mahony, Laferte et al. 1977 Jan) in a more natural and physiological manner than with other more aggressive therapeutic methods.

Until now, UTI and chronic cystitis have not been included within the specific pathologies of the pelvic floor. However, we find that in clinical practise patients have frequent concomitant UTI.

In this study, we investigated the relationship between UTI and incontinence. Scientists agree that UTI facilitates the development of incontinence. Recurrent UTI is defined as at least three episodes of uncomplicated infection documented by culture in a 12-month period in women with no structural/functional abnormalities (Naber 1999). This assertion is maybe challenged since many women diagnosed with recurrent UTI have urethral hyper-motility, stress or urgency incontinence, voiding urgency or subclinical cystocele.

BFB-EMG has shown to be of benefit for women with painful bladder using the same protocol (Borrego Jiménez, Lorenzo Gómez et al. 2007), but also in women with vaginism, pelvic floor myalgia and other similar conditions. (Arlandis-Guzmán and Martínez-Agulló 2002).

There is little information about the importance of the anatomy of the pelvic floor in patients with incontinence. It has been postulated that the irritative voiding symptoms in patients with incontinence can be aggravated by a higher tonicity of the pelvic floor muscles (Griebing and Takle 1999). BFB-EMG program can be an useful adjuvant to the treatment of patients with incontinence (Borrego Jiménez, Lorenzo Gómez et al. 2007). On the other hand, neuromodulation is still finding its role in pelvic pain management. There has been growing evidence in small case series or pilot studies but more detailed research is required (Fariello and Whitmore). Published papers show an important role of BFB for impotence, premature ejaculation, perineal pains and vaginism treatment. For these reasons, a consensus was reached in our Pelvic Floor Unit in order to use BFB-EMG as an adjuvant treatment in patients with chronic inflammatory diseases, both infectious and non-infectious, of the lower urinary tract. Results have been satisfactory.

These findings are in agreement with the experts' opinion contained in the European Association of Urology's guidelines, relating to the design of individual therapeutic protocols for each patient (Grabe, Bjerklund-Johansen et al. 2012).

Biofeedback-EMG is an essential element in the functional treatment of the pelvic floor, providing information about other hidden muscular functions. It has been shown that giving

only verbal or written instructions, fewer than half of the patients could correctly and effectively contract their pelvic floor muscles and in 25% of the case the symptoms worsened. (Theofrastous, Wyman et al. 2002; Gray and David 2005 Jul-Aug) likely due to the strengthen of the antagonist muscles (Llorca-Miravet 1990).

The somatic and the vegetative (with the sympathetic and the parasympathetic components) nervous system are implicated in the micturition cycle. There is an inhibition-excitation balance at any time in this system, the so called "balancing" principle by Schimdt, which explains the hypo-contractile detrusor of women with urethral hyper-activity. In the conscious component of the voiding cycle, the periurethral muscles can influence this balance, re-establishing the correct voiding cycle, and this is the principle for the conservative techniques in voiding re-education (González-Chamorro and Lledó 2001).

Biofeedback can be helpful in the treatment of pelvic floor pain in the process of recognising the muscles' action. EMG is one of the most used input methods for biofeedback (Romanzi, Polaneczky et al. 1999). A study in patients with chronic pelvic pain syndrome participating in a pelvic floor BFB re-education program reported a correlation between the decline in EMG values and symptoms relief (Cornel, van Haarst et al. 2005).

In a study among patients with levator ani syndrome, biofeedback was found to be the most effective therapy. Other modalities used were electrostimulation and massage. Adequate relief was reported by 87% in the biofeedback group, 45% for electrostimulation, and 22% for massage (Chiarioni, Nardo et al.).

Treating the pelvic floor muscles is recommended as the first line of treatment in patients with chronic pelvic pain syndrome. In patients with an overactive pelvic floor, BFB is recommended as adjuvant therapy to muscle exercises (Engeler, Baranowski et al. 2012). None of the present existing treatments have effect on any BPS subtypes or phenotypes. Bladder training may be effective in patients with predominant urinary symptoms and little pain.

Multimodal behavioural, physical and psychological techniques should always be considered alongside pharmacological or invasive treatments. Manual and physical therapy should be considered as a first approach (Engeler, Baranowski et al. 2012).

Investigations on chronic spasms of the pelvic floor muscles in patients with chronic pelvic pain syndrome revealed that all patients had significant voiding symptoms (urgency, frequency, incontinence due to final dripping) and ureteral hypersensitivity concomitant to chronic pain at the perineal area. Up to the 44.3% of patients had previous voiding problems in childhood (enuresis, constipation and retarded urination habit learning) (Bo, Larsen et al. 1988).

Verbal or written instructions for patients using practise equipment at home can be less effective because patients cannot exactly remember the training given at the office or they can have problems following the treatment protocol (Aukee, Immonen et al. 2002).

The main limitations shown by the BFB-EMG are that minimum muscular activity intensity is needed in order to register and visualize any activity at the BFB screen. It is an active technique that requires motivation and a minimum intellectual level that is not suitable for patients with mental problems or retarded. High-quality, reliable and valid equipment is necessary to avoid

interference present in machines of lesser quality. The instructor is an integral part of the method and must evaluate and study how to reach the patient and to devise the therapeutic protocol.

From our experience, the following lower urinary tract inflammatory disorders are eligible for combined treatment including BFB-EMG:

- Infectious:
- Repeated urinary tract infections: more than 3 per year or more than two every 6 months in women without risk factors.
- Repeated urinary tract infections in women with urinary incontinence.
- Urinary tract infections in patients previously treated of urinary incontinence or pelvic floor prolapse.
- Non-infectious: bladder pain syndrome or interstitial cystitis, non-infectious chronic cystitis (follicular, eosinophilic), chronic pain after surgical treatment of urinary incontinence or pelvic floor prolapse.

4. Conclusions

BFB-EMG is a basic and essential technique for the perineal-sphincteric re-education. EMG-guided BFB gives faster and more reliable information, it allows the development of awareness and a faster learning of the perineal work, both contracting and relaxing.

A BFB-EMG therapeutic protocol is very useful as a coadjuvant treatment for chronic inflammatory pathologies of the lower urinary tract, both infectious and non-infectious.

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