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Single-blind trial addressing the differential effects of two reflexology techniques versus rest, on ankle and foot oedema in late pregnancy

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Summary This single-blind randomised controlled trial explored the differential effects of two different foot reflexology techniques with a period of rest on oedema-relieving effects and symptom relief in healthy pregnant women with foot oedema. Fifty-five women in the third trimester were randomly assigned to one of the three groups: a period of rest, 'relaxing' reflexology techniques or a specific 'lymphatic' reflexology technique for 15 min with pre- and post-therapy ankle and foot circumference measurements and participant questionnaire.

There was no statistically significant difference in the circumference measurements between the three groups; however, the lymphatic technique reflexology group mean circumference measurements were all decreased. A significant reduction in the women's symptom mean measurements in all groups ($p<0.0001$) was apparent. A 'perceived wellbeing' score revealed the lymphatic technique group ($p<0.0001$) significantly increased their wellbeing the most, followed closely by relaxing techniques ($p<0.001$) and then the control rest group ($p<0.03$).

Lymphatic reflexology techniques, relaxing reflexology techniques and a period of rest had a non-significant oedema-relieving effect. From the women's viewpoint, lymphatic reflexology was the preferred therapy with significant increase in symptom relief.

Introduction

Oedema is a common and normal physiological symptom in late pregnancy.[1–3] Leg and foot oedema occurs as a result of the weight of gravid uterus which impedes venous return; prostaglandin-induced vascular relaxation; and reduced plasma colloid osmotic pressure.[2,3] Although oedema alone is not dangerous, it can result in discomfort, feelings of heaviness, night cramps and painful paraesthesia.[4]

Past strategies used to control physiological oedema consisted of support stockings, bed rest and diuretics. Diuretics are no longer advocated for pregnancy oedema as any treatment in pregnancy should aim to remove extravascular fluid without disturbing the intravascular components, and diuretics fails to meet this criterion.[5] Studies have examined the oedema relieving effectiveness of a variety of treatments such as pneumatic compression boots,[6] water immersion and bedrest.[7–9] The studies have neglected to investigate the women's viewpoint regarding any perceived benefits, the feasibility of wearing pneumatic boots or sitting in the bath to sustain the effects.

Young and Jewell's[4] systematic review recommended that further research into symptom relief and women's view of their treatment could be

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considered the most relevant outcome. Any strategy or therapy initiated for relieving oedema in pregnancy is only a short-term strategy as the hormones of pregnancy will continue their effects of fluid retention on the body until the birth of the baby. Therefore an effective therapy would provide symptom relief primarily and short-term oedema relieving effects.

From a nursing and midwifery point of view, a therapy or treatment for the relief of common discomforts of pregnancy such as oedema should avoid drugs that may be a risk to the unborn baby, be women friendly and fit within a holistic model of care.[10–12] Consequently, many midwives and women are looking to complementary therapies such as reflexology.[13,14]

Reflexology is described as a natural ancient therapy with the concept that all body organs and glands have corresponding reflex points in the feet, hands and ears.[13,15] The reflexologist uses a specific thumb and finger pressure technique to elicit areas of potential or actual disorder but does not diagnose, prescribe or promise a cure.[12,15–17] Lymphatic reflexology technique can be used for specific conditions such as leg, foot and generalise oedema as it moves extravascular fluid without disturbing intravascular fluid.[12,17] The technique mimics the lymphatic drainage action of the body, i.e. interstitial fluid moves from the lymphatic capillaries to the lymphatic veins, trunks and returns into the circulatory system at the subclavian vein.[17]

An extensive literature search revealed only one published study investigating reflexology and discomforts of pregnancy. Green[18] pilot study of 14 women found a non-significant drop in blood pressure with participants experiencing hypertension in pregnancy receiving reflexology. Participants receiving reflexology had limited improvement with foot oedema.

Reflexology has the potential to provide pain relief[19] and symptom relief,[20] induce relaxation,[21] and reduce blood pressure without harmful side effects.[16,22] In general, studies conducted with reflexology and a variety of health conditions have found that the therapy can be as effective as a recognised conventional treatment for a particular condition and 'does no harm'.[20,23–26]

The study

Methods and analysis

After receiving Area Health Ethic Committee approval, the single-blind randomised controlled trial took place in the antenatal and midwife clinics of Gosford and Wyong Hospitals, Australia. During a 2-year period between September 1999 and August 2001, women were invited to participate by the midwives during routine antenatal visits.

The criteria for admission to the trial included, (a) normal pregnancy greater than 30 weeks gestation (b) visible oedema of ankles and feet (c) able to speak, read and write English, and (e) attending the CCH clinics for pregnancy care. The rationale for the gestational criteria as oedema usually occurs in the last 10 weeks of pregnancy.[1,2] Only English speaking women were invited to participant as the region has a low level of non-English speaking population[27] and there were no budget for language-specific information sheets or consent forms.

It was estimated that the proportion of women experiencing moderate to severe foot and ankle oedema was likely to be approximately 50% of women giving birth at CCH (2800 per year) as revealed by current literature. To achieve 90% power, 40 women were required in each of the three groups. The overall minimum sample size was pre-set at 120 participants. However, it was identified that only half or approximately 1400 women attend the various hospital clinics for pregnancy care. As 50% of women attend visits with their general practitioner, this pool of women would not be recruited into the trial. Therefore, the overall minimum sample size was re-set to 60 participants.

After obtaining written consent, participants were randomly allocated into one of three groups for up to four therapy sessions. A single-blind design was chosen as it is necessary for the reflexologist to know whether they are giving true or placebo therapy.[16] The experimental therapy 1 group received relaxing foot reflexology techniques to the reflex zones of chest, abdomen, spine, pelvis and head. The experimental therapy 2 group received a lymphatic foot reflexology technique—reflex zones to the lymphatic system, liver, gastrointestinal tract and kidneys.[13,17] The control group participants rested on the examination couch for an equal time frame but received no reflexology.

At each session of approximately 15 min duration, participants were nursed in a semi-recumbent position, and circumference measurements of ankles, insteps and foot/toe junctions were recorded on plain paper tapes. The ankle circumference was measured medially and laterally above the malleoli, where the diameter was smallest. The instep circumference was measured over the cuneiform and cuboid bones distal to the heel,

and the third circumference was measured on the distal end of the foot, at the metatarsal–phalanges joint (where toe joins the foot) as shown in Fig. 1. Pre- and post-therapy blood pressure readings were collected. As there was no funding for extra staff, the interventions were restricted to 15 min to allow incorporation with a routine antenatal visit.

The participant self-administered questionnaire contained Likert type and open-ended questions regarding participant's demographic information; existing knowledge of reflexology; pre- and post-therapy levels of stress, tension, anxiety and discomfort; changes in feet after the session; and any perceived benefit of the therapy.

Grapeseed oil was used during the lymphatic technique reflexology to prevent friction and possible increased discomfort.[17] Grapeseed oil was chosen as it has been used in a number of studies because it is absorbed well into the skin, non-sticky, odourless and able to be used by those who suffer from nut allergies.[28]

The quantitative data was analysed using Student's *t*-test to identify differences in blood pressure, foot measurement and perceived symptoms before and after the intervention for the sample as a whole. Student's *t*-test were also used to identify differences within the three treatment groups before and after the intervention. Between group differences were analysed using one-way analysis of variance. Where Bartlett's test for homogeneity of variance showed unequal variances, Kruskal–Wallis one way analysis of variance was used.

Content analysis was utilised for the answers to the four open-ended questions in the participant's questionnaire. The responses were collated and examined for themes. From the responses, five broad themes were identified: swelling/tightness, pain, mobility, comfort/relaxation, and care.

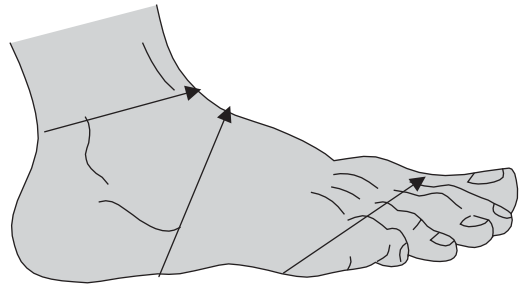

Fig. 1 Ankle and foot circumference measurement.

Results

Ninety six (96) women were invited to participate in the study. Of these, 27 women were not randomised as the women wanted to receive reflexology but did not want to be randomised and this data has not been included. Of the 69 women randomised into the trial, seven women withdrew from the study after being randomised, with three women giving the reason that 'rest doesn't work'. One woman from the rest group gave birth before the first session and six participant's data was incomplete.

Fifty-five (55) women finished session one with complete data, 39 completed session two and 20 participants completing session three. As a result of the dwindling sample size only session one has been analysed and presented. The sustainability of the therapies over a number of sessions cannot be examined as women gave birth after one or two sessions and women withdrew from rest group (verbal feedback to midwives) as they did not perceive any benefit.

The experimental therapy 1 group (relaxing reflexology techniques) consisted of 20 participants; the experimental therapy 2 group (lymphatic reflexology technique) consisted of 25, whilst the control rest group consisted of 10 participants. Descriptive statistics for the three groups' means, standard deviations and ranges are expressed in Table 1.

A number of participants in the rest and relaxing reflexology groups displayed increases in some ankle and foot circumference measurements, however in the lymphatic reflexology technique

Table 1 Demographic characteristics by group

	Rest ($n=10$)			Relaxing reflexology ($n=20$)			Lymphatic reflexology ($n=25$)		
	X	Range	SD	*X*	Range	SD	*X*	Range	SD
Age (years)	29	21–46	8.06	27	18–36	5.66	28.6	22–40	5.15
Gravidity	2.1	1–6	1.52	1.9	1–4	1.02	2	1–6	1.58
Gestation	35.9	33–37	1.28	35.9	32–38	1.79	36.2	30–39	2.06

Table 2 Differences in mean foot measurements across the three groups

Mean measurement changes	Rest ($n=10$)	Relaxing reflexology ($n=20$)	Lymphatic reflexology ($n=25$)	p value
Right ankle	−0.12	0.03	−0.06	0.53
Left ankle	−0.13	0.01	−0.104	0.54
Right instep	0.06	−0.13	−0.03	0.59
Left instep	0.04	1.1	−0.04	0.45
Right MP joint	−0.16	−0.14	−0.03	0.58
Left MP joint	0.14	−0.02	−0.29	0.14

A positive number denotes an increase and a negative number denotes a decrease. MP = metatarsal phalanges joint (where toes join the foot).

Table 3 Mean scores on stress, tension, anxiety, discomfort, irritability, pain and tiredness levels before and after the session ($n=55$)

	Before session 1	After session 1	Mean difference score	p value
Stress	2.13	1.28	0.85	<0.0001
Tension	2.32	1.38	0.94	<0.0001
Anxiety	1.85	1.35	0.5	<0.0001
Discomfort	2.96	1.86	1.1	<0.0001
Irritability	2.23	1.48	0.76	<0.0001
Pain	2.28	1.51	0.77	<0.0001
Tiredness	3.04	2.53	0.5	0.0003

Scale = 1 to 5, with 1 denoting no symptoms and 5 denoting considerable symptoms.

Table 4 Mean wellbeing scores and mean difference scores across the three groups

	Mean wellbeing score before session	Mean wellbeing score after session	Mean wellbeing difference score	p value
Rest ($n=10$)	12.3	11.3	1	<0.03
Relaxing Reflexology ($n=20$)	17.4	11.4	6	<0.0001
Lymphatic Reflexology ($n=25$)	17.6	11.2	6.5	<0.0001
All participants ($n=55$)	16.5	11.3	5.2	<0.001

Kruskal–Wallis = 16.35, df = 2, $p=0002$.

all mean circumference measurements were decreases as shown in Table 2. Despite the decreases, there were no statistically significant differences between the three groups in circumference measurements. The blood pressure readings decreased in all groups after the completion of the session, but were not statistically significant ($t=1.9$, df = 41, $p=0.06$).

The participants' questionnaire, showed statistically significant decreases in mean measurements of the participant's symptoms of stress, tension, anxiety, pain, tiredness, irritability and discomfort levels in all groups as shown in Table 3. A 'perceived wellbeing' score revealed the lymphatic reflexology technique group significantly increased their wellbeing the most, followed closely by relaxing reflexology group and then the control group as displayed in Table 4. A second analysis of variance did not find any significant difference between the two reflexology techniques ($F=0.111$, df = 36, $p=0.74$).

Participants' comments

Fifty-five participants responded to open-ended questions on how they felt after the session. The comments have been summarised into ten (10)

feelings. The majority of the comments made by the participants were very positive.

Forty-nine participants responded to the question 'how do you feel after the session'. One participant (10%) of rest group, 12 participants (60%) of relaxing technique group, and 15 participants (60%) of lymphatic techniques group felt 'relaxed to very relaxed'. More than one feeling was noted with other comments included 'fine', 'great', 'calm', 'sleepy' and 'wonderful'. Three participants in the rest group answered 'same as before'.

Nearly all participants (81%) noticed a difference in their feet after the session. The groups differed with one (10%) participant receiving rest noticing a change compared to 13 (86%) participants receiving relaxing technique and 17 (94%) participants receiving lymphatic techniques. When asked to describe the difference in their feet, participants receiving reflexology responded with key themes: less swelling/tightness, less pain/soreness, more mobility, and comfortable/relaxed.

One participant receiving rest responded with 'relaxed'. Fourteen participants receiving relaxing reflexology responded with: less swelling/tightness (7), less pain/soreness (4), more mobility (3), and comfortable/relaxed (6). One of the participants commented that she could move her toes more easily, while another felt that the 'tightness has eased, my legs feel better as well'. One participant commented that her feet were 'still swollen'.

The participants receiving lymphatic reflexology technique responding to the question (17) documented at least one response: less swelling/tightness (9), less pain/soreness (1), more mobility (1) and comfortable/relaxed (8). A number of participants from this group recorded longer comments: 'swelling went down slightly able to move toes and ankle more freely, not as tight', 'muscle tension less, flexible and nice pink colour all over', and 'feel 100% better'.

Discussion

This study was initiated due to limited women-friendly strategies available to relieve oedema and symptoms in pregnancy especially for busy women who may not have time to wear pneumatic boots or sit in a bath every day. The study goal was based on Young and Jewell's[4] recommendation to investigate recipient's viewpoint regarding symptom relief. The single-blind design was used to gain unbiased information from the women on the two reflexology techniques—if lymphatic reflexology technique was more effective in relieving oedema and symptom relief compared to relaxing reflexology techniques.

The findings indicate that the lymphatic reflexology techniques and to a lesser extent relaxing reflexology techniques have a non-significant clinical effect in reducing ankle and foot oedema than a period of rest. The lymphatic reflexology technique group showed a consistent decrease in all circumferences compared to relaxing reflexology or bed rest. Participants perceived lymphatic reflexology technique more effective in symptom relief than relaxing reflexology or a period of rest. A large percentage of lymphatic reflexology technique recipients noticed less swelling and tightness in their feet after the session compared to the relaxing reflexology recipients and rest recipients. Further research with a longer session time could be of benefit as other studies have employed a 30 min treatment time.[21,24]

The researcher and contributing midwives recognised that a more accurate measuring tool is required as the circumference measurements were not able to record the decrease in skin tension and swelling as experienced by the participants. Katz and colleagues[7] were also unaware of an accurate method of quantifying dependent oedema. Since the completion of our study, Perrin and Guex[29] investigated the various methods of accurately assessing leg and foot oedema.

Reflexology significantly assisted women to cope with symptoms in late pregnancy with a reduction in the levels of stress, tension, anxiety, discomfort, irritability, pain, and tiredness. This resulted in an increased feeling of wellbeing especially when the women had swollen and often painful feet, difficulty with mobility and experienced broken sleep. Previous reflexology studies have also demonstrated in increased general wellbeing[25] and a decrease in pain and anxiety.[21]

The most apparent effect that was reported by the women receiving reflexology was the experience of profound relaxation. The findings are consistent with previous reflexology studies, which noted that many of the women receiving reflexology felt very relaxed, sleepy or fell asleep during the reflexology session.[20] The relaxation response is an integral part of the healing capacity of numerous natural therapies encouraging the release of endorphins, causing analgesic effect and relaxation.[11,30] Of interest, some participants receiving reflexology felt 'pampered' or 'spoiled'. The author acknowledges the benefit of touch and the possible placebo effect on symptom relief.[30,31] However, this study concentrated on the effect of reflexology as a therapy for

oedema and symptom relief rather than reflexology as a touch technique.

In conclusion, the evidence suggests reflexology may offer a useful therapy for health professionals when considering the care of pregnant women with foot oedema. In the women's viewpoint, lymphatic reflexology shows promises as an effective management modality in providing a safe, friendly approach for uncomfortable ankle and foot oedema in late pregnancy.

The results of this study cannot be generalised to other settings such as patients with lymphoedema or generalised oedema. However, the findings raise a number of interesting issues for nurses and midwives to consider for further investigation. It is vital that midwives and nurses continue to examine the effects of complementary therapies through well-designed studies using appropriate research methods.

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