Ultrasound treatment for breast engorgement: A randomised double blind trial

Zoe McLachlan
E. June Milne
Judith Lumley
Barbara L. Walker

The aim of this study was to test the efficacy of thermal ultrasound therapy as a treatment for severe post partum breast engorgement. A randomised double-blind, placebo-controlled trial was conducted on 197 breasts. Two ultrasound machines of identical appearance were used. One was working normally, the other had the crystal replaced with a resistor producing surface heat only. Assessment of effectiveness was subjective, using visual analogue scales for pain and hardness, and objective, using tonometry. Results indicate that both the true and sham machines were effective in reducing subjectively perceived pain and hardness. However, the results of this study show that the effect cannot be attributed to the ultrasound component.

[McLachlan Z, Milne EJ, Lumley J, Walker BL: Ultrasound treatment for breast engorgement: A randomised double blind trial. *Australian Journal of Physiotherapy* 37: 23-29, 1991]

Key words: Post natal care; Breast; Breast feeding; Randomised control trials; Diathermy, Ultrasonic therapy.

Z McLachlan, Dip Phty, formerly, Senior Physiotherapist — Obstetrics and Gynaecology, Monash Medical Centre, 246 Clayton Rd, Clayton, Victoria, 3168.

EJ Milne, Dip. Physio, formerly, Physiotherapist, Obstetrics and Gynaecology, Monash Medical Centre.

J Lumley, MBBS, PhD, Senior Lecturer, Department of Paediatrics, Monash Medical Centre.

BL Walker, B.App.Sc.(Phty), Chief Physiotherapist, Monash Medical Centre

Correspondence: Mrs Walker

Post partum breast engorgement is a common problem. In most cases, the pain is mild and the condition is short lived, resolving rapidly as demand feeding is established. Sometimes the condition becomes severe and painful with blocked milk ducts, feeding difficulties and a depressed milk ejection reflex.

In 1981, anecdotal reporting suggested that treatment with ultrasound was beneficial in severe breast engorgement (Shellshear 1981). Following a second report (Semmler 1982), the treatment was implemented at the Queen Victoria Medical Centre (now the Monash Medical Centre) in 1982. Women receiving the treatment, physiotherapists, midwives and obstetricians all found it to be clinically successful (Milne 1983). However, no clinical trials to evaluate its effectiveness had been attempted.

Increasing discussion about the widespread use of poorly evaluated therapies led to the decision in 1985 to make this treatment available only within a randomised trial. It was clear that the non-ultrasound components of the treatment (warmth, rest, massage, attention, emotional, practical and informational support) might be making a substantial contribution to its perceived effectiveness. The trial was therefore designed to compare two apparently identical treatments, only one of which involved ultrasonic energy.

Method

Equipment

Two new ultrasound machines of identical appearance were used - Medtron model P300 (Metronex Engineering — Bell and Associates). The control machine had the crystal removed and replaced with a resistor to produce surface heat only, with the working dial responding to the intensity control. As the intensity control was turned up, the working dial showed a corresponding increase in thermal output.

The trial machine was calibrated at six-monthly intervals by the manufacturer using appropriate calibration standards and a new crystal was used after 12 months. The serial numbers of the machines were covered and the machines were labelled A and B. Labels were changed weekly by the head of the department who had no role in the ultrasound treatment and did not hold the trial log book. She was provided with a predetermined randomised schedule for the labels.

A digital tonometer was designed specifically for the project in order to have an objective measure of breast hardness. This was a spring-loaded, rounded probe of 8mm diameter, protruding 1cm from a flat plate. When applied to the breast, the movement of the probe against the spring was proportional to the hardness

➥

Table 1.
Comparability of the three treatment groups

			Breast treatment		
			Ultrasound [2]	Ultrasound [1] Sham [1]	Sham [2]
	n	%			
Trial participants	109	[100]	22	64	23
Primiparous	51	[46.8]	8	32	11
Maternal age:					
<19	4	[3.7]	0	4	0
20-29	35	[32.1]	6	16	13
30-39	65	[59.6]	16	41	8
40+	5	[4.6]	0	3	2
Multiple gestation	5	[4.6]	1	3	1
Pre-term delivery:					
<37 weeks	32	[29.4]	4	21	7
Patient category:					
Public	34	[31.2]	4	19	11
Private	75	[68.8]	18	45	12
Drugs:					
Analgesics	73	[67.0]	14	44	15
Antibiotics	8	[7.3]	3	4	1
Syntocinon	11	[10.1]	0	10	1

From Page 23

of the breast. The movement of the probe was linked mechanically to a linear resistor and the resistance measured by a digital multimeter. The linearity and long-term stability were checked monthly to ensure a constant response. The probe was calibrated by applying it to an artificial breast comprised of a plastic fluid-filled chamber in which the pressure was altered in steps to simulate the range of hardness of the breast.

Entry and exclusion criteria

The entry criterion for the trial was referral to the physiotherapists for treatment of breast engorgement. Some women had additional breast problems (e.g. sore nipples) and a few were, in fact, referred post partum with breast lumps. Women were excluded if their spoken or written English was insufficient for informed consent or if they had previously received breast (silicone) implants. Most referrals came from the lactation consultant, but the charge nurse of the post partum ward and the obstetricians could also refer women.

On referral, the physiotherapist discussed the trial with each woman and provided a plain language information sheet before seeking written consent. After this, the woman's name was given to the clerical officer who held the trial log book. She informed the treating physiotherapist which machine (A or B) would be used for each breast according to a balanced block randomisation sequence which had been prepared in advance.

Since each woman might have problems with one or two breasts, each individual breast, rather than each individual woman, was randomised to treatment A or treatment B. Treatment of an individual breast was always by the same machine.

Procedure

Treatment was timed to take place an hour before breast feeding or expression, but demand feeding often made this interval difficult to judge. Before treatment, the physiotherapist recorded data on the birth and feeding history and the woman filled in the horizontal visual analogue scales (Scott and Huskisson 1976). These were straight lines 100mm long with no gradations marked. For the pain scale the left end was marked "no pain" and the right end "pain as bad as it could be". For the hardness scale the left end was labelled "soft" and the right end "as hard as it could be".

Separate scales were completed for each breast and it was emphasised that there were no right or wrong measures. Then, with the woman in a comfortable supine position, a pillow under her head and hands behind her head, a black dot was marked on each quadrant of the breast, and four tonometer readings taken around each dot.

Treatment by the physiotherapist with thermal (continuous) ultrasound was given using aquasonic ultrasound transmission gel as the coupling agent. As in all therapeutic ultrasound treatments, the intensity was adjusted to give a comfortable warmth and the treatment application head was massaged over the breast towards the areola. Firmer pressure was used on the inwards stroke. The duration of treatment ranged from eight minutes for a breast of A cup size to 15 minutes for a breast of DD or greater cup size.

Following treatment, visual analogue scales for pain and hardness were again completed for each breast. The women could see their previous ratings while they did this. The tonometer readings were repeated and the women encouraged to feed their infants (or express milk) as soon as possible.

Women were reassessed each morning and treated again if necessary. Repeat treatments were included in the data collection. Indications for further treatment were poor milk flow, persistent areas of redness or persistent

pain and hardness of the breast.

Occasionally, women were treated twice in one day if their symptoms were severe. The number of treatments given ranged from one to six and a final set of measures (both analogue scales and tonometry) was taken approximately 24 hours after the final treatment.

An obstetric registrar collected additional medical data including a family history of breast cancer, during the treatment course.

Design and analysis

The trial was designed to detect a reduction of 25 per cent in ratings of pain and hardness with ultrasound or a 25 per cent difference in ratings between ultrasound and sham treated breasts ($\alpha = 0.05$, $\beta = 0.20$).

The treatment given to each breast (ultrasound or sham) was decoded from the trial log book and machine allocation schedules after completion of the trial. Data were analysed using a statistical software package (EPILOG). Means and differences were compared using paired or unpaired t-tests as appropriate. Proportions were compared using the Chi-square test. Duration of breastfeeding was assessed in a survival analysis using log-rank statistics. Comparisons involved paired and unpaired t-tests. Chi-square tests and life-table analyses were conducted with log-ranked statistics.

Results

During the 30 months of recruitment, 111 women were referred for treatment of breast engorgement, this being less than 2 per cent of all those giving birth in the hospital. Two refused to participate in the trial. The mean interval between birth and the first treatment was 82 hours.

Since each breast, rather than each woman, was a trial "subject", there were three groups. The first was women in whom both breasts received treatment with ultrasound (22). The second was women in whom both breasts received the sham treatment (23). In the third group, 64 women were combined, in whom one breast received ultrasound and one received sham treatment (43) or women in whom only one breast was treated either with sham or with ultrasound (21). Table 1 summarises sociodemographic, obstetric and paediatric data on the participants and shows that the randomisation procedures produced three comparable groups prior to treatment.

The age range of women in the trial was 16 to 42 years with an average age of 30.4 years. Fewer than half were primiparous. The proportion of women with a pre-term infant was twice that in the hospital population and 36 per cent of participants were separated from their infants because of admission to the special care nursery. The hospital has a rooming-in policy with no routine special care admissions after caesarean or forceps delivery. Fifty per cent of the women had breast fed or expressed within three hours of delivery and 85 per cent had done so by 24 hours. The longest interval was 69 hours.

In Table 2, current breast problems, past breast problems, breastfeeding history and family history are listed to show that the three groups were comparable in these respects also. A high proportion of the women who had given birth before had suffered from engorgement previously (70 per cent), 16 per cent with episodes of mastitis and 29 per cent with lumps. Table 1 and Table 2 show that women referred for treatment were a small proportion of mothers, in whom breastfeeding problems were more likely either because of pre-term birth or problems in an earlier pregnancy. The prior breastfeeding history suggested that participating women had a strong intention to breastfeed, since the average duration of the previous lactation was 21 weeks.

In terms of the primary endpoints of the trial, the comparison was between ultrasound and sham treated breasts. Prior to treatment, the measures of pain and hardness in breasts allocated to ultrasound were not significantly different to the measures in breasts allocated to sham treatment (Table 3). This was further evidence that the randomised allocation to treatment arms had resulted in two comparable groups.

The effect of treatment is summarised in Table 4. Both ultrasound and sham treatments reduced pain and hardness significantly, using the analogue scales as a measure and comparing the paired pre-treatment and post-treatment ratings for each breast.

These findings confirmed the pre-trial experience of a subjective benefit with treatment and showed, in addition, that the improvement occurred with and without the ultrasound component.

By contrast, the effects of treatment on hardness as measured by tonometry were small and inconsistent (Table 4). At the first treatment, ultrasound had a statistically significant effect while sham treatment had no detectable effect. At two other treatments, only the sham treatment had a significant effect. In all cases, the effect was very small.

Women received from one to six treatments. Table 5 shows the distribution of these according to the mode of treatment, ultrasound or sham. There was no significant difference in the number of treatments or the dosage reading. The final measures of pain and hardness, once treatment had been concluded, were virtually identical in the two treatment groups.

The final outcome, which was the duration of breastfeeding, was compared among the three groups described earlier — those in whom both breasts received ultrasound, those in whom both breasts received sham treatment and those in whom the breasts received different treatments.

Three women were lost to follow-up and another whose baby had died was not contacted. The median duration of breastfeeding among the remaining women was 18 weeks. The duration of breastfeeding had a bimodal distribution. No differences could be detected between the three groups defined above on survival analysis

Table 2.
Breast problems and prior breastfeeding in the three treatment groups

	n	%	Ultrasound [2]	Ultrasound [1] Sham [1]	Sham [2]
Current problem(s):					
Engorgement	93	[85.3]	18	55	20
Lumps	34	[31.2]	7	22	5
Sore nipples	21	[19.3]	7	12	2
Prior breast problems:					
Surgery	1	[0.9]	0	0	1
Fibrocystic disease	6	[5.5]	1	5	0
Duration of breastfeeding					
Last birth (weeks]:					
< 13	21	[19.3]	7	10	4
14-26	12	[11.0]	3	7	2
> 26	25	[22.9]	4	15	6
Reason for weaning, after last birth:					
Breast pain	3	[5.2]	1	1	1
Nipple pain	2	[3.4]	0	2	0
Reduced supply	12	[20.7]	4	4	4
Illness (mother)	1	[1.7]	1	0	0
(infant)	1	[1.7]	0	1	0
Return to work	4	6.9]	2	2	0
Choice (mother)	5	8.6]	1	3	1
(infant)	27	[46.6]	4	17	6
Total	58	[100]			
Family history of breast cancer:	10	[9.2]			
Mother	5	[4.6]	2	3	0
Grandmother	3	[2.8]	1	1	1
Maternal aunt	2	[1.8]	0	2	0

From Page 25

taking into account weaning status at final follow up (Chi-square test for homogeneity = 0.09, $p = 0.95$; test for trend 0.002, $p = 0.97$, log rank method).

Discussion

As the two main endpoints in this trial were pain and hardness of the breasts, assessed either as subjective ratings or as measurements by the treating physiotherapist, it seemed essential to mask the treatment mode from both patient and therapist. Before the trial began, the physiotherapists expected that it would be relatively easy to deduce which was the real and which the sham treatment, by their differential effectiveness, but this was not so. Changing labels on the two machines weekly was intended to reduce the possibility that the therapists would be able to identify which machine emitted ultrasound energy.

The women who participated in the trial were at high risk of developing problems with lactation. One factor was a past history of breast engorgement. Other factors included a pre-term birth or a sick infant admitted to the special care nursery. In these cases, there was often a delay between delivery and the first feed with the necessity of expressing milk for the first few days.

There was no evidence that operative delivery increased the probability of breast engorgement, since the operative delivery rates in the trial participants were the same as in the whole hospital population.

The trial confirmed that severe breast engorgement is largely, but not wholly, preventable in a high risk perinatal centre. The incidence fell during the 30 months of recruitment.

The decision to regard each breast as an entry into the trial was made early in the planning phase as a way of dealing with the fact that some women needed treatment for one breast only.

This meant that, in a significant proportion of women, ultrasound and sham treated breasts were closely matched on virtually all factors and it probably accounted for the degree of similarity on pre-treatment measures.

Such close matching should have provided an ideal setting for detecting a real effect of ultrasound treatment. However, the therapists observed that when the analogue scales were being completed after treatment, it was not always easy for the women to make a clear distinction between left and right breast sensations.

Our theoretical understanding of ultrasound effects and of the physiology of the breast initially led to the prediction that the benefits would be most apparent after breastfeeding which followed soon after an ultrasound treatment. It was thought that treatment would facilitate the removal of milk from the engorged

breast by facilitating milk let-down, leading to less pain and hardness. Thus, the expected effects were of faster resolution (fewer treatments) and lower ratings of pain and hardness in the ultrasound treated breasts from the second treatment onwards. Neither of these was found.

The trial demonstrated that pre-trial perceptions of the effectiveness of treatment were correct, but it was also able to show that effective treatment did not depend on the ultrasound component. Further evidence for this placebo effect came from the difference between subjective ratings of hardness and tonometric readings. The subjective ratings improved 15 to 30 per cent with treatment, while the average quadrant tonometer readings scarcely altered at all.

The components which might have contributed to a therapeutic effect were listed in the introduction as warmth, rest, massage, attention and the emotional, practical, and informational support provided by the physiotherapists in the course of treatment.

To these should perhaps be added the perceived benefit of being the recipient of modern technology.

These findings are very similar to those reported from a recent placebo-controlled trial of ultrasound and pulsed electromagnetic energy treatment for perineal trauma (Grant et al 1989). In that trial, 90 per cent of women in all groups thought the treatment had done some good, but there were no significant differences between the ultrasound, the pulsed electromagnetic energy and the placebo groups.

The two trials support the strength of the placebo theory of the perceived effects of treatment by machine.

Although it is possible that lower or higher dosages of ultrasound, different durations of treatment or the use of pulsed instead of continuous wave might have a therapeutic effect beyond the placebo effects detected in this trial, the treatment details selected were those which, having been in use

Table 3.
Pre-treatment measures of pain and hardness in ultrasound and sham treated breasts.

	Pre-treatment scores				
	1st (SEM)	2nd (SEM)	3rd (SEM)	4th (SEM)	5th (SEM)
1. Pain (analog scale)					
Ultrasound	36.8 (2.4)	32.0 (2.8)	23.1 (2.5)	18.7 (3.4)	13.8 (3.2)
Sham	41.6 (2.6)	30.6 (2.7)	23.8 (3.1)	18.2 (3.5)	20.5 (4.3)
2. Hardness (analog scale)					
Ultrasound	72.1 (2.0)	55.6 (2.5)	42.3 (3.1)	32.5 (4.2)	26.1 (5.6)
Sham	74.0 (2.3)	54.4 (3.1)	48.4 (3.9)	35.6 (4.7)	34.7 (7.4)
3. Hardness (tonometry*)					
Ultrasound	31.0 (1.4)	28.8 (1.6)	29.1 (1.7)	28.2 (2.2)	24.1 (3.0)
Sham	29.7 (1.4)	28.5 (1.7)	28.4 (1.8)	27.6 (2.4)	25.1 (2.9)

Mean score *mean of the four quadrant scores

SEM standard error of the mean

No differences between ultrasound and sham-treated breasts were statistically significant.

Table 4.
The effect of treatment on measures of pain and hardness in ultrasound and sham-treated breasts.

	Treatment number				
	1st d (SEM)	2nd d (SEM)	3rd d (SEM)	4th d (SEM)	5th d (SEM)
1. Pain (analog scale)					
Ultrasound	4.4 (1.7)[2]	5.1 (1.4)	4.5 (1.3)	3.2 (1.9)[3]	3.4 (1.8)[3]
Sham	8.4 (1.8)[1]	8.6 (1.7)[1]	2.8 (1.4)[3]	2.7 (1.7)[3]	6.8 (3.2)[3]
2. Hardness (analog scale)					
Ultrasound	10.4 (1.9)[1]	6.6 (1.5)[1]	6.8 (1.4)[1]	4.5 (2.0)[3]	3.9 (1.6)[3]
Sham	11.8 (2.2)[1]	8.8 (1.7)[1]	8.2 (1.4)[1]	6.1 (2.1)[2]	8.5 (4.7)[3]
3. Hardness (tonometry)					
Ultrasound	1.27 (0.41)	10.25 (0.57)	0.70 (1.01)	0.58 (0.85)	-0.93 (1.44)
Sham	0.46 (0.70)	1.40 (0.47)[2]	1.21 (0.60)	1.21 (0.60)	2.05 (1.64)

d mean of the paired differences, pre-post treatment

SEM standard error of mean

[1] $z > 3.10$ $p<0.001$
[2] $z > 2.57$ $p<0.005$
[3] $z > 1.65$ $p<0.05$

From Page 27

in the hospital and elsewhere for the two years prior to the trial, had been found to be clinically effective.

The trial could not detect an objective beneficial effect of ultrasound on breast engorgement. It is obvious that more controlled trials are needed to test modifications of dosage, e.g. pulsed ultrasound and its effect on other physiological conditions of the breast, e.g. unresolved lumps and mastitis. Given the evidence in this trial and in the trial reported by Grant et al (1989) dealing with perineal trauma, it is essential for future trials to be double blind and placebo controlled.

Acknowledgements

We are grateful to the participating women, medical staff, nursing staff and physiotherapy colleagues for their support and collaboration particularly the lactation consultant, Ms Pat Thrussell. We are indebted to Miss Rosemary Cox for her contribution to the management of the trial.

We also thank Mr V Brodecky for the design and calibration of the tonometer and Metronex Engineering Pty Ltd for the donation, modification and calibration of the two machines.

Financial support from the Queen Victoria Medical Centre's Research Committee and the Obstetrics and Gynaecology Special Interest Group (Victoria) of the APA is gratefully acknowledged.

Table 5.
A comparison of ultrasound treated and sham-treated breasts.

			Ultrasound	Sham
	n		*n*	*n*
Left breast	94		53	41
Right breast	103		57	46
Number of treatments:		1	7	6
		2	25	23
X2 = 1 .26 p>0.9		3	36	23
		4	22	20
		5	18	13
		6	2	2
Dosage Watts/cm2			2.4-2.6	2.4-2.6
Final measures			$\bar{X}$ (SEM)	$\bar{X}$ (SEM)
Pain (analog scale)			13.0 (2.5)	13.0 (2.3)
Hardness (analog scale)			22.3 (2.3)	23.7 (2.7)
Hardness (tonometry)			21.4 (1.3)	19.7 (1.6)

$\bar{X}$ mean

SEM standard error of mean.

References

Grant A, Sleep J, McIntosh J and Ashurst H (1989): Ultrasound pulsed electromagnetic energy treatment for perineal trauma: A randomised placebo-controlled trial. *British Journal of Obstetrics and Gynaecology* 96: 434-439.

Milne EJ (1983): Letter. *Australian Physiotherapy Association National Obstetric and Gynaecology Journal* 2: 3-4.

Scott J and Huskisson EC (1976): Graphic representation of pain. *Pain* 2: 175.

Semmler D (1982): The use of ultrasound therapy in the treatment of breast engorgement. *Australian Physiotherapy Association National Obstetric and Gynaecology Journal* 2: 18.

Shellshear M (1981): Therapeutic ultrasound in postpartum breast engorgement. *Australian Journal of Physiotherapy* 27: 15-16.