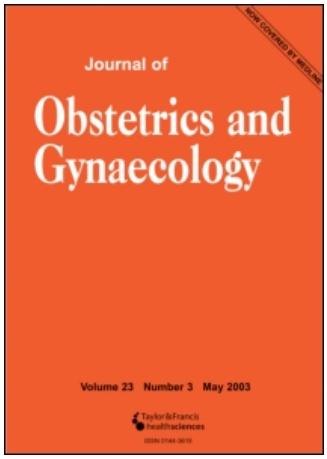

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Treatment of dysmenorrhoea with a new TENS device (OVA)

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Treatment of dysmenorrhoea with a new TENS device (OVA)

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Summary
Transcutaneous electrical nerve stimulation (TENS) is an established method for pain relief in dysmenorrhoea, which does not involve the use of medication. This prospective study evaluated the clinical utility of a new, very small and light, high frequency TENS device in 21 menstruating women during four menstrual cycles. The efficacy measures were pain relief evaluated on a VAS scale and reduction in use of analgesic tablets. All the participants subjectively found the device useful. There was a statistically significant drop in mean pain score from 6.73 to 5.18 points ($p = 0.0009$). Concurrent use of analgesic tablets was also significantly reduced ($p = 0.03$) and seven women stopped taking analgesics while using the device ($p = 0.02$). There were no adverse events. On follow-up 6–8 months post study, 14 of the women were still using the device regularly. This TENS device appears to be a useful treatment alternative for dysmenorrhoea.

Keywords
Dysmenorrhoea, TENS, treatment

Introduction

Dysmenorrhoea is a widespread female problem which causes reduced quality of life, a need for medical treatment, and absence from school or work. A recent Canadian study found that 60% of menstruating women had primary dysmenorrhoea with 51% reporting limitations of daily activities and 17% reporting absenteeism; 60% had moderate or severe pain (Burnett et al. 2005). Dysmenorrhoea is caused by increased prostaglandin secretion from the endometrium causing abnormal uterine contractions leading to reduced uterine blood flow and ischaemic pain (Dawood 2006).

When treatment of dysmenorrhoea is required, the primary modalities used are non-steroidal anti-inflammatory drugs (NSAIDs) and oral contraceptives (OC). NSAIDs have a documented effect and are widely used (Marjoribanks et al. 2003). Treatment with hormonal contraception is also well established. A Cochrane review in 2001 concluded that medium and high dose OCs are effective in relieving dysmenorrhoea, but that proof was lacking for the modern low dose OCs (Proctor et al. 2001). However, a recent study showed that low dose (20 μg) OCs are also effective (Davis et al. 2005). Other treatment options have recently been described in two excellent reviews (Dawood 2006; Proctor and Farquhar 2006).

However, medical treatment may be undesirable for personal reasons, may give insufficient relief, or be contraindicated. Medical treatment may also cause adverse events, limiting its use. Non-medical treatment options are therefore warranted. Transcutaneous electric nerve stimulation (TENS) has been used for several decades in the treatment of dysmenorrhoea, and a Cochrane review in 2002 concluded that high frequency (50–120 Hz) TENS is effective, while the evidence for low frequency TENS was inconclusive (Proctor et al. 2002).

Treatment with TENS has the advantages of being controlled by the patient and does not involve the use of medication. TENS is inexpensive and virtually without risk, and there are few contraindications. High frequency, low intensity current is normally used. TENS works by stimulating large diameter, cutaneous, proprioceptic Aβ nerve fibres without activating the thinner Aδ and C pain fibres. According to the pain gate theory, pain signals from the uterus are prevented from entering the spinal cord, thereby preventing the perception of pain. In addition, TENS can stimulate release of β-endorphins, which also helps to relieve pain (Dawood 2006). It has been suggested that TENS may also reduce ischaemic pain by improving local uterine blood circulation (Milsom et al. 1994), but this has not been documented. The effect is usually evident within minutes of applying the TENS (Milsom et al. 1994).

Standard devices for TENS are typically too large and heavy for easy use during everyday activities. A new TENS device named OVA, specifically developed for treatment of dysmenorrhoea, has recently been marketed (TensCare, Surrey, UK). It is small and light, and can be clipped invisibly on to the user's clothes and be used during daily activities. Its specifications are given in Table I. The user can choose between three preset programmes, all with high frequency stimulation. The user controls the intensity and adjusts it during treatment.

This study was done to test the clinical utility of the OVA TENS device in women with primary dysmenorrhoea.

Methods

The study was approved by the regional ethics committee, reported to ClinicalTrials.gov and participants gave informed consent. It was designed as a prospective clinical trial lasting four consecutive menstrual cycles. The participants used the OVA device during every other cycle,

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while the remaining cycles acted as controls. They were randomised to either start with active treatment or observation. Comparing active cycles and observation cycles, the primary outcome measure was relief of pain on a Visual Analogue Scale (VAS) and the secondary outcome measure was change in use of analgesic medication. Participants were free to use pain medication as needed.

A priori power calculation had shown that 16 participants would be needed to demonstrate a difference of 2 VAS points assuming α 0.05 and β 0.1. A total of 22 volunteers with primary dysmenorrhoea were included from September to December 2005. One woman aged 46 developed amenorrhoea before the first study cycle and was excluded; the remaining 21 women all completed the study. Their mean age was 24 years (range 12–41); seven were under 20 years old, 10 between 20 and 29, three between 30 and 39 and one was 41 years old. Their mean score for pre-study dysmenorrhoea was 6.87 VAS points (median 7, range 2–10, SD 2.12). A total of 20 participants (95%) habitually used analgesic tablets for dysmenorrhoea.

During each menstruation throughout the study, participants rated their pain on a 10-point VAS scale (0 = no pain, 10 = worst possible pain) and noted any use of analgesic tablets, duration of the use of the OVA device and which programme(s) they used, and duration of menstruation. The forms were mailed to us at the end of each menstruation, allowing for a degree of blinding between cycles. The participants were instructed to attach the skin electrodes suprapubically on either side of the midline, or on the lower back in the case of insufficient effect with abdominal placement and dysmenorrhoea experienced mainly in the back.

Participants were allowed to keep the devices after study completion. At 6–8 months after the last study cycle, all participants answered a questionnaire on continued use of the device.

Table I. Specifications of the OVA TENS device

Size (mm)	55 × 35
Weight (g)	28
Current output (mA)	0–60
Number of electrodes	2
Battery	Flat, 3 volt lithium, lasting 8 h at 52 mA
Pulse form	Biphasic, asymmetrical, rectangular
Programme A	Frequency 110 Hz and pulse width 110 μsec
Programme B	Frequency 110 Hz and pulse width 50 μsec
Programme C	Pulse trains (bursts) at frequency 100 Hz and pulse width 2 μsec

Statistics

The two-sided *t*-test for paired data and χ^2 tests were used with level of significance at $p = 0.05$.

Results

Mean duration of menstrual bleeding was 5 days (range 2–7, SD 1.04), and mean number of days with dysmenorrhoea was 3 days (range 0–6, SD 1.43). There was no significant difference in duration of menstrual bleeding or pain with or without the device ($p = 0.86$).

As can be seen from Table II, there was a highly significant reduction in pain scores and number of analgesic tablets used. All participants stated that they had found the device useful; 18 women (86%) had a lower pain score with treatment than without, and seven (35%) did not need to take analgesics while using the device. Some 18 participants stated that they preferred programme A on the device, three preferred programme B and none programme C. Mean duration of use was 4.1 h/day (range 20 min to 12 h).

Although all participants found the device useful, two actually had an increased pain score with use. One of these two stated that while the device had little effect on her pain, she had not experienced her usual cycle-related migraine attacks during treatment with the device.

At 6–8 months post-study, 14 participants were still using the device regularly at least every other cycle. Among the seven women not using the device, two stated that this was due to lack of effect; four because using it required too much effort and taking tablets was easier; and one had amenorrhoea due to injectable gestagen contraception. All participants recommended the device to friends.

Discussion

There are many treatment options for dysmenorrhoea today – high frequency TENS being one (Dawood 2006; Proctor and Farquhar 2006). Treatment with TENS has the advantage of not involving medicines, and being controlled by the user. The analgesic effect of TENS in dysmenorrhoea is similar to that of naproxen (Milsom et al. 1994) and somewhat inferior to that of ibuprofen (Dawood and Ramos 1990).

Our study showed a statistically highly significant reduction in pain scores with TENS treatment using the new OVA device, while the need for analgesic medication was halved. Is the reduction in pain scores also clinically significant? In the literature, a change of 0.9–1.5 (or 2) on a 0–10 point scale or a 10% difference between groups is usually considered to be clinically significant (Kelly 1998; Abbot et al. 2001; Douglas et al. 2006; Cruise et al. 2006;

Table II. Pain scores and use of analgesic tablets with and without the OVA device

	Pain scores			Analgesic tablets (*n*/day)			Number of women using analgesic tablets
	Mean	Range	SD	Mean	Range	SD	
Control cycles	6.73	2.5–10	2.3	2.89	0–12	2.30	20/21
Active cycles	5.18	0–8.6	2.2	1.36	0–5.5	1.42	13/21
p value		0.0009*			0.003*		0.024†

*Two-sided paired *t*-test; †χ^2 test.

Appell et al. 2006). In our study, the reduction was 1.55 VAS points, corresponding to 23%, indicating that our results are clinically significant.

The study design was chosen to save resources, as each participant acting as her own control reduces the required number of participants for statistical analysis, but the lack of a placebo group does raise the possibility of the results being due to the placebo effect. However, several factors count against this: (1) the reduction in perceived pain during active cycles was both clinically meaningful and statistically highly significant, (2) there was a significant reduction in use of analgesic tablets during active cycles, as evaluated both as mean tablet consumption and number of women not requiring analgesics, (3) 14 participants have continued to use the device more than 6 months post-study and (4) all have recommended it to friends.

Almost all the participants (18/21) preferred programme A among the three different programmes available on the device. The settings in programme A (110 Hz, 110 μsek) correspond to those which have previously been shown to work against dysmenorrhoea (Johnson 2002; Proctor et al. 2002).

Treatment options not requiring medication are needed, as some women cannot or do not wish to take medicines. In addition, a supplement is needed when medical treatment gives insufficient relief. High frequency TENS, such as with the OVA device, appears to be a useful treatment modality. The OVA device is small and can be discreetly hidden underneath the user's clothes. TENS treatment is safe; there were no adverse events in the study. TENS treatment does, however, entail more work for the user than taking a tablet, and this is illustrated by four of our participants not continuing to use the device for this reason.

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