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### ABSTRACT

The current study was conducted to determine the effectiveness of biofeedback assisted training of pelvic floor muscle in reducing pelvic floor over activity and decreasing symptoms of vulvar vestibulitis. This study was carried out on 30 women from the Outpatient Clinic, Department of Gynecology, Faculty of Medicine Cairo University, Their ages ranged from 22-29 years, all of them were married and they all complained of dyspareunia. They were classified randomly into 2 equal groups (A&B), patients of group A (control group) treated by overnight Lidocaine 5%, calcium citrate supplement and follow law oxalate diet for 8 weeks while, patients of group B (study group) received Biofeedback assisted training of pelvic floor muscle for inhibiting pelvic floor over activity, three times weekly in addition to the same treatment as group A for 8 weeks. All participants were evaluated before starting the first session of treatment and after the end of treatment through: Modified Oswestry Sex life index as well as measurement of Pelvic floor contraction & hyperirritability by electronic preniometer. On comparing the pre and post treatment values of all results measurements, revealed significant improvement of both groups, yet the improvement was more obvious and more significant (P < 0.001) in group (B). According to the results of the present study it could be concluded that biofeedback-assisted exercise program of the pelvic floor muscles significantly reduces and, in some cases, eliminates symptoms of vulvar vestibulitis syndrome.

*Key words:* Vulvar vestibulitis - biofeedback - lidocaine - pelvic floor muscles.

### **INTRODUCTION**

Wulvodynia or vulvar pain syndrome is a multifactoral clinical syndrome of vulvar pain, sexual dysfunction, and psychological distress. The most common subtypes of vulvodynia are vulvar vestibulitis, cyclic vulvovaginitis, dysesthetic vulvodynia, and vulvar dermatoses. The term vulvodynia has now been recommended by the International Society for the Study of Vulvar Disease (ISSVD) to describe any vulvar pain, regardless of etiology<sup>16</sup>. Vestibulodynia, or simply vulvar vestibulitis is vulvodynia localized to the vestibular region. It tends to be associated with a highly localized "burning" or "cutting" type of pain<sup>22</sup>.

Vulvar vestibulitis syndrome (VVS) is a heterogeneous, multisystemic and multifactorial disease and is one of the leading causes of dyspareunia in women of fertile age<sup>5,14</sup>. VVS has been described as a clinical disease characterized by three symptoms and signs: (a) severe pain on vestibular touch or attempted vaginal entry; (b) tenderness when pressure is localized within the vestibule; and (c) physical findings confined to vestibular erythema of various degrees<sup>16</sup>. This distressing etiological syndrome has no clear determinants, although it has been associated with repeated yeast infections and other urogenital inflammatory conditions<sup>22</sup>.

Vulvar pain syndromes provoke psychological as well as physical distress. Sexual relationships become seriously strained in women with vulvodynia. Women tend to feel defective, less womanly, less sexually attractive ashamed and embarrassed<sup>4</sup>.

Medical therapies have been advocated management of this distressing for the problem. These include antihistamines, tricyclic antidepressants, compresses, topical anesthetics and lubricants<sup>18</sup>. Topical remedies do not cure the condition, but lidocaine solution have been reported to produce temporary and partial relief of symptoms in some patients<sup>6</sup>. Steroids have been tried for anti-inflammatory effect<sup>1</sup>. their Local injections of alpha interferon (r-alpha IFN) in selected patients have not proven entirely successful, but immunotherapy may be beneficial in some cases<sup>15</sup>. Dietary restrictions and reduction of irritants in the urine or in topical agents are reported as being successful in some cases<sup>17</sup>.

During intravaginal digital palpation, the levator muscles of women suffering from vulvar vestibulitis manifest considerable chronic "tension and spasticity". These specialists requested the use of biofeedback which is self regulation training technique derived from well established principles of human learning to correct this muscle abnormality and results were good<sup>21</sup>.

The rational for studying pelvic floor muscles in-patients with vulvar vestibulitis is the fact that these patients usually demonstrate hyperirritability of the pelvic floor muscles. This hyperirritability could be activated by localized tissue disturbances. Some success has been reported with physical therapy, internal massage, and biofeedback as well<sup>3</sup>.

Glazer, et al.  $(2002)^{12}$  has recommended the use of electro-myographic biofeedback of pelvic floor musculature in order to reduce the instability and hyper-tonicity of pelvic floor muscles as an approach to the management of the vulvar pain.

The aim of this clinical trail was to determine the effectiveness of biofeedback assisted pelvic floor exercise in reducing pelvic floor hyperirritability and consequently relieve dyspareunia as well as improve vulvar vestibulitis syndrome.

### SUBJECTS MATERIALS AND METHODS

# Subjects

The current study was carried out on 30 women from the Outpatient Clinic. Department Gynecology, Faculty of of Medicine Cairo University, Their ages ranged from 22-29 years, all of them were married and they all complained of dyspareunia. They were classified randomly into 2 equal groups (A&B), patients of group A (control group) treated by overnight Lidocaine 5%, calcium citrate supplement and follow law oxalate diet for 8 weeks while, patients of group B (study group) received Biofeedback assisted training of pelvic floor muscle for inhibiting pelvic floor over activity, three times weekly in addition to the same treatment as group A for 8 weeks.

### Materials

Preniometer (Peritron 9300): Designed by Cardio Design Pty ltd. Australia. It is supplied with vaginal sensor. Technical specification: Numerical readout 0-300 cm H<sub>2</sub>O, Resolution 1cm H<sub>2</sub>O, Accuracy  $\pm$ 1cm H<sub>2</sub>O for 95% of readings, Display liquid crystal 3.5 digits, 12.7mm high with indicator for battery low charge, Output option 0-3.5 VDC into 3.5 K ohms min. proportional to sensor pressure with connecting tube with end fittings has a (T) with one way valve for optional air inflation and vaginal sensor 28 mm diameter; 30 mm active surface, consist of an air-tight seamless silicone rubber sheath over a skeleton that allows the central section to be pressed in radically response in to а muscular contraction. Silicone rubber is chosen for its high biocompatibility, excellent flexibility, high durability and suitability for autoclaving. The wall thickness of the sheath kept to a minimum to transmit pressure with high sensitivity unaffected by temperature over the physiological range. Condoms were used for covering the vaginal probe to avoid cross infections and jell was used for lubrication before introducing into the vagina.

In practice, the air displaced from the detachable vaginal sensor travels to a pressure transducer in the monitor unite via a connecting tube. The signal from the transducer is interpreted by microprocessor displayed either numerically and in centimeters water pressure or as a multi-range bar graph for biofeedback. Peak and average readings for the contraction and its duration can be recorded. It was used for objective assessment of the hyper tonicity and strength of pelvic floor muscles contractions before starting and after the treatment for both groups (A&B) as well as for training of pelvic floor muscle & inhibition of pelvic floor over activity for patients of group (B).

### Method

All patients included in this study evaluated by the gynecologist before starting the treatment according to the following standardized protocol: 1- A urine sample was obtained: 2- A brief interview about past medical history, medication and obstetric gynecologic history including painful intercourse; 3- Vaginal cultures were taken for Candida, and Trichomonas; 4- A cotton swab palpation of the labia majora and labia minora 5- The degree of vestibular erythema. (Friedrich's criteria to diagnose vulvar vestibulitis syndrome)<sup>14</sup>.

## A- Assessment procedures:

(before starting the first session of treatment, and at the end of twenty four sessions of treatment for all participants of both groups A&B).

- All were subjected to Modified Oswestry Sex life score<sup>7</sup> to assess the pain induced by sexual intercourse ( the score range is 0-5): zero indicates that sex life is normal and causes no extra pain and five indicates that sex life is nearly absent because of pain and pain prevents any sex life at all.

- Pelvic floor contraction & hyperirritability (objective measurement) by Preniometer (Peritron 9300) evaluating the maximum contraction (highest readings) and hypertonicity reading without voluntary contraction (lowest readings), the peak, average readings and the duration in seconds can be recalled by holding in the button for more than two seconds.

B- Treatment procedures:

Pelvic floor training (for group B): Before starting the treatment sessions patients were asked to evacuate their bladders. Ask the patient to assume crock lying position, a pillow or two under her head for comfort, knees and feet 30 cm apart; Covering the vaginal sensor by condom and handle the sensor by the tail of the connector of the connecting tube; Turns on Peritron in numerical mode with the readout display in cm  $H_{20}$  pressure.

# The protocol of training

The women was asked to continue contraction and relaxation of the pelvic floor muscle against the vaginal electrode (sensory feedback) trying to reach a higher reading than the number already visible to her on the screen (visible feedback) aim to increase the muscle strength hence, after that relax and trying to reach a lowest reading than the number already visible to her on the screen (visible feedback) aim to decrease the Hyperirritability of the pelvic floor muscles<sup>2</sup> as follow:

- (5- Second) just holding the vaginal electrode without contraction (stretching).
- (Fast twitch fiber) Tighten and relax the pelvic floor muscle against the vaginal electrode as quickly as possible 10 times in a row. Relax for a count of 10, and then repeat.
- (5- Second) just holding the vaginal electrode without contraction (stretching).
- (Slow twitch fiber) Tighten the pelvic floor muscle against the vaginal electrode as hard as you can for a count of 10. Relax for a count of 10, and then repeat.
- Ten seconds of rest.

The exercises program lasted for twenty minutes three times a week for eight consecutive weeks. Patients were instructed to do strong muscle contractions of the pelvic floor muscles (Pubovaginalis, Puborectalis, both fibers together) at home as follows: 60 repetitions of 10 seconds of rest followed by 10 seconds of muscle contraction twice daily with several hours between the 2 practice sessions. (Quoted from Glazer, et al 1999)<sup>11</sup>.

Lidocaine Overnight 5%. calcium citrate& Low-Oxalate Diet (for both groups A&B): All patients were asked to use the lidocaine cream on the vulva and perineum daily (at night) together with oral tablet of calcium citrate (twice daily) in addition to limitation of their intake of oxalate, highoxalate foods, such as nuts, nut butters, soy, soy foods, whole wheat, bran cereal, blackberries, blueberries, raspberries, spinach, celery, beets, eggplant and beans, are not permitted. Small amounts of medium-oxalate foods, such as yogurt, apples, oranges, pears, bagels, brown rice, white bread, broccoli, carrots, corn and tomatoes could be consumed and low-oxalate foods, including cheese, milk, avocado, bananas, mangoes, pork, poultry, beef, pasta, white rice, cabbage, cucumber and mushrooms were allowed.

### **Statistical Analysis**

The collected data were fed into computer for statistical analysis using SPSS software and the statistical significance at a confidence of 95% ( $\alpha$ -level of 0.05).

### RESULTS

In this study the Modified Oswestry Sex life score was investigates, before starting the treatment, for group (A) the majority of the represent 7 out of 15 subject (46.7 participants) had pain prevents any sex life at all, after treatment this percentage was to 6.6% (only one subject), but decreased there was none of the participants express a normal, pain free sex life . For group (B) also,

the majority of the subject (46.70%) had pain prevents any sex life at all before starting the treatment, but following treatment this percentage was disappeared and 7 patients (represent 46.70%) express a normal, pain free Comparing both groups after sex life. the differences showed treatment. a statistically highly significant improve in sex life score (P < 0.001), favoring participants of group (B). [Table (1)].

Table (1): Shows the mean percentage of modified oswestry sex life score, before starting & at the end of treatment for both groups (A&B).

	Modified Oswestry Sex life score					Z value	P Value		
		5	4	3	2	1	0		
Crown A	Before	46.70%	40.00%	13.30%	0.00%	0.00%	0.00%	-4.45	0.001*
Group A	After	6.60%	26.70%	26.70%	20.00%	20.00%	0.00%		
Carry B	Before	46.70%	46.70%	6.60%	0.00%	0.00%	0.00%	-4.91	0.001*
Group B	After	0.00%	0.00%	6.60%	20.00%	26.70%			
Comparison after treatment	Group A	6.60%	26.70%	26.70%	20.00%	20.00%	0.00%	-4.97	0.001*
	Group B	0.00%	0.00%	6.60%	20.00%	26.70%	46.70%		

Z-value: Chi-square

My sex life is normal & causes no extra pain 0:

1: My sex life is normal but causes some extra pain

My sex life is nearly normal but is very painful 2:

Results illustrated in table (2) and Fig (1), revealed highly significant (P < 0.001) increase in the mean values of the pelvic floor measurement) (objective contraction by evaluating Preniometer the maximum contraction (highest readings) when comparing pre and post treatment results of each group. P- value: Probability value

5:

My sex life is severely restricted by pain 3: 4:

My sex life is nearly absent because of pain

Pain prevents any sex life at all

After the end of treatment, the mean value of pelvic floor contraction was 56.48± 12.97 CmH<sub>2</sub>O for group (A) and 101.58±26.73 CmH<sub>2</sub>O for group (B). Comparison between both groups revealed highly significant (P< 0.001) increase in pelvic floor contraction favoring group (B).

Table (2): Shows the mean values of pelvic floor contraction ( $CmH_2O$ ) before starting & at the end of treatment for both groups (A&B).

	Group A		Gro	up B	Comparison after treatment		
	Before	After	Before	After	Group A	Group B	
Х	32.81	56.48	33.61	101.58	56.48	101.58	
SD	10.59	12.97	11.56	26.73	12.97	26.73	
MD	-23.67		-67	. 97	-45.1		
t-value	-12.52		-12	2.81	-10.24		
P-value	0.001*		0.0	01*	0.001*		

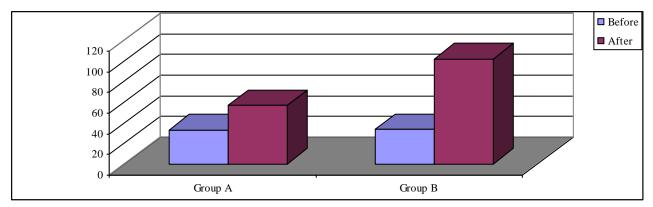


Fig. (1): Illustrate pelvic floor contraction ( $CmH_2O$ ) before starting & at the end of treatment for both groups (A&B).

The pelvic floor hyperirritability (evaluating the hyperirritability by lowest readings without voluntary contraction) was statistically highly significant (P< 0.001) decrease following treatment in both groups (A&B) as the mean value was decreased from  $55.29\pm 5.72$  CmH<sub>2</sub>O to  $32.32\pm 6.14$  CmH<sub>2</sub>O

in group (A), and from  $56.19\pm5.68$  CmH<sub>2</sub>O to  $17.55\pm8.2$  CmH<sub>2</sub>O in group (B).

Comparison between both groups revealed highly significant (P < 0.001) decrease in pelvic floor hyperirritability favoring group (B). [Table (3) & Fig.(2)].

Table (3): Shows the mean values of pelvic floor hyperirritability  $(CmH_2O)$  before starting & at the end of treatment for both groups (A&B).

	Gro	Group A		up B	Comparison after treatment			
	Before	After	Before	After	Group A	Group B		
Х	55.29	32.32	56.19	17.55	32.32	17.55		
SD	5.72	6.14	5.68	8.2	6.14	8.2		
MD	22	22.97		36.64		14.77		
t-value	19	19.65		.56	16.77			
P-value	0.0	0.001*		01*	0.001*			

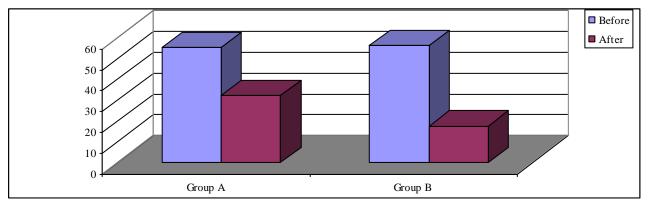


Fig. (2): Illustrate pelvic floor hyperirritability ( $CmH_2O$ ) before starting & at the end of treatment for both groups (A&B).

#### DISCUSSION

Pelvic floor dysfunction (PFD) has traditionally been described as resulting from laxity or poor tonus of the pelvic floor musculature and/or ligaments. Damage of this nature usually results from aging, straining, or trauma and causes urinary or fecal incontinence and organ prolapse. More attention is focused now on identifying and understanding so-called "high-tone" PFD, a product of hypertonic or spastic musculature, leading to symptoms such as vulvar pain, dyspareunia, and orgasmic dysfunction<sup>13</sup>.

Pelvic EMG activity in typical vulvar vestibulitis composed of elevated and unstable

resting baseline, poor recruitment, spasm on sustained contraction and fatigue, poor recovery and post contraction baseline remains elevated with high amplitude and instability, Eighty eight percent (88%) of patients with a clinical diagnosis of vestibulitis satisfy at least three or more of these abnormal electromyographic criteria<sup>20</sup>.

The results of this study suggest significant benefit of using the intravaginal biofeedback assisted training of the pelvic floor musculature in the management of women with vulvar vestibulitis may be attributed to strengthening the levator ani muscle there is not only improved contraction strength, more relaxed but also increased stability, muscle less fatigue and а corresponding fall in resting tension. This appears to be associated with and indicative of a less active pudendal nerve which leads to a reduction of pain and an increase in intercourse  $^{10,12}$ .

The results of this piece of work were supported by those of Travell and Simmons<sup>23</sup> who reported that such muscle disturbances are reflected in discoordination of the electromyography (EMG) and are prone to develop in muscles that lie within the pain reference zone of the disturbed tissue and in turn reflex back through a dorsal root spinal cord mechanism to perpetuate tissue disturbances via its effect on local tissue (sympathetic mediated activity, including vascular changes and histamine release). One factor that perpetuates the vulvar skin disturbance is destabilization of pelvic floor muscles and thus the restablization of the muscles should allow this condition to resolve.

The results of intravaginal biofeedback came in agreement with Glazer et al.  $(1997)^9$ who demonstrated a slightly more than 50% cure rate with an average self-reported improvement of 83%, and 80% of sexually patients resuming abstinent regular intercourse. The research showed that only changes in the standard deviation of the resting SEMG signal predicted pain change. This finding confirmed the anecdotal experience that the treatment is essentially an SEMG stabilizing program to decrease the hyperirritability of the pelvic floor muscles. This paper also concluded, The response to this therapy suggests that whatever the initial insult or etiologic factor, vulvar vestibulitis syndrome may be a result of autonomically mediated pain. In 2000<sup>th</sup> a study was published that concluded that 3-5 years after successful treatment, 100% of those studied remained completely asymptomatic with no reports of either vulvar dysesthesia or introital dyspareunia<sup>8</sup>.

Result of intravaginal biofeedback confirm the findings of McKay et al. (2001)<sup>19</sup> who studied the effectiveness of pelvic floor SEMG biofeedback in the management of patients with moderate to severe vulvar vestibulitis syndrome and reported that 84.7% of treated patients reported either negligible or mild pain at the end of the study and 70% resumed sexual activity; this compares favorably to the results of perineoplasty surgery for the treatment of vulvar vestibulitis.

The good results of this study agreed with Bergeron et al.  $(2001)^3$  who reported a controlled comparison randomized of vestibulectomy, electromyographic biofeedback, and group sex therapy/pain management in the treatment of dyspareunia resulting from vulvar vestibulitis. And concluded that both medical and psychological treatments are effective in relieving dyspareunia and recommended a multimodal approach to treatment.

In conclusion, pelvic floor muscle instability is a critical factor in pain associated with vulvar vestibulitis syndrome. A biofeedback-assisted exercise program that stabilizes and decrease over activity of the pelvic floor muscles significantly reduces and, in some cases, eliminates symptoms of vulvar vestibulitis syndrome.

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الملخص العربي

# فعالية تمرينات عضلات الحوض الرافعة بمساعدة التغذية الرجعية الحيوية في علاج التهابات المدخل الفرجي

أجريت هذه الدراسة لتحديد فعالية تمرينات لعضلات الحوض الرافعة بمساعدة التغذية الرجعية الحيوية في تقليل النشاط الزائد لعضلات الحوض الرافعة و العسر في الجماع لدي السيدات اللائي تعانين من متلازمة التهابات المدخل الفرجي. وقد أجريت الدراسة على ثلاثين سيدة متزوجة تعانين من العسر في الجماع لدي السيدات اللائي تعانين من متلازمة التهابات المدخل الفرجي. وقد أجريت الدراسة على ثلاثين سيدة مستشفي أمراض النساء و التوليد كلية طب جامعه القاهرة وتم تقسيمهن إلى مجموعتين ( أ & ب) ، المجموعة (أ) (المجموعة الصابطة) مستشفي أمراض النساء و التوليد كلية طب جامعه القاهرة وتم تقسيمهن إلى مجموعتين ( أ & ب) ، المجموعة (أ) (المجموعة الضابطة) مستشفي أمراض النساء و التوليد ( أ ي ب) ، المجموعة (أ) (المجموعة الضابطة) تمرينات عضلات الحدة لأولى معن في حين أن المرضى من المعيدة (ب) تم علاجهن بواسطة العلاج المتبع لمثل هذه الحالات لمدة 8 أسابيع في حين أن المرضى من المجموعة (ب) (المجموعة الضابطة) الأولى لمدة 8 أسابيع في حين أن المرضى من المجموعة (ب) (المجموعة الصابطة) الأولى لمدة 8 أسابيع. وقد تم تقبيم جميع المشاركات لمادة لا وحين الدونية ثلاث مرات أسبوعيا ، بالإضافة إلى نفس العلاج الذي تتلقاه المجموعة الأولي لموية 8 أسابيع. وقد تم تقبيم جميع المشاركات قبل بدء الدراسة وبعد انتهاء العلاج عن طريق: مقياس الحية الجنسية لأوسويستري وكذلك قياس قوة انقباض ودرجة النشاط الزائد لعضلات الحوض الرافعة . وظهرت النتائج فروق ذات دلالة إحصائية ايجابية ف ي وكذلك قياس قوة انقباض ودرجة النشاط الزائد لعضلات الحوض الرافعة . وظهرت النتائج فروق ذات دلالة إحصائية ايجابية ف ي وكذلك قياس قوة انقباض ودرجة النشاط الزائد لعضلات الحوض الرافعة . وظهرت النتائج فروق ذات دلالة إحصائية ايجابية ف ي وكذلك قياس قوة انقباض ودرجة النشاط الزائد لعضلات الحوض الرافعة . وظهرت . وظهرت الموعن قري في الموع في قلي الموع في أوسويستري . وكذلك قياس قوة انقباض ودرجة النشاط الزائد لعضلات الحوض الرافعة . وأظهرت النتائج فروق ذات دلالة إحصائية ايجابية ف ي وكثر وضوعا في المجموعة ( معتنين عند مقارنتها بالنتائج الأولية قبل إجراء الحوض الرافعة . وأظهرت المجموعة (ب) . ومن هذه النتائج يمكن أن المحوض أل موي تقليل النشاط الزائد لعضلات الحوض ألموع . وأظهرت المجموعة (ب ، مون ها في قول في المحالا الموض الموض ألموض ألموض

ا**لكلمات الدالة :** تمرينات عصلات الحوض الرافعة- التغذية الرجعية الحيوية- مُتلازمة التهابات المدخل الفرجي .