Altered pelvic floor muscle activity associated with the use of intravaginal probes in severe vulvodynia

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Abstract

Vulvodynia is usually associated with a hypertonic dysfunction of the pelvic floor muscles (PFM), so surface electromyography (sEMG) can be used to assist patient's assessment. Although recordings are typically performed with intravaginal probes, they provoke pain and may alter PFM activity, so the aim of this study was to assess differences in sEMG signals recorded with self-adhesive electrodes in the presence vs. absence of an intravaginal probe according to pain intensity. Twenty-four patients with vulvodynia were treated with incobotulinumtoxinA and monitored after treatment. Their PFM activity and pain were assessed by monopolar and bipolar sEMG recordings with self-adhesive electrodes and by Visual Analogue Scale (VAS), respectively. Recordings performed before treatment and in a follow-up visit were classified into two groups: severe pain and moderate/mild/no pain. Root mean square (RMS), median frequency (MDF) and sample entropy (SampEn) of signals were compared when the probe was into vs. out of the vagina in both groups. In severe pain group, PFM contractile activity had a significantly lower power when the probe was into the vagina than out of it, as shown by lower RMS values in monopolar recordings, especially in M3 (median[interquartile range] in vs. out: 3.8[2.7]mV vs. 4.4[2.5]mV; p-value<0.01). This implies that deep PFM activation decreases during contractions when a probe is inserted into the vagina in severe vulvodynia, probably because of the patients' reluctance to perform maximum contractions, given the pain elicited by the pressure of the probe. Patient's evaluation should thus avoid using intravaginal probes and increase that of self-adhesive electrodes.

1. Introduction

Vulvodynia has been estimated to affect up to 16% of women in their lifetime and has a broad impact on patients' work, couple and social life [1]. It relates to a widespread or localized pain at the clitoris, labia or vestibule for at least 3 months without any identifiable cause [2], for which there are different therapeutic options, such as hormone replacement therapy, amitriptyline or botulinum neurotoxin type A (BoNT/A) injections [3].

Vulvodynia may be associated with different pathophysiological factors, among which are hypertonic dysfunctions of the pelvic floor muscles (PFM) [2]. They consist of different muscle bundles that are typically grouped as superficial PFM and deep PFM, the latter showing a more intense total electrical activity during contractions than the former [4]. PFM play a key role in vital functions such as pelvic organ support, micturition, defecation and sexual function, which may not be correctly fulfilled in PFM dysfunctions [5].

Given the relationship between vulvodynia and PFM dysfunctions, the patient's evaluation usually comprises an assessment of her PFM tonicity and voluntary activity, for which surface electromyography (sEMG) has proved to be a suitable tool [4]. sEMG recordings can be performed with intravaginal/rectal probes or self-adhesive electrodes attached to the perineum. While probes are usually preferred by researchers, they are uncomfortable and their insertion can even provoke pain [6]. Therefore, although previous studies have shown that they do not alter PFM activity in healthy subjects [7], this may not be true in patients with pelvic pain since this may prevent them from contracting their PFM at maximum, thus deriving in a wrong perception of their PFM function. The aim of the present study was to assess whether PFM myoelectrical activity monitored by sEMG with self-adhesive electrodes is different depending on the presence or absence of an intravaginal probe and pain intensity in vulvodynia.

2. Materials and Methods

2.1. Overview of the clinical study

This study was performed in the framework of a prospective and longitudinal study carried out in the Pelvic Floor Unit of Hospital Politècnic i Universitari La Fe (Valencia, Spain), which met the Declaration of Helsinki and was approved by the ethics committee of the hospital. Twenty-four patients with vulvodynia that reported an overall >3 pain score according to the Visual Analogue Scale (VAS) provided their informed consent to participate in the study. Additional exclusion criteria were ages under 18 or over 65, vulvar dermatological lesions, pudendal nerve entrapment and active pelvic/vulvovaginal infections. Patients' mean age and number of pregnancies were 42.7±12.5 years and 1.0±1.1, respectively, and 25% of them had menopause.

The study consisted of a first visit (Week 0), in which patients were treated with injections of BoNT/A into the

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vulvar vestibule, and three additional follow-up visits scheduled 8, 12 and 24 weeks after. Patients' clinical status and PFM myoelectrical activity were monitored in all visits according to clinical questionnaires (including VAS) and sEMG, respectively.

2.2. BoNT/A treatment

Vulvar vestibule tenderness in {1, 3, 5, 6, 7, 9, 11} clock positions was tested with a cotton swab by applying pressures of 0.2 – 0.4 kgf, which were measured with a digital algometer (Wagner FPIX™, WAGNER INSTRUMENTS, Greenwich, CT, USA). Points where the patient reported a moderate or severe pain (VAS>3) with pressure were infiltrated with 25-33 I.U. of incobotulinumtoxinA (Xeomin®, Merz Pharmaceuticals GmbH, Frankfurt, Germany).

2.3. sEMG signal acquisition

Patients' PFM electrical activity was monitored by sEMG performed with 4 self-adhesive Ag/AgCl electrodes (Red Dot 2660-5, 3M, St. Paul, MN, USA) attached to both labia majora and 2 to ischiatic spines (reference and ground), and an intravaginal probe (Periform®+, Neen Healthcare Mobilis Healthcare Group, Oldham, Lancashire, UK). Perineum skin was previously exfoliated with an abrasive gel (Nuprep 114g, Weaver and Company, Aurora, CO, USA) to reduce skin-electrode impedance and the probe was coated with lubricating gel (Kefus SL, Beniarbeig, Alicante, Spain). Self-adhesive electrodes were arranged as in [8], so that four monopolar (M1, M2, M3, M4) and two vertical bipolar (B1, B2) sEMG signals were recorded. Signals were acquired with a multipurpose amplifier (Grass 15LT+4 Grass 15A94, Grass Instruments, West Warwick, RI, USA) with a gain of 20.000 and a 3-1000 Hz band-pass bandwidth, and sampled at 10 kHz.

Patients were instructed to stay still for 1 minute and then to perform 5 PFM maximum voluntary contractions of 5s, with resting periods of 10s between them. This protocol was carried out twice after a minute of rest: 1) with the probe into the vagina and 2) with the probe out of it. Figure 1 shows two of the five contractions recorded by M1 channel when the probe was into and out of the vagina.

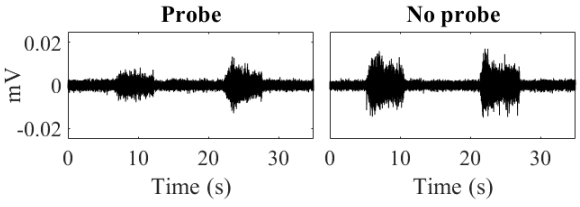

Figure 1. *sEMG signal of M1 channel recorded of a patient when the probe into (left) and out of (right) the vagina.*

2.4. sEMG signal preprocessing

Signals were filtered with a zero-lag 4th order Butterworth band-pass filter (cut-off frequencies: [30, 450] Hz) to remove undesired signal components such as motion artifacts and with a comb filter (notch frequency: 50Hz) to attenuate the power line interference in the signals. Then, the five contractions and a 10s-segment of baseline activity before the first contraction were manually annotated in the recorded sEMG signals.

2.5. sEMG signal parametrization

sEMG signals power, spectral content and level of complexity/irregularity were assessed by three parameters that have proved to yield relevant information on PFM myoelectrical activity in previous studies [8], [9]:

Root mean square (RMS) is a temporal metric typically used to characterize signal amplitude, computed as the square root of the signal power. It is related to the number of recruited motor units during muscle activation [10].

Median frequency (MDF) is a spectral measure whose value depends on the conduction velocity of muscle fibers, the volume conduction effect of the tissue, among others [10]. MDF is the frequency of the signal bandwidth that divides its power spectral density (PSD) into two regions with the same total energy.

Sample entropy (SampEn) is a non-linear measure used to assess the complexity/irregularity of signals. It is computed as the negative natural logarithm of the conditional probability that two segments within a signal that are similar at m samples are also similar at m+1 samples, according to a tolerance r and ignoring self-matches [11]. SampEn was computed as in [8], [9], i.e. on signals with zero mean and unit variance and with m=2 and r=0.15.

RMS, MDF and *SampEn* were computed of contractile and relaxation segments annotated in signals. The median of the parameters in the five contractions was obtained.

2.6. Data analysis

Two of the four recording sessions performed per patient were selected and divided into two groups: 1) severe pain and 2) moderate/mild/no pain. The first group included recordings at Week 0 if the patient reported a severe pain (VAS>6), or alternatively the recording of one of the other visits (Week 8, 12 or 24) at which the patient reported the highest VAS, as long as it was >6. The second group included the recording of the follow-up visit at which the patient reported the lowest VAS, as long as it was ≤6. Groups comprised 24 recordings each and their mean VAS scores were 8.5±1.1 and 3.7±1.8, respectively.

Statistically significant differences between parameter distributions when the probe was into vs. out of the vagina were assessed by a paired-sample T-test or Wilcoxon signed-rank test depending on normality of data, which was assessed by Kolmogorov-Smirnov tests (confidence level: 5%). Comparisons were independently carried out for the different signal channels.

3. Results

Table 1 shows the summarized values of the parameters computed from the sEMG signals acquired when the probe was into and out of the vagina, and highlights those cases when both distributions were significantly different. It can be seen that all statistically significant differences between both recording scenarios (probe into vs. out of the vagina) were obtained in monopolar rather than bipolar signals. Moreover, RMS during PFM contractions in severe pain

		CONTRACTION						RELAXATION					
		Severe pain			Moderate/mild/no pain			Severe pain			Moderate/mild/no pain		
		RMS (μV)	MDF (Hz)	SampEn	RMS (μV)	MDF (Hz)	SampEn	RMS (μV)	MDF (Hz)	SampEn	RMS (μV)	MDF (Hz)	SampEn
M1	IN	3.8 [1.8]	156 [28]	0.52[0.08]	4.0 [1.3]	152 [29]	0.51[0.08]	1.2 [0.5]	160 [50]	0.59[0.17]	1.0 [0.7]	161 [60]	0.62[0.17]
	OUT	4.1 [1.9]	146 [36]	0.50[0.09]	4.2 [1.9]	151 [33]	0.51[0.08]	1.3 [0.8]	158 [51]	0.60[0.14]	1.0 [0.8]	172 [50]	0.64[0.17]
M2	IN	5.8 [2.9]	147 [32]	0.53[0.07]	6.5 [1.7]	145 [34]	0.51[0.07]	1.7 [0.5]	136 [38]	0.52[0.09]	1.5 [1.0]	148 [39]	0.54[0.12]
	OUT	6.3 [2.2]	149[32]	0.52[0.08]	5.9 [3.1]	152 [33]	0.52[0.06]	1.7 [0.1]	139 [23]	0.54[0.08]	1.3 [0.9]	138 [49]	0.57[0.10]
M3	IN	3.8 [2.7]	123[27]	0.45[0.09]	4.3 [2.5]	128 [26]	0.45[0.05]	1.3 [0.6]	137 [38]	0.55[0.13]	1.1 [0.4]	146 [47]	0.60[0.14]
	OUT	4.4 [2.5]	125[22]	0.44[0.12]	4.4 [2.9]	127 [20]	0.45[0.04]	1.4 [0.8]	142 [56]	0.57[0.16]	1.0 [0.6]	156 [58]	0.63[0.15]
M4	IN	6.6 [2.5]	131[30]	0.50[0.09]	6.8 [3.0]	134 [27]	0.47[0.07]	1.9 [0.8]	122 [28]	0.49[0.10]	1.6 [0.8]	134 [29]	0.53[0.10]
	OUT	6.9 [2.0]	130[31]	0.47[0.07]	6.3 [4.0]	138 [23]	0.48[0.06]	1.8 [0.1]	126 [29]	0.50[0.10]	1.2 [0.9]	129 [52]	0.55[0.11]
B1	IN	3.2 [1.8]	126[24]	0.47[0.09]	3.5 [1.6]	126 [25]	0.47[0.08]	1.2 [0.5]	140 [41]	0.58[0.12]	1.1 [0.5]	154 [59]	0.63[0.15]
	OUT	3.6 [2.0]	125[27]	0.45[0.10]	3.4 [1.8]	127 [22]	0.47[0.09]	1.4 [0.7]	152 [55]	0.59[0.17]	1.0 [0.5]	161 [66]	0.66[0.17]
B2	IN	3.4 [2.2]	118[27]	0.44[0.12]	3.5 [1.7]	117 [27]	0.44[0.07]	1.2 [0.6]	141 [54]	0.60[0.17]	1.1 [0.7]	153 [60]	0.63[0.17]
	OUT	3.9 [1.9]	117[32]	0.42[0.10]	3.6 [2.0]	119 [24]	0.44[0.07]	1.3 [0.7]	148 [59]	0.59[0.18]	1.0 [0.7]	167 [78]	0.66[0.20]

Table 1. *Median [interquartile range] of parameters computed with the probe into and out of the vagina (IN, OUT) during PFM contraction and relaxation according to pain intensity. Shadowed cells: p-value (IN vs. OUT) <0.05*

group was the only parameter that showed significantly different values in all monopolar channels when the probe was inserted. MDF and SampEn also showed some significant differences when the probe was into vs. out of the vagina, although they were only found in one of the four monopolar channels.

The distribution of RMS values in monopolar recordings during PFM contractions in both pain groups has been represented in Figure 2, and statistically significant differences have been highlighted with asterisks. It can be seen that statistical differences were associated with a lower p-value (<0.01) in M3 than in the other monopolar channels.

4. Discussion

According to our results, PFM activity changes in the presence vs. absence of an intravaginal probe in patients with a severe pain. In these patients, sEMG monopolar signals had a lower power during PFM contractions when the probe was inserted, as shown by a lower RMS. The value of this parameter is associated with the number of recruited motor units [10], so that it increases when a higher number of motor units are excited and develop action potentials. Therefore, the aforementioned differences suggest a lower PFM activation in patients with severe pelvic pain when a probe is inserted into their vagina.

Significant differences between both recording scenarios (probe into vs. out of the vagina) were obtained in monopolar signals, while bipolar signals were not influenced by the presence of the device. This could be related to the type of activity that is mostly detected with each configuration: unlike monopolar recordings, the contribution of far electrical fields to bipolar signals is minimum since they are almost equally detected by both electrodes and thus cancelled when their differential potential is obtained, implying that the signal is mostly originated by local myoelectrical activity. Considering that deep PFM activity has a higher total power than that of superficial PFM activity [4], external monopolar and bipolar recordings would mostly contain deep and

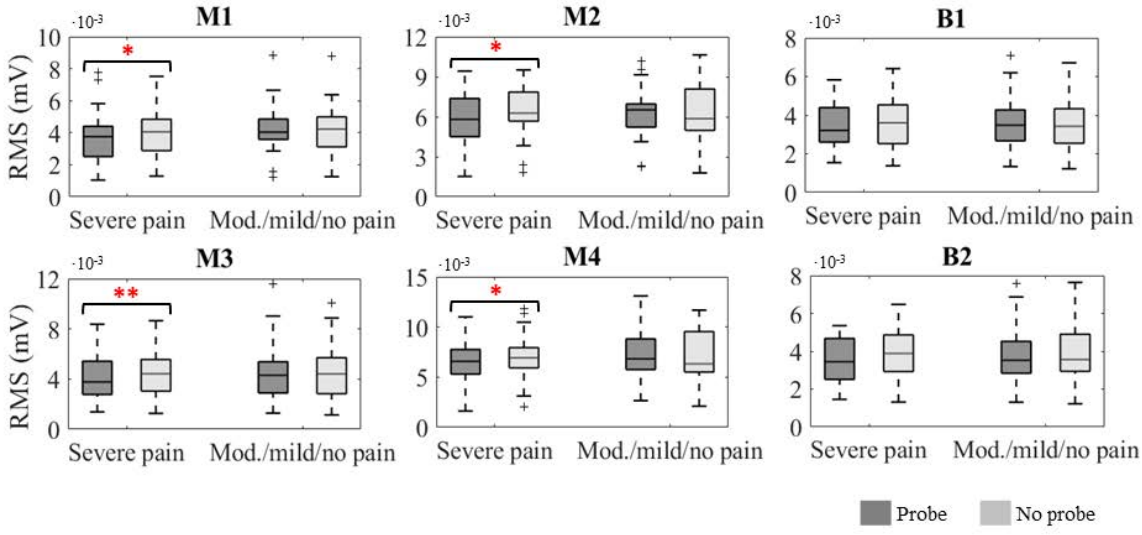

Figure 2. *RMS of monopolar (M1, M2, M3, M4) and bipolar (B, B2) sEMG signals of both pain groups during PFM contraction when the probe was into (dark boxes) and out of (light boxes) the vagina. (*): p-value<0.05. (**): p-value<0.01.*

superficial PFM activity, respectively, leading to the conclusion that the deep muscle bundles are the ones that show a different myoelectrical activity when a probe is inserted. This seems a reasonable outcome, since the pressure that it exerts on superficial PFM is minimum once it is in place.

Unlike PFM contractile activity, the power of resting activity was not influenced by the presence of the probe. Aunchincloss and McLean [7] assessed the PFM contractile activity of healthy women with fine wire electrodes when a probe was placed into and out of their vagina, and proved that the magnitude of any possible change induced by the device on the PFM sensory feedback, muscle length or tissue position was not high enough to translate into a significant change in the signal amplitude. This, together with the absence of significantly different RMS values in the moderate/mild/no pain group in the present study, implies that the differences observed in patients with severe pain would be associated with their reluctance to perform maximum voluntary contractions when the probe was inserted to avoid pain. Therefore, considering that PFM resting activity cannot be voluntarily controlled, the absence of significant differences during muscle relaxations would be an expected outcome. On the other hand, the intensity of the PFM activity is much lower during relaxations than during contractions, so that any possible differences between both recording scenarios during PFM relaxation could have been masked by common mode interferences and other noise sources [6].

Differences in signal power during PFM contractions were associated with a much lower p-value in M3 channel than in the other monopolar channels. M3 electrode was closer to the reference electrode than the others [8], [9], implying that crosstalk from neighboring muscles and other common mode signals were more similar between them than between the reference electrode and M1, M2 or M4, and thus more efficiently rejected in M3 signal. Therefore, differences shown by PFM activity when inserting an intravaginal probe would be greater in this signal. For this reason, other locations for the reference electrode should be considered in further studies to avoid its effect in the results obtained from the analysis. Further studies should also verify that the non-significant influence of the probe in the moderate/mild/no pain was associated with pain relief rather than other effects of BoNT/A treatment. Besides, they should make further efforts to increase the sample size to ensure that results can be reliably extrapolated to the global population.

Conclusion

Intravaginal probes may alter deep PFM contractile activity in patients that suffer from a severe pelvic pain associated with vulvodynia. Given that self-adhesive electrodes can detect the activity of both deep and superficial PFM and they are not uncomfortable for patients, their use should be extended in clinical practice. Nonetheless, technical issues such as the reference electrode placement or rejection of common mode interferences in monopolar signals should be improved.

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