

Alleviating Perineal Trauma

The APT Study

by Dr Mary Steen, Research Fellow in Midwifery

Abstract

Objectives: To evaluate the effectiveness of a new cooling device (gel pad) with a standard regimen (ice pack) and compare these with a no localised treatment regimen (control).

Design: A randomised controlled trial initially based in hospital and then continued in the community.

Setting: A Midwifery Unit in the North of England and then in women's own homes. Participants: 450 women who had undergone either a normal or an instrumental delivery that required suturing of an episiotomy or second degree tear.

Measurements and Findings: 316 (71%) of completed questionnaires were returned. A significant reduction in the levels of oedema was observed in favour of using cooling treatments at Day 2 and Day 5 $p=0.016$, $p=0.018$ and there was a significant reduction in bruising at Day 10 $p=0.01$, (using the Kruskal Wallis test). Self reported pain was less in the cooling gel pad group. A significant reduction in pain was demonstrated at Day 5, Day 10 and Day 14, $p=0.023$, $p=0.007$, $p=0.058$ (Kruskal Wallis test). A reduction in pain was reported earlier on Day 2, Day 3 and Day 5 when making a binary comparison of moderate or severe pain, with none or mild, $p=0.0038$, $p=0.037$, $p=0.017$ chi square test. Maternal satisfaction in the cooling gel pad group was rated highly significantly when compared to the other two groups, $p=0.0001$, (Kruskal Wallis test). There was no clinical significant differences monitored between groups when assessing healing.

Key Conclusions: This clinical trial confirms earlier findings in a previous study and provides evidence that the use of a specifically designed cooling gel pad is a safe and effective localised method to alleviate perineal trauma without any adverse effects on healing.

Introduction

Perineal pain in the early post-natal period has been reported to be one of the most common causes of maternal morbidity (Sleep, 1990) and Walker (1990) suggested that 'Pain and discomfort from perineal trauma can dominate the experience of early motherhood. Pain resulting from perineal wounds is conventionally managed through the use of oral analgesia, bathing and is supplemented in some hospitals by the local application of ice packs. (Steen & Cooper, 1999) Associated risks have been voiced with regard to a delay in healing (Walker, 1990; Grundy, 1997) and ice burns to the perineal region. (Harris, 1992) To counteract the difficulties reported when using ice packs, exploratory studies and developmental work involving women and midwives has recently instigated the designing of a specific cooling maternity gel pad. (Steen & Cooper, 1999) An initial clinical trial conducted in 1993/94 demonstrated that cooling gel pads has the potential to reduce perineal pain during the first 48 hours following childbirth (Steen et al, 2000) The purpose of this article is to report the preliminary findings from a further clinical trial which compared the effectiveness of the cooling gel pads with ice packs and no localised treatment over a longer period of time.

Methods

Following approval by the Local Clinical Research Ethics Committee and funding from the NHS Executive Northern and Yorkshire Region and additional funding from the Smith and Nephew Nursing Foundation, a randomised controlled trial was conducted at St James's University Hospital, Leeds. To test the study design a pilot study was carried involving 60 women who had undergone either a normal or an instrumental delivery requiring suturing of an episiotomy or a second degree tear. Analysis of the pilot study data

demonstrated that, at 24 hours overall, 50% of women reported that they experienced 'moderate' or 'severe pain'. At 5 days the percentage of each group experiencing either of these higher levels of pain were gel pad 16%, ice pack 37% and no localised treatment 26%. To detect a difference at 5 days a sample size of 136 women per group were required on the basis of 95% power and a 5% significance level. Following this 450 women were recruited during the period 1 August 1998 to 15 June 1999.

The following hypothesis was tested: The use of a new treatment (cooling gel pad) is more effective at reducing levels of perineal pain, oedema and bruising following either a normal or an instrumental delivery involving the suturing of an episiotomy or second degree tear when compared with the standard regimen (ice pack) or no localised treatment (control).

Information for women was adapted from the initial trial (1993/94) leaflet. One of these was distributed to each of the women at 34 weeks gestation and additional copies were made available at parentcraft classes, on admission to the ante-natal ward and finally, following suturing.

Midwives Training

Prior to the trial, 10 workshops were organised for both hospital and community based midwives with the aim to increase awareness and knowledge of the trial protocol, to standardise the use of the previously validated visual evaluating tool used to aid the assessment of levels of oedema and bruising, (Steen & Cooper, 1997) and the assessment of healing. All midwives at the study hospital were asked to read the trial protocol and sign an attached sheet to confirm that they had read and understood the protocol procedures. Treatment Protocol: Plastic boxes containing either twenty normal saline sachets or two gel pads were placed in a freezer on the delivery suite for a minimum of two hours. These boxes were labelled with the mothers addressograph and given to them on transfer to the post-natal ward and these accompanied the mothers on returning home.

Both cooling treatments were covered with sterile gauze prior to application to the perineal wound. The normal saline sachets were disposed of after use and the gel pads were cleansed with hot soapy water and dried thoroughly with paper towels before being replaced in the plastic container for further use. A series of microbiological challenge tests were conducted by the Control of Infection department and these showed the presence of normal skin flora in low concentrations. This was considered not to create a risk of infection when used by the same woman. Safety approval was obtained from the COSHH department. Mothers were informed that in the unlikely event of a gel pad being punctured, it was to be withdrawn from use.

Clinical Trial

A written consent was obtained and randomisation was carried out by a specially commissioned computer program which generated random numbers (with a block size of six) giving each woman an equal chance of being allocated to one of the three groups. This was carried out during the computerised documentation of the delivery data.

Entry Criteria: Age 16 - 45 years, English speaking, cephalic presentation, conventional birth position, term fetus, singleton birth, normal or instrumental delivery, episiotomy or 2nd degree tear sutured with vicryl rapide.

Main Outcome Measures: The outcome measures chosen were

the levels of self-assessed pain, maternal satisfaction and midwives estimates of oedema, bruising, healing.

Data Collection: Two questionnaires, one completed by midwives and the other by mothers recorded both quantitative and qualitative data. The severity of perineal oedema and bruising was assessed by the midwife, initially within half an hour following suturing, then daily from Day 1 to Day 5, then at Day 10 and finally at Day 14. The overall intensity of mother's self-assessed pain was measured by use of a verbal rating scale, (none, mild, moderate, severe) at the same time points. Healing of the perineal wound was monitored by community midwives at Day 5, Day 10 and Day 14 by use of a series of categorical scales and ordinal scales.

Maternal satisfaction was measured by use of a 5-point ordinal scale describing the categories; poor, fair, good, very good, excellent at Day 10. Mother's were given the opportunity to document anything else they wanted to say concerning the treatment they had received.

Analysis of Data

This was carried out using SPSS for Windows. All analysis was carried out on a basis of intention to treat. For the analysis of the effect of treatment on self-assessed pain, oedema, bruising, healing and maternal satisfaction, the chi-squared test and Kruskal-Wallis test were used.

Results

The final number of questionnaires returned was 316 (71%) of those initially enrolled. Table 1 shows the number of mothers in each group following randomisation.

Fig. 1, shows the percentage of mothers with some oedema (mild, moderate, or severe) at all time points. The results demonstrate that the majority of mothers (60%-69%) already had recognisable perineal oedema within 30 minutes of suturing. There was no significant effect of treatment at Day 1 and the percentage with some oedema increased (71%- 74%). From Day 2 onwards there was a noticeable downward trend in the levels of oedema observed. There was a statistically significant difference in the median of women with some oedema in the cooling gel pad group at Day 2 and Day 5, $p=0.016$; $p=0.018$ (Kruskal Wallis test,) By Day 14 levels of oedema had resolved in 98% of the mothers.

Fig. 2, shows the percentage of mothers with some bruising (mild, moderate, or severe) at the same measuring points. The results demonstrate that between 30% and 37% of mothers had some bruising at initial assessment. This was mainly in the mild category. There was an increase in bruising on Day 1 and Day 2. On Day 3 a decline in the level of bruising commenced and this continued steadily. At Day 10 there was a statistical significant difference in the median of women with some bruising in favour of the cooling groups, $p=0.010$ (Kruskal Wallis test). By Day 14 levels of bruising had resolved in 97% of the mothers.

Fig. 3, Shows the percentage of mothers reporting some (mild, moderate or severe) pain. Between 53% and 59% of mothers reported pain following suturing. However, the majority of mothers (64%-80%), had an epidural and some women will have had continuing pain relief for a few hours following suturing. A high proportion of mothers reported some pain for the first 5 days. A smaller percentage reported some pain in the cooling gel pad group from Day 5 onwards. There was a statistically significant difference in the median of reported pain between the three groups at Day 5, Day 10 and Day 14 , $p=0.023$, $p=0.0077$, $p=0.058$ $df=2$. (Kruskal Wallis test).

Fig. 4, Shows the percentage of mothers reporting moderate/ severe pain. Between 7% and 19% of mothers reported moderate or severe pain at the initial assessment and similar increased levels of pain were reported on Day 1 (51% to 54%). This percentage continued to increase in the no treatment group on Day 2 (54%) but decreased in the cooling treatment groups on Day 2 and Day 3 for ice pack and gel pad, respectively, (42% and 25%; 36% and 31%).

At Day 3 mothers in the control group reported a lower percentage with moderate or severe pain (42%). A change in trend was noted on Day 4, the no treatment and cooling gel pad groups continued to have less moderate or severe pain (25% and 31 %) but the ice pack group reported an increase (34%) which continued on Day 5. By Day 10 only a small number of mothers in all groups reported moderate or severe pain (3% to 8%) and only two mothers reported moderate pain at Day 14. There was a statistically significant difference of reported moderate or severe pain between the three groups at Initial assessment, Day 2, Day 3 and Day 5, $p=0.024$, $p=0.038$, $p=0.037$, $p=0.017$ $df=6$. (Kruskal Wallis test).

Fig. 5, illustrates maternal satisfaction with regards to the overall perineal care that they received. The median for no localised treatment and ice pack groups was rated as 'Good' whilst the cooling gel pad group rated it to be 'Very Good' . This was statistically significant $p=0.0001$, (Kruskal Wallis test). There were no statistically significant differences between the three treatment groups when assessing healing of the wound, the approximation of the wound edges and signs of infection at Day 5, $p=0.69$ $df=4$, $p=0.070$ $df=6$, $p=0.40$ $df=4$) and at Day 10, $p=0.54$ $df=4$, $p=0.41$ $df=6$. $p=0.16$ $df=4$ (chi square test) There was, however, a statistically significant difference in healing reported at Day 14, $p=0.039$ $df=4$) but a similar pattern of approximation of wound edges, rate of wound infection, sutures removed or snipped, evidence of scar tissue and the small number of mothers required resuturing 5 (1.5%) indicates that there was no clinically significant differences overall between the three treatment groups.

Table 1

Raw Data of the treatment groups

	Group 1 (no treatment)	Group 2 (ice pack)	Group 3 (gel pad)	Statistical Significance
Numbers recruited	150	150	150	No statistically significant differences in the numbers assigned to the three treatment groups (x2 test p=0.83 df=2)
Returned Questionnaires	101	108	109	
Withdrawals		1	1	
Final Numbers	101 (67%)	107 (71%)	108 (72%)	
Age Range Mean Age	(16-43 years) 28.5 years	(18-41 years) 28.6 years	(17-38 years) 27.7 years	No statistically significant difference in median age (K-W test p=0.6, df=2)
Ethnic Group White UK Other	87 (86%) 14 (14%)	96 (90%) 11 (10%)	101 (94%) 7 (6%)	No statistically significant differences between ethnic group (x2 test p=0.6 df=2)
Primigravidae Multigravidae	64 (64%) 37 (36%)	64 (60%) 43 (40%)	73 (68%) 35 (32%)	No statistically significant differences in the proportions (x2 test p=0.50, df=2)
Length of Labour Normal Delivery Forceps Delivery Ventouse Failed Ventouse/Forceps	77 (76%) 13 (13%) 9 (9%) 2 (2%)	80 (75%) 9 (8%) 16 (15%) 2 (2%)	74 (69%) 11 (10%) 18 (17%) 5 (4%)	No statistically significant differences in type of delivery (x2 test p=0.4 df=2) No statistically significant difference in mean (one-way ANOVA test p=0.4 df=2)
How soon Sutured Episiotomy Second Degree Tear Episiotomy/T ear	49 (49%) 48 (48%) 3 (3%)	54 (50%) 49 (46%) 4 (4%)	63 (58%) 45 (42%) 0	No statistically significant differences in type of perineal wound (x2 test p=0.3 df=2) Measured in half hourly time bands (x2 test p=0.25 df=2)
Vulval lacerations No perineal wound	18 (18%) 1 (1%)	19 (18%) 0	18 (17%) 0	No statistically significant differences (x2 test p=0.9 df=2)
Haemorrhoids	16 (16%)	12 (11%)	26 (24%)	Statistically significant difference (x2 test p=0.043 df=2)
Epidural	65 (64%)	76 (71%)	87 (81%)	Statistically significant difference (x2 test p=0.042 df=2)

Fig 1. Treatment effect on the percentage of mothers with some oedema

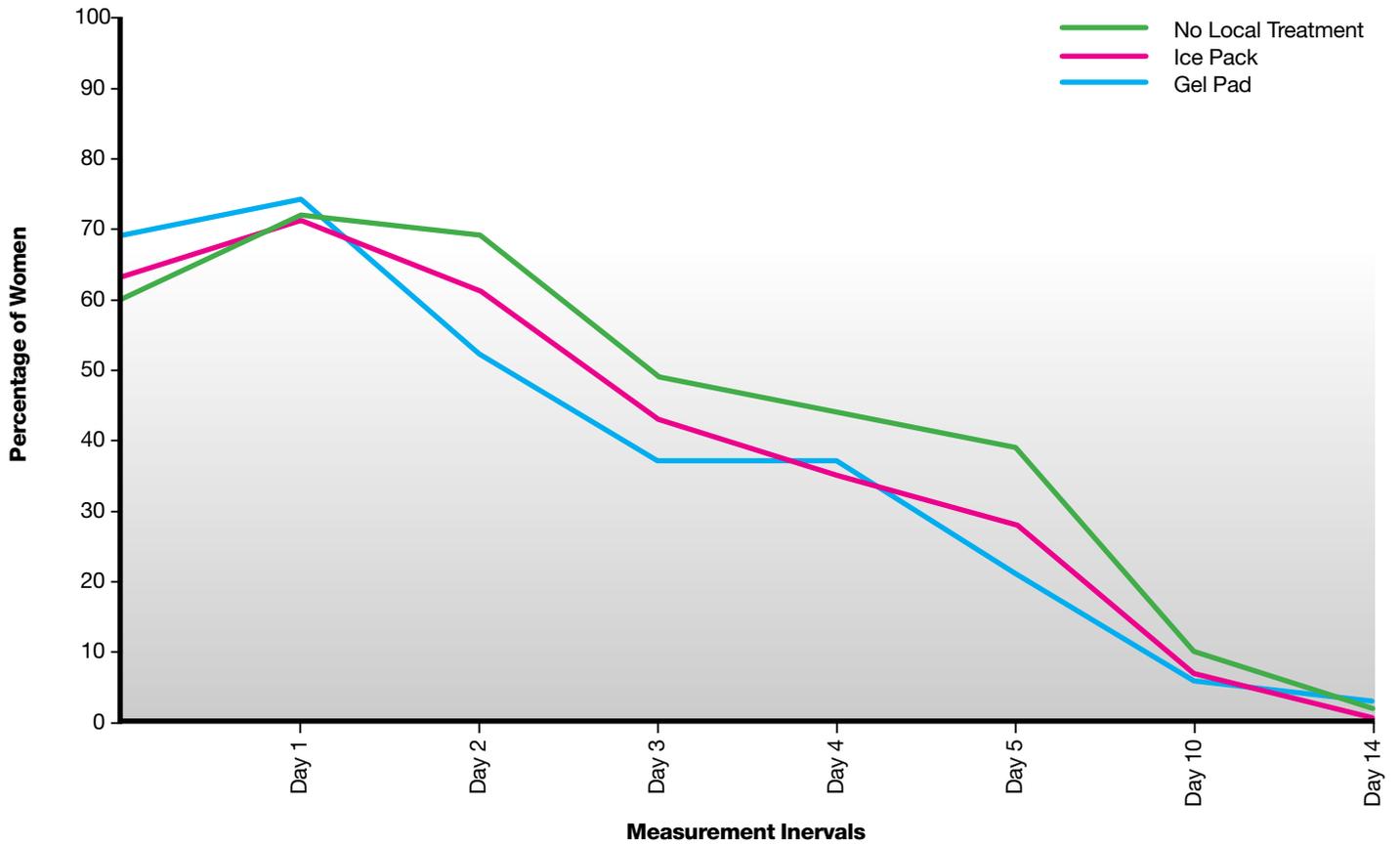


Fig 2. Treatment effect on the percentage of mothers with some bruising

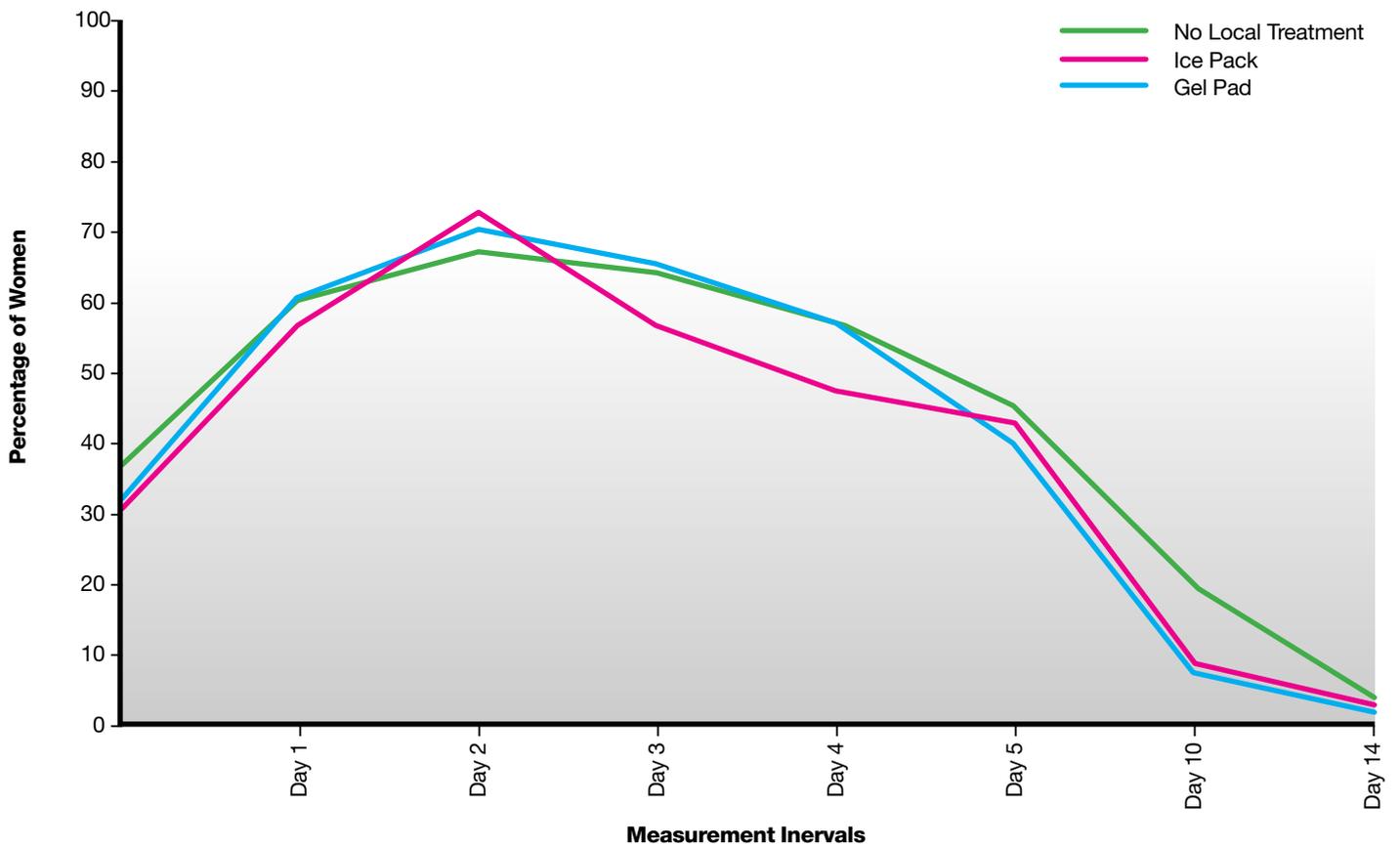


Fig 3. Mothers reporting some mild/moderate/severe pain

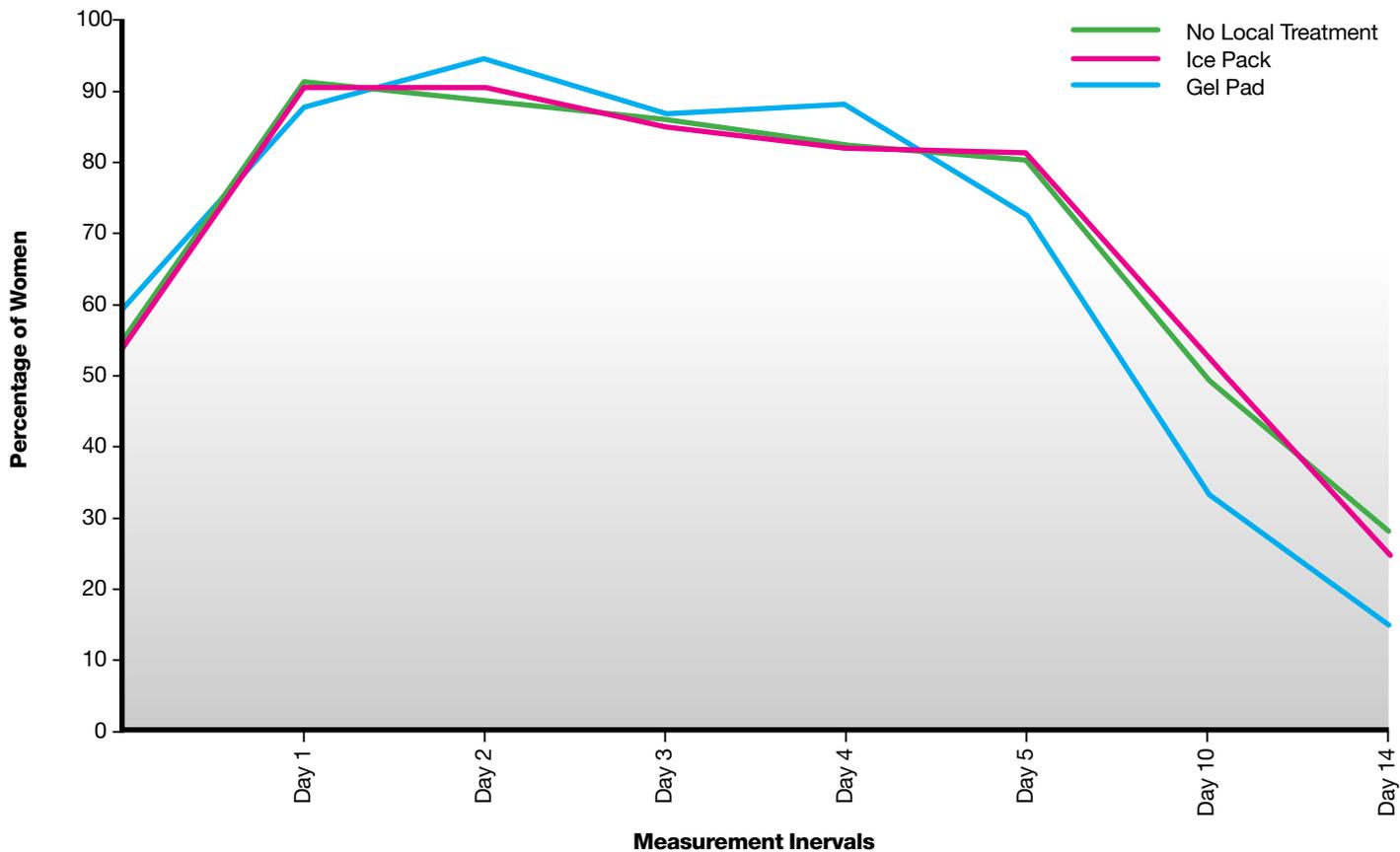


Fig 4. Mothers reporting moderate or severe pain

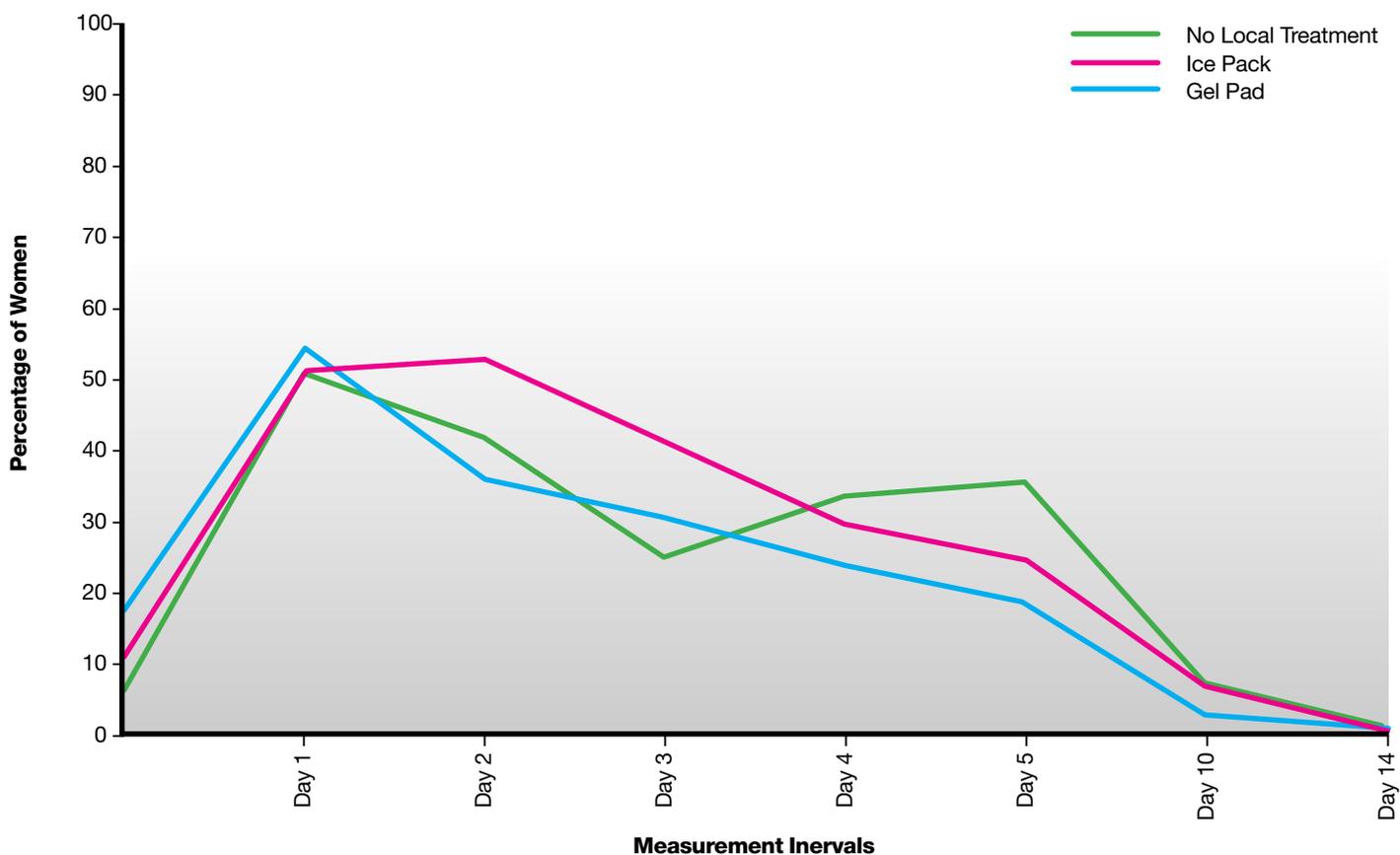
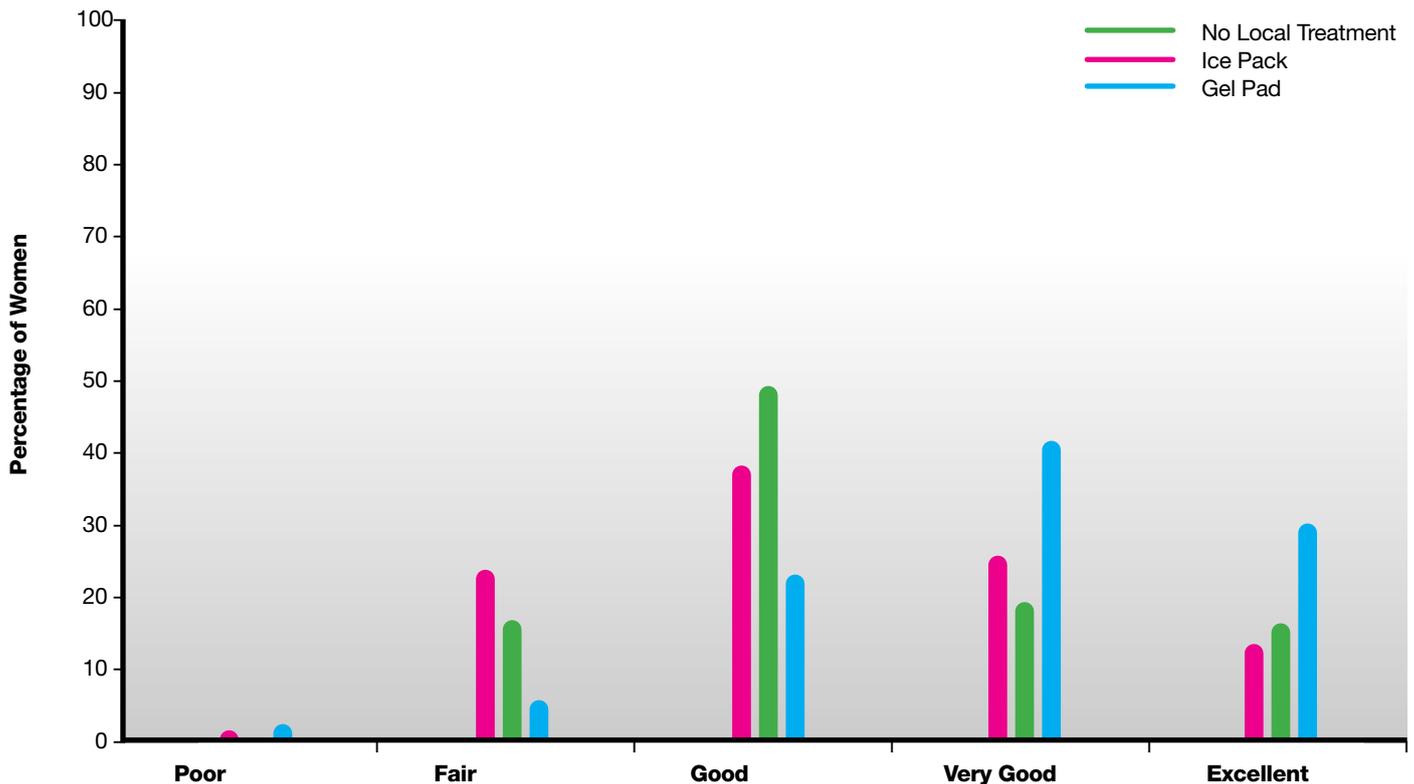


Fig 5. Level of satisfaction with overall perineal care



Discussion

Application of localised cooling treatments is not a new concept; Hippocrates (Father of Medicine) used snow. (McMasters, 1977) Cooling treatments have been shown to attenuate the levels of pain by numbing the superficial tissue surrounding the injury through its action on local nerve fibres and by reducing the levels of oedema of soft tissue damage. (McMasters, 1977; Steen and Cooper, 1997) Treatment was applied within half an hour of suturing in an attempt to quickly counteract the inflammatory response, as suggested by Steen et al, (2000). The pattern of oedema and bruising observed in this trial is consistent with normal physiological processes associated with the healing process (Mera, 97) and this confirms earlier findings in an initial trial (Steen et al, 2000). Both the ice pack and cooling gel pad appear to reduce the inflammatory response when compared with no localised treatment but an increase in pain was reported by mothers in the ice pack group on Day 4. This may be explained by the fact that women reported ice packs to be rigid, hard, uncomfortable and the sharp corners hurt. The controlled cooling properties, sanitary towel shape and larger surface area application of the gel pad allows it to remain pseudoplastic at cold temperatures, this enables mouldability and comfort. This also, ameliorates the pain associated with hyperanalgesia of the surrounding area of the perineal injury. Post-partum haemorrhoids can be an additional problem for some women and it has been reported to affect approximately 35% of newly delivered mothers. (Thomas et al, 1993) Mother's reported the gel pad to be also effective at relieving pain and itching associated with haemorrhoids. Cooling treatments are not readily available for use in mothers' own homes, therefore, many mothers will improvise and use frozen packs of peas as recommended by Jane Hatt (1991). The findings of this trial has provided evidence that a specially designed cooling gel pad can comfortably alleviate the symptoms of perineal trauma and most importantly the associated pain during the first two weeks following childbirth.

Limitations

One unavoidable limitation in the design of this study was the impossibility of concealing the type of treatment each mother received. The differences in the shape, size and composition of the cooling devices and the no application treatment made it not possible to blind the mothers and midwife assessors. The suture technique for skin closure of the perineal wounds was difficult to standardise. The most clinically acceptable method was to have midwives using an interrupted technique, for skin closure when suturing mothers who had undergone a normal delivery and obstetricians to use a subcuticular technique, following an instrumental delivery. Although the method of suturing was different the material was standardised. Mothers were sutured with a polyglycolic suture material Vicryl Rapide as there is evidence to suggest that it is the most suitable suture material to use (Gemynthe et al, 1996). The response rate was fairly good when taking into account that the good will of midwives and mothers had to be relied upon when completing the daily assessments and recording information up to Day 14. The exclusion of non-returns from the analysis could potentially bias the findings, however, the non- response was evenly distributed between the three treatment groups.

References

- Gemynthe A, Langhoff-Ross J, Sahl S, Knudsen J. (1996) New VICRYL* formulation: an improved method of perineal repair? *British Journal of Midwifery* 4:5 230-233
- Grundy L. (1997) The role of the midwife in perineal wound care following childbirth. *British Journal of Nursing* 6:10 584-588.
- Harris M. (1992) The impact of research findings on current practice in relieving post-partum perineal pain in a large district general hospital. *Midwifery* 8: 123-131
- Hatt J. (1991) Letters: Medicinal peas. *New Scientist* 132: 1796 66.
- McMasters WC. (1977) A literary review on ice therapy in injuries. *The American Journal of Sports Medicine*. 5:3 124-126.
- Mera S. (1997) *Pathology & Understanding Disease Prevention*. StanleyThomas Ltd. Cheltenham.
- Sleep J. (1990) Postnatal Perineal Care: In: Alexander J, Levy V, and Roach S. (Eds). *Midwifery Practice. A Research-based Approach*. Macmillan Press: London.
- Steen MP, Cooper KJ, Marchant P, Griffiths-Jones M, Walker J. (2000) A randomised controlled trial to compare the effectiveness of icepacks and Epifoam with cooling maternity gel pads at alleviating postnatal perineal trauma. *Midwifery*. 16:1 48-55
- Steen MP, Cooper KJ. (1999) A new device for the treatment of perineal wounds. *Journal of Wound Care*. 8:2 87-90. Steen MP, Cooper KJ. (1997) A tool for assessing perineal trauma. *Journal of Wound Care*. 6: 9 432-436
- Thomas IF, Erian M, Sarson D, Yan Lillian, White S, Battattistutta. (1993) Postpartum haemorrhoids – evaluation of a cooling device (Anurex) for relief of symptoms. *The Medical Journal of Australia*. 159: 459
- Walker P (1990) Episiotomy issues for practice. *Wound Care. Nursing Times*. 4:15 18-22.