

ORIGINAL ARTICLE

## EMG biofeedback versus topical lidocaine gel: a randomized study for the treatment of women with vulvar vestibulitis

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### Abstract

**Background.** To evaluate the efficacy of electromyographic biofeedback and topical lidocaine treatment for women with vulvar vestibulitis. **Methods.** A prospective randomized study where 46 women with vulvar vestibulitis were randomized to receive either electromyographic biofeedback or topical lidocaine treatment for four months. Assessments with vulvar pressure pain thresholds and questionnaires regarding quality of life, psychosocial adjustments, and sexual functioning were made before treatment, after treatment, and at six- and 12-month follow-ups. Nonparametric statistical methods were used to analyze differences in outcomes. **Results.** Nine women (9/46) dropped out during the treatment period. Both treatments showed significantly improved values for vestibular pressure pain thresholds, quality of life measurements, and sexual functioning at the 12-month follow-up. No differences were found between the two treatment groups. No severe side effects were reported. **Conclusions.** Four months' treatment with electromyographic biofeedback and topical lidocaine gave statistically significant improvements on vestibular pain measurements, sexual functioning, and psychosocial adjustments at the 12-month follow-up. No differences in outcome between the two treatments were observed but a larger sample may be needed to obtain significance. The treatments were well tolerated but the compliance to the electromyographic biofeedback training program was low. A combination of both treatments could potentially benefit many women with vulvar vestibulitis.

**Key words:** Vulvar vestibulitis, vulvodynia, vestibulodynia, randomized treatment study, vestibular pain thresholds

**Abbreviations:** EMG: electromyographic, QOL: quality of life, CBT: cognitive behavioral therapy, iqr: interquartile range

Even though knowledge about vulvar vestibulitis syndrome has increased over the past 10–15 years, its treatment is still a great challenge. As it is a common disorder, clinicians long for a simple and effective treatment with few side effects (1,2). So far few randomized treatment studies have been published but several authors have urgently pointed out the necessity of such trials (3–5). To help fill this gap, the results of a randomized study with EMG biofeedback and locally applied lidocaine gel will be reported here.

In 1987 Friedrich introduced vulvar vestibulitis as the clinical diagnosis for a condition of severe pain on vestibular touch or attempted vaginal entry,

tenderness to pressure from a cotton swab, vestibular erythema, and with a duration of at least six months (6,7). The condition is currently also known as provoked vestibulodynia (8). The etiology of vulvar vestibulitis seems multifactorial, including both physical and psychosexual causes (9–14).

Surgery with partial vestibulectomy was previously the main treatment for vestibulitis and several uncontrolled studies have been published (15,16). However, today surgery is most often recommended as second- or third-line therapy (17,18). Electromyographic (EMG) biofeedback for vulvar vestibulitis was introduced by Glazer et al. in 1995 and has been evaluated in two uncontrolled studies with

seemingly good results (19,20). The rationale for using EMG biofeedback is explained by the fact that women with vulvar pain disorders often demonstrate hyperirritability of the pelvic muscles and that the EMG biofeedback training could re-establish a normal function (19,20). Bergeron et al. used EMG biofeedback, vestibulectomy, and group cognitive behavioral therapy (CBT) in a randomized study (4). The conclusion was that EMG biofeedback and CBT were promising treatment alternatives to vestibulectomy.

Several locally active drugs have been tried without success (3,5). However lidocaine ointment and lidocaine infiltrations in combination with prednisolone have shown encouraging results in two uncontrolled studies (21,22). Topical lidocaine is commonly prescribed and used for immediate pain relief (18). It exerts its analgesic activity via blockade of sodium channels on peripheral nociceptors and by blocking transmission of discharges from peripheral sensory nerves (23,24). Sensitization of the peripheral vestibular nerves has been suggested as a possible mechanism of the pain in vulvar vestibulitis (12,13), and the theory behind the use of lidocaine in this study was to achieve a long-lasting desensitization of the vestibular nerves.

The purpose of this study was to evaluate the efficacy of EMG biofeedback and topically applied lidocaine gel in a prospective randomized study as reflected on pain measurements, sexual functioning, psychosocial adjustments, and quality of life (QOL). After careful consideration the decision was taken not to include a non-treated control group. We anticipated great problems in recruiting women with prolonged and severe vulvar vestibulitis, especially as a long follow-up period was regarded as important.

## Methods

Forty-six women from two different vulvar clinics in Sweden were included in the study during 2003. All women with vulvar vestibulitis (diagnosed by one of two physicians) visiting one of the two clinics were asked if they would participate. Inclusion criteria were introital pain, severe vestibular tenderness to pressure from a cotton swab, moderate to pronounced pain during most intercourse attempts, duration of symptoms  $\geq 6$  months and age  $\geq 18$  years. Exclusion criteria were severe medical, psychiatric or psychological disorders, pregnancy, and prior vestibulectomy or CBT. All women who fulfilled the criteria joined the study. Twenty-three participants were randomized to each treatment group.

A joint computer-generated randomization list was used for the two clinics. All women gave their written informed consent before randomization. The women filled in a questionnaire on their demographic, reproductive, and medical history and were examined by one of the two physicians on day 5–13 of the menstrual cycle to standardize for any differences in pain perception during the cycle. Pressure pain thresholds in the vestibule were measured. During the gynecological examination the women were instructed where and how to use the gel. The pelvic floor muscles were pointed out and they were all instructed in how to contract and relax them. After the examination the women were asked to fill out two more questionnaires. The participants were asked to keep a diary with daily notes of the number of lidocaine applications or EMG training sessions and possible side effects. The women randomized to lidocaine application had a one-month follow-up while the women randomized to EMG biofeedback received three sessions in four months.

Both treatments were continued for four months, followed by three post-treatment follow-ups: at the end of the treatment period, 6 and 12 months afterwards. The same procedures were performed at the follow-ups as at enrolment. Before the study started the two physicians jointly examined three patients and made all assessments.

For the topical treatment 2% lidocaine gel and 5% lidocaine ointment were used (Xylocain gel 2%/Xylocain ointment 5%, AstraZeneca International, Sodertalje, Sweden). For the first two months the women were instructed to apply the gel in the painful areas of the vestibule five to seven times per day. The ointment was recommended in the same way for the subsequent two months provided it provoked no pain. If it did the women were to continue with the gel for altogether four months.

Biofeedback treatment was mainly carried out according to Glazer et al., with home training exercises and computerized assessments of the pelvic floor muscles in the office (19,20). The equipment used was a single user surface EMG vaginal sensor (Model T6050) and a portable surface EMG biofeedback instrument (U-control model SA8800), all manufactured by Thought Technology Ltd (Montreal, Canada). The computerized data, not reported in this study, were analyzed using the Myo-Trac 3 Continence Software, Version 1.2.2. The computerized EMG assessment was carried out once a month during the treatment and at the three follow-ups. The participants were informed about the EMG biofeedback training and were encouraged to carry out three daily 10-min practice sessions. Each

session included: 1. ten maximal-intensity 5-s contractions, each contraction followed by a 5-s rest, then another ten contractions repeated once after a 60-s rest, 2. fifteen maximal-intensity 10-s contractions, each contraction followed by 10 s of rest, and 3. one maximal-intensity 60-s contraction.

#### *Outcome measures*

Pressure pain thresholds in the vestibulum were measured by a vulvar-algesiometer described and manufactured by Pukall et al. [25]. It is a simple mechanical device consisting of a set of cylindrical devices that contain metal springs of varying compression rates. The set is calibrated and exerts a wide range of forces from 3 to 1,000 g. At the bottom of each device a cotton swab is fitted. Pain thresholds were measured in two separate areas of the vestibular mucosa, i.e. the anterior part of the vestibule (site A) and the posterior part (site B), by slowly applying higher force levels until pain was reported. At this point participants rated pain intensity on a VAS from 0 to 100.

Two questionnaires were used. Short form 36 (SF 36) is a measure of functional impairment and well-being and assesses nine domains. The items Physical functioning, Role limitations due to physical health, Bodily pain and General health primarily represents physical health, while Vitality, Social functioning, Role limitations due to emotional problems and Mental health account primarily for mental health. Health transition measures the subjective change in health rating during the last 12-month period. The SF 36 is widely used and has a high validity and reliability, and a study using the Swedish version supports the cross-cultural stability of the ratings (26–28).

To further evaluate psychosocial and sexual functioning, a structured questionnaire was constructed. Two screening questions for depressive disorders from the Primary Care Evaluation of Mental Disorders (PRIME MD) were included, as well as a quality-of-life (QOL) measurement (29). For the QOL measurement the women were asked before the treatment started to define three major factors in their lives where the suffering caused by vulvar vestibulitis was most evident. A Visual Analogue Scale (VAS) of 0–100 was used with 0 corresponding to no suffering and 100 to unbearable pain or suffering (negative QOL factors). Positive QOL factors were set as “sexual desire” and “joy of living” where VAS was reversed with 0 representing very dissatisfied and 100 very satisfied. The method has been used in evaluating chronic pain conditions and also in a treatment study for vulvar vestibulitis using

acupuncture (30,31). VAS was also used for questions regarding sexual functioning and coital pain. Further questions about sexuality and pain had multiple choice answers, while still others could only be answered with yes or no.

#### *Statistical methods*

Statistical analyses were conducted using the SPSS program 12.1 for Windows. Standard methods were used for analyzing means, medians, and interquartile range (iqr). Nonparametric methods were used, including the Wilcoxon Signed Ranks test for analyzing differences in VAS and pressure pain values before treatment and at the 12-month follow-up and the Mann–Whitney test for comparisons between the two treatments before and at the 12-month follow-up. Chi-square test was used for categorical data to compare differences in outcome. The level of significance used was 0.05.

The sample size was estimated to 36 women provided there was a difference of at least 20 scale units between the means of the two treatment groups in the QOL measurements at the 12-month follow-up. The power used was 80%, SD 14, and the significance level 0.05. The local ethics committees approved the study.

#### **Results**

The demographic data for the two treatment groups are shown in Table I. All 45 women started the treatment but at the first post-treatment follow-up nine women had dropped out. Reasons for not completing the treatment were lack of motivation ( $n=4$ ), moving out of the region ( $n=2$ ), broken relationship ( $n=2$ ), and candida infection ( $n=1$ ). Thirty-seven women continued the study, 18 in the EMG biofeedback group, and 19 in the lidocaine treatment group. One woman in the EMG biofeedback group completed only the treatment part, due to a sudden death in the family. At visits three and four there were two further dropouts, with the reasons given for not continuing the study being pregnancy and moving out of the region.

None of the women allocated to EMG biofeedback practiced for 10 min three times per day as instructed. Ten out of 18 women (56%) completed two training sessions per day while the rest completed only one. A few women complained about pain on insertion of the vaginal probe, but it did not prevent them from using it. One woman reported problems with candida infections. No other side effects were reported. The women using topical lidocaine were instructed to apply it five to seven

Table I. Social, demographic and medical history of the patients.

Patient characteristics	EMG <i>n</i> = 23 (%)	Lidocaine <i>n</i> = 23 (%)
Age mean (range), years	23.3 (18–30)	25.8 (19–36)*
Education: 9–12 years	9 (39)	6 (26)
> 12 years	14 (61)	17 (74)
Married or cohabiting	15 (65)	13 (57)
Regular partner	20 (87)	20 (87)
Duration partnership median, (iqr) months	36 (12.5–48)	36 (20–57)
Ever pregnant	5 (22)	5 (22)
Parity	2 (7)	2 (7)
Oral contraceptives	17 (74)	18 (78)
Duration symptoms, median (iqr) months	36 (18–60)	38 (30–20)
Last intercourse, median, (iqr) months	1.5 (0.25–11)	6.5 (0.5–6.5)
Primary vestibulitis	5 (22)	10 (43)
Other frequent pain symptoms	10 (43)	13 (57)
Gastrointestinal	2 (7)	4 (17)
Shoulder/neck	10 (43)	16 (70)
Back/pelvis	5 (22)	2 (7)
Joints	2 (7)	4 (17)

iqr, interquartile range; \**p* = 0.03.

times a day and 18/19 (95%) women had used an average number of five applications or more per day. Approximately 50% switched to the 5% ointment after two months, while the rest continued with the gel. Most women used about 40 g gel/ointment per month. The only reported side effect was a slight stinging pain at application, which was more pronounced for the ointment than the gel.

The results of the vestibular pain threshold measurements are shown in Figures 1 and 2. There was a significant increase in pain thresholds at both vestibular sites and for both treatment groups at the 12-month follow-up as compared to before treatment. The median pain thresholds in the EMG biofeedback group increased from 25 g to 70 g in site A (*p* = 0.002) and from 20 g to 40 g in site B (*p* = 0.02). In the lidocaine group the pain thresholds increased from 30 g to 50 g in site A (*p* = 0.008) and from 20 g to 30 g in site B (*p* = 0.007). No significant difference was observed between the two treatment groups. VAS for pain intensity was unchanged for both treatments in site A before and at the 12-month follow-up. A small but statistically significant reduction in pain intensity was observed in site B for the women treated with lidocaine at the 12-month follow-up, median VAS 40 (iqr: 24–51) as compared to before treatment VAS 45 (24–56), *p* = 0.04. Four women who considered themselves to be completely cured at the 12-month follow-up had pain thresholds in vestibular sites A and B of between 50 and 110 g at the same visit, while four participants with at least

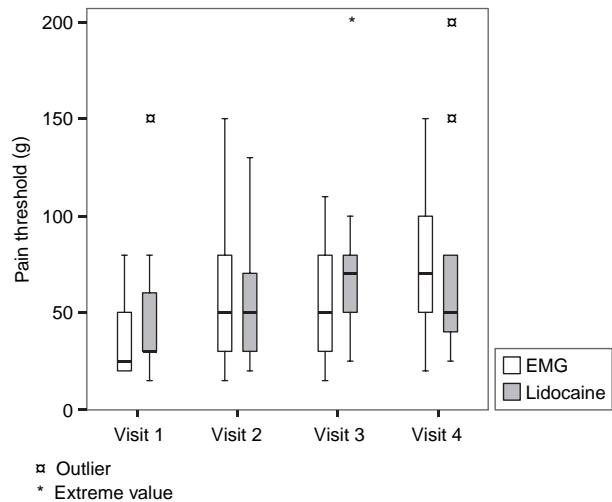


Figure 1. Pressure pain thresholds for vestibular site A before treatment (visit 1) and at the follow-ups (visits 2–4). Differences in pain threshold between visit 1 and visit 4: for EMG treatment group *p* = 0.002, for lidocaine *p* = 0.008, for the two treatment groups analyzed together *p* = 0.000. No difference in outcome between the two treatment groups at 12-month follow-up, *p* = ns.

one pain threshold over 110 g did not regard themselves as cured.

VAS for the negative QOL measurements was significantly improved for both groups analyzed separately and together (Figure 3), but no significant differences between the two groups were found. The most common negative factors mentioned were coital pain, inability to have intercourse, lack of sexual desire, anxiety, and shame. As to SF 36 at the 12-month follow-up, there was a tendency towards

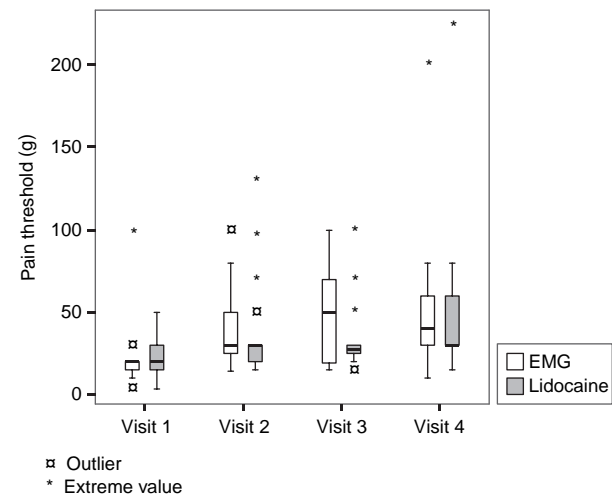


Figure 2. Pressure pain thresholds for vestibular site B, before treatment and at the follow-ups. Differences in pain thresholds between visit 1 and visit 4: for EMG treatment group *p* = 0.02, for lidocaine treatment group *p* = 0.007, for the two treatments analyzed together *p* = 0.000. No difference between the treatment groups at the 12-month follow-up, *p* = ns.

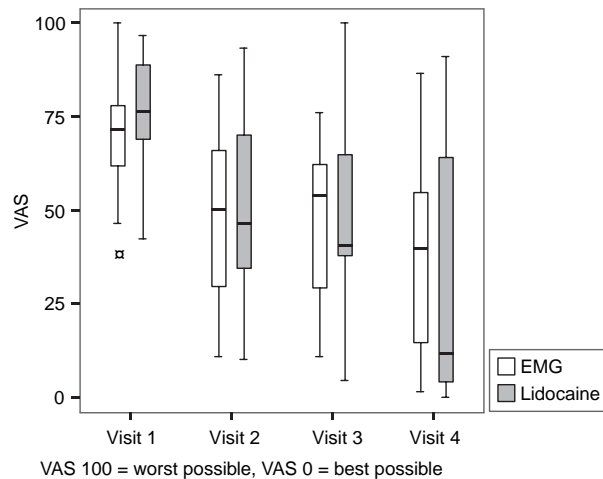


Figure 3. Negative QOL measurements before treatment and at the follow-ups. Differences in VAS between visit 1 and visit 4: for EMG treatment group  $p=0.001$ , for lidocaine treatment group  $p=0.002$ , for the two treatment groups analyzed together  $p=0.000$ . No significant difference between the treatment groups,  $p=ns$ .

improvements for all items in both groups but not all reached statistical significance. However, both treatment groups improved their scoring in Bodily pain and Health transition ( $p < 0.05$ ), while the lidocaine group also improved the scoring in Physical functioning and Role limitations due to emotional problems ( $p < 0.05$ ).

The results of the questions regarding sexual functioning, pain, depressive symptoms, and "positive QOL factors" are shown in Table II. Significant improvements were observed for many variables analyzed for the two treatment groups both separately and together. Only one variable, vestibular pain not related to coitus, showed a small but statistically significant difference in outcome between the treatments.

At the 12-month follow-up 2/18 in the EMG biofeedback group considered themselves as completely cured, 12/18 had improved, 3/18 reported no change, and one person did not answer. The treatment outcome was similar for the women in the lidocaine group with 2/19 completely cured, 10/19 improved, 3/19 with no change, and four missing values.

The women were asked before the treatment was started whether or not they believed the treatment they were randomized to would suit them. In the lidocaine group 9/19 (47%) answered that they thought the treatment would, while eight did not know. Among the women in the EMG biofeedback group, the corresponding figures were 10/18 (55%) and eight. There was no correlation between

the confidence in the allocated treatment and the dropout rate.

## Discussion

In this randomized study of women with vulvar vestibulitis treated with EMG biofeedback and topical lidocaine gel we have found that both groups reported significantly improved values regarding pain measurements, sexual functioning, and QOL at the 12-month follow-up compared to before the treatment. However, very few statistically significant differences in outcome between the two groups were found. As we were mostly interested in the long-term results we have chosen to focus primarily on differences in the outcome from the first visit to the 12-month follow-up.

This is the first treatment study to measure vestibular pain with standardized forces while earlier studies have used the cotton swab test (4,21,25). The pain thresholds increased for both vestibular sites at the 12-month follow-up, as compared to before the treatment started. However, the differences in pain thresholds were small, with median values rising from approximately 20–25 g to 30–70 g. These values are much lower than the mean pain threshold ( $285 \pm 86$  g) in healthy women as reported by Pukall et al. using the same device (25). An interesting observation in our study is that none of the women who considered themselves cured obtained pain thresholds above 110 g, while some women, who did not consider themselves recovered, had the same or even higher pain thresholds. This emphasizes the lack of reference values for women who have recovered from vestibulitis but also that the pain threshold is only one outcome variable of vulvar vestibulitis. Furthermore, site B was more sensitive in both treatment groups at all visits. Also non-provoked vulvar pain and discomfort improved over time in both treatment groups.

Sexual function, as reflected in the questionnaire, showed significantly better values at the 12-month follow-up on almost all items, especially when the two treatments were analyzed together. Symptoms of partial vaginismus were very common before the treatment started and less common at the 12-month follow-up, but unexpectedly not for the EMG treatment group.

In clinical practice it is often obvious that the psychological impact on the affected women varies and that in some cases it causes pronounced disturbances in daily life activities. Signs of anxiety and depression are common. The women in both treatment groups showed major improvement regarding the negative QOL measurements at the

Table II. Evaluation of questionnaire. VAS given in median (iqr) before treatment (visit 1) and at the 12-month follow-up (visit 4).

Question	Lidocaine			EMG			$p^*$	$p^{**}$
	Visit 1	Visit 4	$p$	Visit 1	Visit 4	$p$		
Joy of living, last month, VAS <sup>1</sup>	45 (19–71)	64 (42–80)	NS	62 (44–79)	69 (57–80)	NS	NS	NS
Sexual desire, last month, VAS <sup>1,3</sup>	16 (8–57)	42 (12–77)	0.035	41 (18–49)	59 (22–72)	NS	0.005	NS
Sexual satisfaction, last month, VAS <sup>1</sup>	20 (4–50)	63 (25–77)	0.033	19 (10–49)	47 (25–55)	0.046	0.004	NS
Number of coitus, last month, mean (range) <sup>3</sup>	1 (0–6)	3.4 (0–10)	NS	0.9 (0–5)	4.3 (0–10)	NS	0.025	NS
Number of sex, not coitus, last month, mean (range) <sup>3</sup>	2.4 (0–12)	1.9 (1–4)	NS	2.4 (0–9)	3.7 (1–7)	NS	NS	NS
Symptoms of partial vaginismus, last coitus, $n$ (%)	15 (79)	7 (36)	0.031	15 (83)	10 (56)	NS	0.009	NS
Orgasm last 4–5 coitus, sometimes–often, $n$ (%)	10 (53)	7 (36)	NS	10 (56)	12 (67)	NS	NS	NS
Pain at last coitus, VAS <sup>2</sup>	74 (50–87)	42 (21–72)	0.055	77 (60–94)	65 (28–74)	0.011	0.001	NS
How often non-coital vestibular pain last month, VAS <sup>2</sup>	12 (1–53)	3 (1–8)	0.046	34 (6–59)	16 (6–26)	0.003	0.000	0.009
Vestibular pain disrupting life, last month, VAS <sup>2</sup>	37 (20–84)	7 (2–38)	0.003	52 (28–59)	15 (6–33)	0.001	0.000	NS
Yes on 1–2 screening questions for depression, $n$ (%)	13 (68)	4 (21)	0.007	9 (50)	4 (22)	NS	0.002	NS

<sup>1</sup>VAS positive: 0 worst possible and 100 best possible. <sup>2</sup>VAS negative: 0 best possible and 100 worst possible. <sup>3</sup>Women with regular partner only.

$p$ -values given for the difference between visit 1 and visit 4 for each treatment ( $p$ ) for the two treatments analyzed together ( $p^*$ ) and for the differences between the two treatments at visit 4 ( $p^{**}$ ).

12-month follow-up. Another indication of improved psychological health was that fewer women answered yes to either of the two screening questions for depression at the 12-month follow-up as compared to before the treatment started. Significant improvements were seen also in SF-36 in both treatment groups for several of the items at the 12-month follow-up. The differences in results between the two treatments were small and can hardly be of any clinical importance.

The EMG training program used in this study was not in accordance with the program introduced by Glazer et al., who advocated 20 min twice per day (4,19,20). Bergeron et al. have reported that adherence to the program was low (4) and another set-up was designed for this study, with 10 min training three times a day. The compliance to this program was low as well. It is a well known problem that adherence to any physical training program is low (32). On the other hand it seemed much easier for the women to comply with the instructions for using the lidocaine. The intention was that the women randomized to lidocaine would switch to the 5% ointment after two months' treatment. Only half of them did so, due to stinging pain. The amount used was far from the quantity mentioned in reports of lidocaine toxicity, which some authors have warned about (18,33). The hypothesis that frequent applications of topical lidocaine could

induce a desensitization of the vestibular nerves was strengthened by the finding of a sustained increase in vestibular pain thresholds at the 12-month follow-up. Whether a longer treatment period or the addition of nightly application as used by Zolnoun et al. (21) would result in further improvement remains to be shown.

A shortcoming of the study was the high rate of dropouts. All women eligible for the study did in fact join, but 20% did not complete the treatment. Lack of motivation was the most common cause reported. Some of the women were also dissatisfied that signs of improvement took longer than expected. This shows how important it is to give thorough information about treatments and expected effects.

Very few significant differences were found between the two treatments at the 12-month follow-up. There might be at least two reasons for that. The most obvious reason is that there were no differences. Another possible reason is that there were too few patients to obtain significance. The differences between the two treatment groups were smaller for some variables and the variations within in the groups were larger than estimated in the power calculation. Moreover less women than calculated completed the whole study. In planning the study we decided not to have a non-treated or placebo-treated group as we considered it extremely hard to conduct such a study. Furthermore, as there is no treatment

generally regarded as the gold standard, there was no obvious treatment to use instead of placebo. But based on the experiences of this study we believe it is important for researchers to try to overcome the difficulties and proceed with larger randomized controlled treatment studies.

Some authors have argued for a multimodal approach with more than one treatment at a time (18,34). As EMG biofeedback and topical lidocaine have different modes of action on vulvar pain, a combination of the two treatments might potentially be of use for women with vestibulitis.

## Conclusion

Four months' treatment with EMG biofeedback or topical lidocaine gel/ointment for women with vulvar vestibulitis significantly improves vestibular pain, sexual functioning, and QOL measurements. The efficacy of the two treatments was equal at the 12-month follow-up, but larger samples would be needed to make an evaluation of differences in outcome measures possible. The treatments were well tolerated but compliance to the EMG training program was low. We have reason to believe that women with vulvar vestibulitis would benefit from a combination of EMG biofeedback and topical lidocaine.

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