Ultrasound Therapy for Persistent Post-natal Perineal Pain and Dyspareunia

A randomised placebo-controlled trial

Tina Everett
Jeanne McIntosh
Adrian Grant

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Ultrasound, pain, perineal, dyspareunia, randomised, placebo.

Summary
Persistent post-natal perineal pain is commonly treated with therapeutic ultrasound. To assess its effectiveness, 69 women were recruited to a randomised placebo-controlled trial. 'Treatment' was given three times a week for up to eight sessions. Active ultrasound was transmitted at a frequency of 3 MHz, intensity of 0.5 W/cm^2, with 1:1 pulse interval. The women in the study tended to improve over the course of the study, irrespective of trial allocation. There were no clear differences between the groups when assessed six weeks after recruitment in respect of the principal measures of outcome, which included perineal pain and dyspareunia. Secondary analyses tended to favour the actively treated group but not consistently; this group had less pain during vaginal penetration, and less pain when standing. Because of the sample size, the estimates of effects of active therapy are prone to random errors; further, larger, placebo-controlled trials are required to confirm or refute the suggestions of benefit from this study.

Introduction

Dyspareunia (pain or discomfort associated with sexual intercourse) is a common problem after childbirth, which may persist for months (Sleep *et al*, 1984), and even years (Sleep and Grant, 1987a). It often remains untreated because formal post-natal care has been completed by the time it becomes a 'persistent' problem. When treatment is given it usually consists of reassurance, sometimes combined with symptomatic treatment with a simple vaginal lubricant, or local anaesthetic ointment or cream.

Therapeutic ultrasound is widely used in physiotherapy to treat soft tissue injuries. The mechanisms by which it may improve tissue repair and reduce pain have been reviewed by Dyson (1987). Controlled clinical trials of ultrasound therapy suggest that it is effective for some injuries, such as tennis elbow (Binder *et al*, 1985), pressure sores (McDiarmid *et al*, 1985), and leg ulcers (Dyson *et al*, 1976; Roche and West, 1984; Callam *et al*, 1987), and following oral surgery (El Hag *et al*, 1985). These findings may, however, reflect a 'placebo' effect of therapy (Hashish *et al*, 1986, 1988).

The place of ultrasound therapy in post-natal care remains uncertain. It has been tested in the early puerperium for the prevention of maternal morbidity (including dyspareunia) in three controlled trials. The largest of these (Grant *et al*, 1989) failed to identify any benefit, but the two smaller, incompletely reported studies (McLaren, 1984; Creates, 1987) suggested a reduction in perineal pain following active treatment. One hitherto unreported small trial of ultrasound treatment for persistent dyspareunia failed to identify any benefit (J Sleep and J McIntosh, personal communication).

The aim of this study was to assess more reliably whether ultrasound treatment reduces the severity and duration of persistent perineal pain, dyspareunia, or both.

Methodology

The trial was conducted at Milton Keynes General Hospital and the Royal Berkshire Hospital, Reading. The study design and protocol were approved by the ethics committees of both hospitals.

Women were eligible for trial entry if, following childbirth complicated by episiotomy or vaginal tear, they complained of dyspareunia or vaginal soreness of at least two months duration. Local general practitioners and obstetricians were notified of the study and encouraged to refer such women to the obstetric physiotherapy department.

At the first assessment, potential participants were checked to ensure that:

1. They had not received any gynaecological surgery since the index delivery.
2. There was no vaginal or urinary infection.
3. They were not pregnant.

A full explanation of the study was then given and the women invited to join the trial. A total of 69 women were approached, all of whom agreed to join the study. The physiotherapy secretary recorded the name and address of each participant in a trial register, adjacent to the next available trial number. The correspondingly numbered, sealed envelope was then handed to the woman, and later opened by the physiotherapy researcher. Each ultrasound machine was specially adapted for the study by the hospital electronics department with the permission of the manufacturers. Each machine was fitted with a 12-number dial, and the machines modified so that six randomly chosen numbers gave active treatment, and the other six only allowed placebo treatment. Each envelope contained a random allocation to one of the 12 numbers on the dial. Randomisation was, therefore, organised

within each centre in balanced blocks of 12. There was no other prognostic stratification. The therapist was unable to distinguish active from placebo treatment.

Active ultrasound was transmitted at an operating frequency of 3 MHz, at an intensity of 0.5 W/cm², with 1:1 pulse interval giving an average power of 0.2 W/cm². The diameter of the ultrasound head was 1 cm with a radiating area of the transducer of 0.78 cm².

The treatment regimen was chosen to coincide with the regimens most commonly used for this indication, as judged by informal inquiry of members of the Association of Chartered Physiotherapists in Obstetrics and Gynaecology, and other physiotherapists using therapeutic ultrasound for other scar tissue. All participants were asked to attend three times a week until they had completed eight treatment sessions. The standard length of treatment in each session was five minutes, although this was curtailed if the patient found it uncomfortable. The area treated was about twice the surface area of the transducer's head. During treatment, the ultrasound head was covered with a single layer of 'cling-film' to reduce the risk of infection, and then placed in direct contact with the tender area of the vagina using KY jelly contact medium. Before the study began, a check was made that the cling-film and contact medium did not restrict the output of ultrasound (Dr M Dyson).

Outcome was assessed six weeks after trial entry using a self-administered questionnaire to the women, in the presence of a physiotherapist who was not directly involved in the trial. These instruments have been used in a series of controlled trials over the last few years. They have been shown to be reliable in two senses: they have produced remarkably consistent results when used on comparable groups of women at different times; and they have been able to identify important differences between randomised groups in some of these trials (for example, Sleep *et al*, 1984; Sleep and Grant, 1987a, 1987b; Sleep and Grant, 1988; Mahomed *et al*, 1989; Grant *et al*, 1989). Further physiotherapy, including known active ultrasound, was subsequently given to participants if considered necessary.

The sample size was dictated by the time available for recruitment. A trial with 35 women in each group has about a 50% chance of showing a statistically significant difference ($2\sigma = 0.05$) if the true effect of active ultrasound is a reduction in persistent perineal pain from 80% to 60%. For the purpose of analysis, women were retained in the treatment group to which they had been allocated, regardless of subsequent management. Differences between the groups was compared using the Chi square test for categorical variables and the Student's t-test for continuous variables. Differences in categorical outcome measures have been expressed as odds ratios with 95% confidence intervals. Odds ratios above 1 suggest an improvement with active therapy; a difference is statistically significant if the confidence interval does not include 1 (see Chalmers *et al*, 1989, for fuller details). Changes in a scale were compared using the Chi square test for trend. Secondary stratified analyses were performed to adjust for differences between the groups as randomised in prognostic variables. There were no interim analyses.

Results

A total of 69 women were recruited to the study. Table 1 describes the randomised groups at trial entry. Most women were complaining of dyspareunia, but seven women allocated to active treatment who had not achieved sexual intercourse since their last delivery, presented with perineal pain only. The extent of perineal pain and tenderness was similar in the two groups, however.

Compliance with the allocated regimen was good, and nearly 90% of women received the full course of eight treatments (table 2). Thirty women in the actively treated group and 28 in the placebo group received more than a total of 35 minutes treatment. The use of other forms of treatment, such as lubricant gel, was also similar in the two groups.

Two women were lost to follow-up in each group, leaving 35 women in the active group and 30 in the placebo group.

There was no clear difference between the groups in the principal measures of outcome when the women were questioned six weeks after trial entry (table 3). Women in the active group tended to report less perineal pain but this difference did not reach statistical significance (Chi square for trend = 3.31, $0.05 < P < 0.10$).

Table 4 shows the results of the sub-group analyses, the strata being defined by the problem at the time of trial entry. The number of women in each stratum is small, and again there were no clear differences.

Table 5 describes the changes in symptoms between the time of trial entry and the follow-up assessment. The differences tended to favour the actively treated group, although the only difference that was statistically significant was in discomfort when standing (odds ratio for 'free of discomfort when standing' = 3·7; 95% CI 1.3–10.9).

Discussion

This is the first published report of a placebo-controlled trial of therapeutic ultrasound therapy for persistent post-natal dyspareunia. There was a symptomatic improvement in both groups over the course of the study and this underlines the importance of a properly selected control group if techniques such as ultrasound therapy are to be evaluated reliably.

The groups as randomised were generally similar at trial entry, complaining of similar amounts of pain (table 1). By chance, women allocated to the active group were less likely to have achieved sexual intercourse since their last delivery. Secondary analyses stratifying for this factor did not alter the interpretation of the trial results, however.

Compliance was good, both with active and with placebo therapy (table 2), the treatment schedule matching the regimens mostly commonly used to treat this condition in the United Kingdom.

The main limitation of the study is that the sample size was not as large as expected, despite extending the period of recruitment. The analyses are therefore prone to random errors, and this is reflected in wide confidence

intervals of the differences observed, and some apparently large absolute differences not reaching conventional levels of statistical significance.

Table 1: Description of groups at trial entry

	Active n = 37 (%)	*Placebo n = 32 (%)*
Maternal age — mean [SD]	27.7 [4.6]	26.5 [3.8]
Primiparity	31 (84)	26 (81)
Previous delivery		
spontaneous vaginal	23 (62)	18 (56)
instrumental vaginal	14 (38)	14 (44)
Time (weeks) since delivery		
median	16	22.5
(interquartile range)	(8 – 36)	(11 – 32)
Trauma sustained at last delivery		
none	1 (3)	1 (3)
1° or 2° tear	7 (19)	6 (19)
episiotomy with no extension	22 (59)	13 (41)
episiotomy with extension	6 (16)	9 (28)
3° tear	1 (3)	0 (0)
not known	0 (0)	3 (9)
Presenting complaint		
dyspareunia only	7 (19)	5 (16)
perineal pain only	7 (19)	0 (0)
dyspareunia and pain	21 (57)	24 (75)
dyspareunia and other	2 (5)	3 (9)
Previous ultrasound treatment	20 (54)	10 (31)
Tenderness		
diffuse	5 (14)	5 (16)
discrete, on scar	2 (5)	1 (3)
discrete, not on scar	30 (81)	25 (78)
not known	0 (0)	1 (3)
Perineal pain		
none	5 (14)	3 (9)
mild	14 (38)	13 (41)
moderate	15 (41)	12 (38)
severe	3 (8)	3 (9)
not known	0 (0)	1 (3)
Sexual intercourse		
not achieved since delivery	17 (46)	8 (25)
painful	15 (41)	2 (69)
not painful	5 (14)	2 (6)
Feeling in self		
very happy	19 (51)	14 (44)
quite happy	14 (38)	14 (44)
not very happy	3 (8)	4 (13)
not at all happy	1 (3)	0 (0)

Table 2: Description of management

	Active n = 37 (%)	*Placebo n = 32(%)*
Active treatments		
8	33 (89)	0 (0)
1 – 7	4 (11)	0 (0)
Placebo treatment		
8	0 (0)	28 (88)
1–7	0 (0)	4 (12)
Length of trial treatment		
mean [SD]	36.6 [8.3]	36.5 [9.4]
Use of other 'treatments' between trial entry and assessment of outcome		
lubricant gel	9 (24)	7 (22)
anaesthetic gel	1 (3)	2 (6)
pain killers	2 (5)	2 (6)

Differences in the principal measures of outcome tended to favour the active group but this was not true for all variables (table 3). The numbers in the subgroup analyses

Table 3: Principal outcome measures

	Active n = 35 (%)	*Placebo n = 30 (%)*	*Odds ratio (95% CI)*
Perineal pain in preceding weeks			
none	15 (43)	8 (27)	2.0
mild	14 (40)	11 (37)	(0.7 – 5.3)
moderate	6 (17)	9 (30)	
severe	0 (0)	2 (7)	
Pain during sexual intercourse			
pain-free	12 (34)	6 (20)	2.0
mild	10 (29)	11 (37)	(0.7 – 5.9)
moderate	6 (17)	12 (40)	
severe	1 (3)	0 (0)	
intercourse attempted but not achieved	4 (11)	0 (0)	
intercourse not attempted	2 (6)	1 (3)	
Pain-free penetration	12 (34)	7 (23)	1.7 (0.6 – 4.9)
Pain-free after sexual intercourse	18 (51)	19 (63)	0.6 (0.2 – 1.6)
Pain-free next day	25 (71)	26 (87)	0.4 (0.1 – 1.3)
No bleeding after intercourse	30 (86)	28 (93)	0.5 (0.1 – 2.2)
No soreness wearing jeans	22 (63)	24 (80)	0.4 (0.1 – 1.3)
No soreness when standing	29 (83)	24 (80)	1.2 (0.3 – 4.2)
Use of tampons	17/30 (57)	15/24 (63)	0.8 (0.3 – 2.3)
Feeling quite or very happy	33 (94)	29 (97)	0.6 (0.1 – 5.9)

Table 4: Outcome in sub-groups identified at trial entry

	Active	*Placebo*	*Odds ratio (95% CI)*
Women with pain during intercourse	n = 15	n = 20	
number (%) with less pain	10 (67)	16 (80)	0.5 (0.1 – 2.3)
mean [SE] change in linear analogue scale	33.6 [6.8]	33.7 [4.8]	
Women with pain after sexual intercourse	n = 11	n = 20	
number (%) with less pain	9 (82)	14 (70)	1.8 (0.3 – 9.5)
mean [SE] change in linear analogue scale	32.2 [6.2]	17.5 [5.5]	
Women with pain day after sexual intercourse	n = 4	n = 8	
number (%) with less pain	3 (75)	6 (75)	1.0 (0.1 – 14.2)
Women who had not achieved sexual intercourse	n = 17	n = 8	
number (%) achieving intercourse	10 (59)	8 (100)	0.2 (0.0 – 1.0)
not known	1 (6)	0 (0)	

are even smaller than in the main tables so these analyses may be particularly distorted by the play of chance.

Table 5: Changes in status since trial entry

Total women with known outcome	*Active n = 35(%)*	*Placebo n = 30(%)*	*Odds ratio (95% C)*
Perineal pain			
less pain	20 (57)	13 (43)	1.7 (0.6 – 4.5)
unchanged	12 (34)	9 (30)	
more pain	3 (9)	8 (27)	
Vaginal penetration			
less pain	16 (46)	10 (33)	3.5* (1.2 – 10.3)
unchanged	7 (20)	11 (37)	
more pain	1 (3)	8 (27)	
intercourse attempted for first time since delivery	9 (26)	1 (3)	
intercourse not attempted since delivery	2 (6)	0 (0)	
Sexual intercourse			
less pain	10 (29)	16 (53)	0.4 (0.1 – 1.5)
unchanged	7 (20)	4 (13)	
more pain	2 (6)	2 (7)	
intercourse achieved for first time since delivery	10 (29)	8 (27)	
intercourse attempted for first time since delivery	4 (11)	0 (0)	
intercourse not attempted since delivery	2 (6)	0 (0)	
Discomfort when standing			
less discomfort	14 (40)	4 (13)	3.7* (1.3 – 10.9)
unchanged	21 (60)	24 (80)	
more discomfort	0 (0)	2 (7)	
Discomfort when walking			
less discomfort	11 (31)	5 (17)	2.2 (0.7 – 6.7)
unchanged	24 (69)	23 (77)	
more discomfort	0 (0)	2 (7)	
Discomfort wearing jeans			
less discomfort	12 (34)	5 (17)	2.3 (0.7 – 7.4)
unchanged	16 (46)	15 (50)	
more discomfort	3 (9)	4 (13)	
not known	0 (0)	2 (7)	
not applicable (does not wear jeans)	4 (11)	4 (13)	

Women who had achieved sexual intercourse between delivery and trial entry	*n = 20 (%)*	*n = 24 (%)*	
Pain after sexual intercourse			
less pain	9 (45)	14 (58)	0.6 (0.2 – 2.0)
some pain	8 (40)	7 (29)	
more pain	1 (5)	1 (4)	
not known	2 (10)	2 (8)	
Pain next day			
no pain any longer	3 (15)	6 (25)	0.6 (0.1 – 2.5)
unchanged	15 (75)	17 (71)	
pain started since entry	1 (5)	1 (4)	
not known	1 (5)	0 (0)	
Bleeding after intercourse			
no bleeding any more	4 (20)	5 (21)	1.0 (0.2 – 4.4)
unchanged	13 (65)	19 (79)	
bleeding started since entry	2 (10)	0 (0)	
not known	1 (5)	0 (0)	

*P < 0.05

Symptomatic changes over the course of the study did not consistently favour one group or the other, although the active group did have a significantly greater improvement in pain during penetration, and discomfort when standing (table 5).

This study did not include a group that was openly given no ultrasound therapy. It is therefore impossible to measure whether the improvement seen in the placebo group simply reflected the natural history of the condition, or was a placebo effect (as suggested by the work of Hashish and colleagues, 1986, 1988), or was a combination of the two.

Conclusion

It is not certain on the basis of the results of this trial that active ultrasound therapy for persistent post-partum perineal pain and dyspareunia is more effective than placebo. Women in both groups tended to improve over the course of the study. Further larger trials are now needed to clarify whether active therapy conveys any extra benefit.

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Authors

Tina Everett MCSP was a senior obstetric physiotherapist, Milton Keynes General Hospital.

Jeanne McIntosh MCSP is a senior obstetric physiotherapist, Royal Berkshire Hospital, Reading.

Adrian Grant DM FRCOG is director of the Perinatal Trials Service, National Perinatal Epidemiology Unit, Radcliffe Infirmary, Oxford.

Address for Correspondence

Mrs T Everett MCSP, Senior Physiotherapist in Mental Health, Campbell Centre, Milton Keynes General Hospital, Standing Way, Milton Keynes MK6 5LD.

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