British Journal of Obstetrics and Gynaecology
April 1989, Vol. 96, pp. 434–439

Ultrasound and pulsed electromagnetic energy treatment for perineal trauma. A randomized placebo-controlled trial

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Summary. Ultrasound and pulsed electromagnetic energy therapies are increasingly used for perineal trauma sustained during childbirth. The study included 414 women with moderate or severe perineal trauma randomly allocated to receive active ultrasound, or active pulsed electromagnetic energy, or corresponding placebo therapies; the allocation was double-blind for each machine. Overall, more than 90% thought that treatment made their problem better. There were no clear differences between the groups in outcome either immediately after treatment, or 10 days or 3 months postpartum, other than more pain associated with pulsed electromagnetic energy treatment at 10 days. Bruising looked more extensive after ultrasound therapy but then seemed to resolve more quickly. Neither therapy had an effect on perineal oedema or haemorrhoids. The place of these new therapies in postnatal care should be clarified by further controlled trials before they become part of routine care.

As many as 70% of women suffer trauma to the perineum during vaginal delivery which is sufficiently severe to require surgical repair (Sleep *et al.* 1984). This trauma commonly causes pain and discomfort which may persist for months (Sleep & Grant 1987), particularly if the injury is extensive. Ultrasound and, to a lesser extent, pulsed electromagnetic therapy are increasingly being used in the first few days after delivery to treat this problem: in a telephone survey of 36 randomly selected consultant maternity units conducted in 1987 (Sleep & Grant 1988) ultrasound therapy was being used to treat perineal trauma in 15 (42%), and pulsed electromagnetic energy being used in 3 (8%).

The mechanisms by which therapeutic ultrasound may improve tissue repair and reduce pain have been reviewed by Dyson (1987). The few well-conducted controlled trials of the clinical efficacy of ultrasound have all been small (Partridge 1987), but there is evidence that ultrasound therapy is effective for some soft tissue injuries, such as tennis elbow (Binder *et al.* 1985), leg ulcers (Dyson *et al.* 1976; Roche & West 1984; McDiarmid *et al.* 1985; Callam *et al.* 1987), and following oral surgery (El Hag *et al.* 1985). Two small controlled trials of therapeutic

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ultrasound for perineal trauma have been incompletely reported (McLaren 1984; Creates 1987). Both suggest a reduction in pain associated with active treatment, and one reported more rapid dispersal of bruising. However, these two studies on their own do not provide a firm basis for practice.

Pulsed electromagnetic energy therapy is also claimed to improve wound healing and reduce pain. A number of possible mechanisms have been suggested (Hayne 1984) and a controlled trial of therapy for perineal trauma suggested that pulsed electromagnetic energy may accelerate resolution of bruising and healing (Bewley 1986; A. W. Bird, personal communication).

We report a randomized controlled trial comparing ultrasound and pulsed electromagnetic energy therapy with double-blind, placebo treatments begun within 24 h of delivery, for moderate or severe perineal trauma.

Patients and methods

The trial was conducted at the maternity unit of the Royal Berkshire Hospital. The study design and protocol were approved by the research and ethics committee for West Berkshire. Recruitment took place on the postnatal wards on weekdays (Monday to Friday). Women were eligible for entry to the trial if they (i) required operative vaginal delivery; or (ii) sustained perineal trauma involving extensive damage to the anal sphincter or damage to the rectal or anal mucosa; or (iii) developed severe perineal oedema, bruising or haematoma within 24 h of delivery. Eligibility was checked by the midwife researcher who then sought consent to participation before formal trial entry: 419 women were invited of whom 414 agreed to participate. At entry, basic descriptive data were recorded adjacent to the next available trial number. The correspondingly numbered, sealed, opaque envelope was then allotted, and this was later opened by the physiotherapist researcher. Once the seal was broken, the mother had entered the trial irreversibly and remained in the study for analysis regardless of subsequent management. Each envelope contained the random treatment allocation: first to either ultrasound or pulsed electromagnetic energy and second to a number which signified random allocation to either active or placebo therapy. Each machine had a specially fitted 12-number dial: eight settings were active and four placebo. The codes for the switches were arranged by the manufacturers (EMS Medical Supplies) and held in sealed envelopes until the end of the trial. These codes were changed at 2-monthly intervals to minimize the risk of the operator breaking the code and thereby introducing bias. The therapists were also checked for sensitivity to the vibration of the ultrasound transmitter (Therasonic 1030) and it was confirmed that they could not distinguish the active from the inactive mode. Each week the output of the machines was checked by a physiotherapist who worked in a different part of the hospital. The ultrasound was transmitted at an operating frequency of 3 MHz, an intensity of 0·5 W/cm^2 and a pulse interval of 1:4; treatment was given for 2 min to each area of trauma equal to the size of the transmitting head. EMS ultrasound couplant was used as recommended by the manufacturers. The pulsed electromagnetic energy (Megapulse) unit was set at an operating frequency of 27 MHz, a pulse repeat rate of 100 pulses/s and a pulse width of 65 μs, pulse ratio normal, the duration of each treatment was set at 10 min.

Therapy was started about 12 h (always within 24 h) after delivery, a maximum of three treatments being given during a 36-h period. Assessments before and within 2 h after treatment were made by the mother (in respect of perineal pain, using 10-cm linear analogue and categorical scales) and by the midwife co-ordinator who documented the extent of oedema, bruising and haemorrhoids and any analgesia required over the course of treatment. A further assessment of pain and healing was made by the mother and the community midwife 10 days after delivery. Finally a postal questionnaire, self-administered by the mother, assessed maternal morbidity 3 months postpartum. All assessments were made 'blind' to whether the treatment was active or placebo. In most cases the research midwife and community midwives also did not know which type of machine had been allocated.

There were two main hypotheses tested in the trial. The first was that ultrasound or pulsed electromagnetic energy therapy or both would reduce the frequency and severity of perineal pain on the 10th day after delivery. The second was that active treatment would reduce the time to resumption of sexual intercourse and increase the frequency of pain-free intercourse 3 months after delivery. The effects of the two therapies on perineal pain at other times, the use of oral analgesia, perineal oedema, bruising and haem-

Table 1. Description of the trial groups at entry

	Pulsed electromagnetic energy (n=135)	Ultrasound (n=140)	Placebo (n=139)
Maternal age (years) mean [SD]	27·3 [4·2]	26·9 [4·5]	27·1 [5·3]
Primigravida n (%)	103 (76)	99 (71)	92 (66)
Gestational age (weeks) mean [SD]	39·8 [1·7]	39·8 [1·4]	39·9 [1·7]
Birthweight (g) mean [SD]	3291 [530]	3377 [445]	3402 [521]
Instrumental or breech delivery n (%)	91 (67)	90 (64)	103 (74)
Type of perineal injury n (%)			
1° or 2° perineal tear	21 (16)	24 (17)	24 (17)
Uncomplicated episiotomy	78 (58)	81 (58)	85 (61)
Episiotomy + 2° extension	26 (19)	27 (19)	21 (15)
Extension of episiotomy or tear through anal sphincter or rectal mucosa	6 (4)	6 (4)	5 (4)
Other	4 (3)	2 (1)	4 (3)
Perineal pain at trial entry n (%)			
None	5 (4)	8 (6)	8 (6)
Effective epidural	9 (7)	4 (3)	9 (7)
Mild	20 (15)	18 (13)	22 (16)
Moderate	70 (52)	79 (57)	70 (51)
Severe	31 (23)	30 (22)	29 (21)
Bruising at trial entry n (%)	68 (51)	82 (60)	74 (53)
Oedema at trial entry n (%)	45 (33)	52 (37)	42 (30)
Haemorrhoids at trial entry n (%)	28 (21)	33 (24)	33 (24)

orrhoids and maternal feelings of well-being were also examined.

A sample size of 400 women was prespecified. This was based on an expected prevalence of perineal pain 10 days after delivery in the placebo group of 50%. A trial of this size has an 80% chance of showing a statistically significant difference if active treatment reduces this prevalence by one third.

The results for the two placebo groups were so similar that they were amalgamated to give a single pooled placebo group of the same size as the two actively treated groups for the purpose of analysis. χ^2 and t-tests with one-way analysis of variance were used where appropriate. Confidence intervals for relative risks were calculated using the method recommended by Katz *et al.* (1978). Ten-day forms were returned for 129 (96%) women in the pulsed electromagnetic energy group, for 134 (96%) in the ultrasound group, and for 131 (94%) in the placebo group. Three-month questionnaires were returned by 124 (92%), 126 (90%) and 125 (90%) women respectively.

Results

Table 1 describes the women who joined the study and demonstrates the comparability of the groups at trial entry. Overall, 69% had been delivered by forceps, vacuum extraction or assisted breech delivery; 18% had extensions of an episiotomy and a further 4% had third-degree perineal trauma; 79% had moderate or severe perineal pain at the time of recruitment.

All women received the allocated treatment. Women in the pulsed electromagnetic energy groups received three treatments each of 10 min duration, except for two women allocated to active pulsed electromagnetic energy who had two treatments each for 10 min. All women allocated ultrasound received three treatments. Duration of treatment in the ultrasound groups was more variable, the total ranging from 6 to 18 min; the mean duration in the actively treated group was 8·2 (SD 3·1) min, and in the placebo ultrasound group 7·5 (SD 3·0) min. Two women in the active ultrasound group had further active ultrasound therapy a few days after the trial regimen had been completed.

Table 2. Post-treatment assessment

	Pulsed electromagnetic energy (n=135)		Ultrasound (n=140)		Placebo (n=139)	
	n	(%)	n	(%)	n	(%)
Mother's assessment						
A little worse or no better	11	(8)	10	(7)	15	(11)
A little better	75	(56)	70	(50)	73	(53)
A lot better	49	(36)	60	(43)	50	(36)
Pain-free	17	(13)	17	(12)	17	(12)
Improvement in linear analogue pain rating (if pain at pretreatment assessment) (mm) mean [SE]	21·6	[1·9]	25·3	[1·8]	21·1	[2·1]
Bruise-free	70	(52)	60	(44)	69	(54)
Mean reduction in bruise size (if bruised at first) (mm) mean [SE]	2·9	[0·9]	0·7	[0·8]	3·2	[0·8]*
Oedema-free	109	(81)	111	(80)	108	(78)
Haemorrhoid-free	107	(79)	114	(82)	108	(78)
Mean change in size (if haemorrhoid at first) (mm) mean [SE]	4·1	[0·7]	4·4	[0·8]	4·0	[0·7]

*P<0·05.

At the post-treatment assessment 91% of the participants felt that treatment had made them better; these rates were similar in the three groups (Table 2). The pattern of perineal pain, oedema and haemorrhoids was also similar, and the greater improvement in the linear analogue pain scale in the ultrasound group was not statistically significant (t=1·56; 0·1<P<0·2). However, the ultrasound group did have more bruising when assessed after treatment and showed significantly smaller reduction in the extent of bruising over the course of treatment compared with the placebo ultrasound group (t=2·21; P<0·05).

Women in the pulsed electromagnetic therapy group were more likely to report perineal pain than women in the other two groups when assessed 10 days after delivery (Table 3) (χ^2=6·14,d.f.2, P<0·05, relative risk compared with placebo group = 1·4 [95% CI 1·0 to 2·1]). At that time the ultrasound group had the lowest prevalence of bruising but this difference was not statistically significant (relative risk compared with placebo group = 0·8, 95% CI 0·4 to 1·5).

Of the women who returned 3-month questionnaires, 57 (15%) still had perineal pain but there were no statistically significant differences between the trial groups (Table 4; relative risk compared with placebo group for pulsed electromagnetic energy group = 1·1 [95% CI 0·6 to 1·9], and for ultrasound = 0·6 [95% CI 0·3 to 1·2]). Similarly, rates of dyspareunia, urinary incontinence (overall prevalence 16%), faecal incontinence (overall prevalence 4%) and women's general feelings of well-being did not differ between the groups.

Discussion

The women who participated in this trial were indeed at high risk of persistent perineal pain as judged by their prevalence rates of pain. Compared with a series of 1000 women who had normal deliveries (Sleep *et al.* 1984) the rates at 10 days and at 3 months after delivery were three times (66% *vs* 23%) and two times (15% *vs* 8%) higher respectively. Randomization generated comparable groups at entry. There was no possibility of concealing from the mothers which type of treatment machine was used although in most cases the research midwife and community midwives were 'blind'. But the precautions taken to 'blind' the active treatments were successful and the strength of a placebo-controlled study is illustrated by the fact that over 90% of women in all groups thought that 'treatment' had done some good. Treatment was given early for the

Table 3. Outcome 10 days after delivery

	Pulsed electromagnetic energy (n=129)		Ultrasound (n=134)		Placebo (n=131)	
	n	(%)	n	(%)	n	(%)
Perineal pain in last 24 h* (reported by mother)						
None	33	(26)	53	(40)	48	(37)
Mild	57	(44)	50	(37)	44	(34)
Moderate	30	(23)	24	(18)	33	(25)
Severe	9	(7)	7	(5)	6	(5)
Use of pain-killers in previous 24 h	31	(24)	30	(22)	25	(19)
Community midwife's assessment						
Perineal wound breaking down	6	(5)	6	(4)	3	(2)
Haemorrhoids	33	(26)	35	(26)	33	(25)
Bruising	22	(17)	14	(10)	18	(14)
Oedema	13	(10)	10	(7)	11	(8)

*$P<0{\cdot}05$.

practical reason that many women leave hospital after 2 days, and also because it was felt that early treatment might prevent problems in the longer term. Women in the pulsed electromagnetic energy group had more pain 10 days after delivery but there were no statistically significant differences between the groups at 3 months postpartum.

Bruising tended to be more extensive immediately following ultrasound therapy (Table 2) but also seemed to disappear more rapidly thereafter (Table 3). This latter finding is consistent with claims made about ultrasound and with the controlled study reported by McLaren (1984). This pattern was not seen in the placebo ultrasound group so is likely to be a consequence of ultrasound treatment rather than perineal massage during therapy. We were surprised by these findings of no clear benefit of active therapy, particularly in respect of ultrasound because this therapy has been shown to be effective for some other soft tissue injuries and because we were impressed by its apparent efficacy before the trial. A possible explanation is that we chose the wrong operating frequencies, intensities or pulse intervals. Nevertheless, the settings used in the trial are in line with current practice as judged by the replies to an informal survey of senior physiotherapists made by one of us (J.M.) before the trial commenced.

Because we wished to assess whether the treatment modalities are useful in this context we did not include a 'no treatment' group. If we had, we might have demonstrated an important

Table 4. Outcome 3 months after delivery

	Pulsed electromagnetic energy (n=124)		Ultrasound (n=126)		Placebo (n=125)	
	n	(%)	n	(%)	n	(%)
Perineal pain (worst pain in last week)						
None	101	(82)	113	(90)	104	(83)
Mild	14	(11)	6	(5)	20	(16)
Moderate	8	(7)	7	(6)	1	(1)
Severe	1	(1)	0	(0)	0	(0)
Resumed sexual intercourse	101	(81)	93	(74)	100	(80)
Pain-free sexual intercourse	41	(33)	33	(26)	37	(30)

placebo effect resulting from extra attention from a physiotherapist in the first 48 h after delivery.

More than 40% of consultant obstetric units now have access to therapeutic ultrasound or pulsed electromagnetic energy treatment or both (Sleep & Grant 1988). In the light of the results presented here, current enthusiasm for the new therapies should be tempered. Further controlled trials are needed; first to replicate our design; second to assess different machine settings and length of treatment; and third to assess the usefulness of ultrasound and pulsed electromagnetic energy in other obstetric settings.

Acknowledgments

We thank the women who took part in the study; Hilary Thompson, Anne Tudor and other colleagues at the Royal Berkshire Hospital and the National Perinatal Epidemiology Unit; Electro-Medical Supplies for loan of the equipment; and David Oliver for his help in conducting the study. Funding for this project came from the locally organized research scheme of the Oxford Regional Health Authority; the National Perinatal Epidemiology Unit is supported by a grant from the DHSS.

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Received 20 May 1988
Accepted 24 November 1988