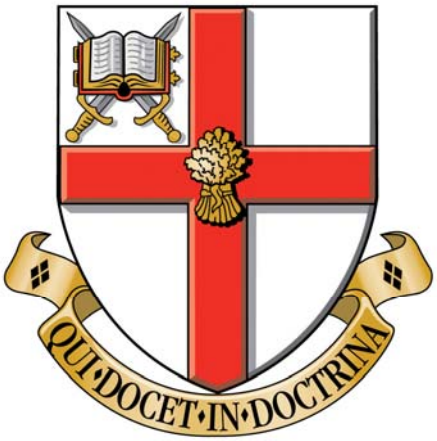

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A randomised controlled trial to compare the effectiveness of icepacks and Epifoam with cooling maternity gel pads at alleviating postnatal perineal trauma

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Objective: to evaluate the effectiveness of standard regimes (ice packs and Epifoam) at relieving perineal trauma and compare these with a new cooling device (maternity gel pad).

Design: a randomised controlled trial involving three treatment groups. The women were free to choose the time of initial application (within four hours after delivery) in all treatment groups and the number of subsequent treatments up to 48 hours after suturing.

Setting: a midwifery unit in the north of England and then continued in the women's own homes.

Participants: 120 women who had undergone an instrumental delivery and had a 48 hours post-delivery stay in a postnatal ward.

Measurements and findings: the ordinal scale of none, mild, moderate and severe was used to determine the levels of perineal oedema and bruising at initial assessment (less than 4 hours), 24 hours and at 48 hours, by use of a newly developed visual evaluating tool. Self-assessed pain was recorded using a ID-point visual analogue scale within four hours, at 24 hours, 48 hours, and finally at five days after suturing. Women's opinions as to the effectiveness of their treatment was rated by use of a 5-point scale describing the categories; poor, fair, good, very good and excellent. A high proportion of women had some perineal oedema at initial assessment. A statistically significant difference in the proportion of women with oedema was found between treatment groups at 48 hours ($p = 0.01$), which was in favour of the maternity gel pad group.

This was particularly noticeable for women with initial levels of mild oedema (p = 0.017). Localised treatment with the gel pad caused a significant decrease in reported pain at 48 hours in women who initially demonstrated moderate or severe pain (p = 0.048). A significant increase in the proportion of women with some bruising was seen across all treatment groups from initial assessment, through 24 hours to 48 hours (p = 0.0005). The bruising was significantly less in the gel-pad group in women who initially had no bruising (p = 0.021). There was no statistically significant effect of treatment at other initial levels of severity for oedema, bruising or pain at 24 hours, 48 hours and five days (for pain).Women in the gel-pad group rated the effectiveness of their localised treatment to be significantly higher than women in the other two treatment groups (p = 0.0005).

Key conclusions: this trial demonstrated that a high proportion of women experience perineal oedema, bruising and pain following an instrumental delivery, which continues for at least five days for perineal pain, despite oral analgesia. Maternity gel pads, which were specially designed to cool the perinea) region, were more effective in alleviating perineal trauma when compared with hospital standard regimens and were more highly rated by women.

INTRODUCTION

Perineal trauma can cause considerable distress and discomfort to many women following childbirth. Its severity is frequently under-estimated and many women suffer unnecessarily, often in silence, Perineal pairs in the early postnatal period has been reported to be one of the most common causes of maternal morbidity (Sleep 1990). For example, Kitzinger and Walters (1993) showed that following an episiotomy women experience more perineal pain and are more likely to experience dyspareunia when compared with other degrees of permeal trauma. Support for this claim was highlighted in an extensive literature review of 350 articles and books published during the period of 1860-1980 (Thacker & Banta 1983). This concluded that 'pain following an episiotomy appears to be universal…' (p. 331) and reported the level of moderate-to-severe pain as high as 60%. A delay in healing may increase the duration of perinea) pain, and studies by McGuiness et al. (1991) and Henriksen et al. (1994) noted a significant delay in the healing of episiotomies when compared with other perineal outcomes. An instrumental delivery is commonly aided by an episiotomy and this appears to cause greater levels of perineal pain when compared with a normal delivery (Cater 1984).

Cryoanalgesia is defined as the application of cold therapy to a localised part of the body to block local nerve conduction of painful stimuli (Evans 1981) and ice application can produce a strong analgesic effect in many painful conditions (Ernest & Fialka 1994). Perineal trauma, however, involves more than simply an increase in localised pain. It has been suggested that the oedema which appears soon after childbirth is a major contributing factor to the

distress and discomfort incurred by women and immediate application of ice packs can reduce its severity (Pinkerton & Beard 1961).

Applications of hot/cold compresses have been in use for centuries as a form of localised treatment to relieve the inflammation of acute soft tissue injuries and it would appear that cold therapy is the preferred choice of the two (McMaster 1977). A national survey of midwifery practice undertaken by Sleep and Grant (1988) reported ice packs to be the most commonly used form of localised treatment to alleviate perineal pain and discomfort and a more recent National Childbirth Trust survey supports this conclusion (Hulme & Greenshields 1993). Concerns about a possible delay in wound healing caused by the accompanying vase-constriction effect: when cold therapy is applied to the perineum have been expressed by Sleep (1990) and Grundy (1997). A recent review of the literature, however, concluded that there is no strong evidence to support this (Steen & Cooper 1998). There is, nevertheless, an associated risk of freeze/ice burns to adjacent areas surrounding the perineal region due to the shape and rigidity of ice packs which can cause unnecessary distress to women (Harris 1992) and the use of crushed ice, sandwiched between two protective layers of a pad and applied for restricted periods, has been recommended by Sleep (1990).

Epifoam is an alternative form of treatment for perineal pain and consists of an anti-inflammatory steroid-based foam which is applied directly to the perineal injury. There appears to be some controversy concerning its use, although it has been specifically developed for that purpose. Evidence obtained from a randomised controlled trial showed that Epifoam was an effective treatment for relieving oedema and perineal pain (Bouis et al. 1981), and Moore and James (1989) concluded that Epifoam was as effective as ice packs with no delay in healing. The results of another randomised controlled trial indicated that Epifoam had no effect on the level of oedema and caused no delay in healing, although it was found to be superior to the placebo in that less oral analgesia was required when Epifoam was applied (Hutchins et al. 1985). An association between Epifoam treatment and wound breakdown was seen in a small double-blinded randomised controlled trial (Greer & Caineron 1984). There is some evidence that steroid treatment can impair wound healing (Walter & Israel 1979) and the use of Epifoam may be contra-indicated, although, as yet, there is no clear evidence to condemn its use.

Evidence from the above studies indicates that both ice packs and Epifoam are able to alleviate perineal trauma in post-delivered women. The effects of cooling, however, produced by the ice packs and the anti-inflammatory action stimulated by Epifoam and on the severity of oedema and bruising have not been fully evaluated. A systematic, non-intrusive method to classify the severity of permeal trauma, in terms of the severity of oedema and bruising has recently been developed by two of the authors (Steen & Cooper 1997). The study described here was designed to use this tool to test the effectiveness of a new cooling device (maternity gel pad) at alleviating perineal trauma and compare this with the two standard treatment regimes (ice packs and Epifoam) at the study hospital. Women's opinions were also rated as to how effective they considered their treatment to be.

METHODS

Following Local Research Ethics Committee approval and funding support from the Elizabeth Clark Charitable Trust, a randomised controlled clinical trial involving 120 women who had undergone an instrumental delivery was conducted over a period of seven months (13 September 1993 to 31 March 1994) at St James's University Hospital, Leeds. During this period 140 women became eligible to enter the trial. The sample size was calculated to be 120 women after allowing for exclusions and intense periods of activity in the delivery suite. A power calculation confirmed this based on two-thirds of the women in the ice-pack and Epifoam groups and one-third in the gel-pad group showing evidence of some oedema at 48 hours (significance at 5% and power at 95%).

The following hypotheses were tested:

1. The use of a new device (maternity gel pad) is more effective at reducing levels of perineal oedema, bruising and pain in post-delivered women following an instrumental delivery when compared with standard regimes (ice packs and Epifoam) at the study hospital.
2. The maternity gel pads are considered a more effective treatment than ice packs or Epifoam for perineal trauma by women.

An information sheet describing the trial was piloted in a separate group of 10 women and their views as to the layout and use of language were incorporated into the final information sheet given to women in the clinical trial. The final version was distributed to all women eligible for the trial at the 34 weeks" antenatal screening visit and additional copies were made available during parentcraft classes, on admission to the antenatal ward, prior to induction of labour, and finally following an instrumental delivery. This procedure enabled all women to make an informed decision on whether to enter the trial before delivery. Following an instrumental delivery written consent was obtained from each woman to be entered into the trial. Randomisation to groups was carried out by a specially commissioned software programme for the Delivery Suite computer giving each woman an equal chance of being allocated to one of the following three treatments:

(Group 1)	(Group 2)	(Group 3)
ICE PACKS (38)	EPIFORM (42)	GEL PADS (40)

Women who had undergone an instrumental delivery were allocated to groups during the computerised documentation of the delivery details. The midwives were blind to the random allocation to treatment groups, which was carried out by the compute] programme. The outcome measures chosen were levels of oedema, bruising and self-assessed pain in the three treatment groups. The women were followed up in their own homes to determine their opinions as to the effectiveness of the three treatments.

Preparation

Several medical companies who already manufactured cold compresses, i.e. sports injury packs, were approached to produce a specifically designed maternity gel pad. As a result of their reluctance to produce the pads, a

midwife (MPS) and obstetrician (MGJ) developed and manufactured 100 maternity gel pads for the trial. These pads consisted of a heat-welded soft plastic sachet containing a high thermal capacity cellulose-based gel combined with a propylene glycol anti-freeze. The shape was similar to a slender sanitary towel (5 cm in width, 23 cm in length and 1.5 cm in depth).

Prior to the trial, six workshops were organised for twelve midwife assessors to standardise use of the visual tool and data collection. These assessors were midwives from the delivery suite and postnatal wards in the study hospital who met the following criteria:

1. in full-lime employment
2. had a minimum of 2 years' post-registration experience
3. were willing to undergo training in use of the visual assessment tool.

The tool consisted of typical life-size photographs representing varying degrees of severity in the levels of oedema and bruising using a 4-point ordinal scale of none, mild, moderate and severe as described by Steen and Cooper (1997). They concluded that this visual tool is a standardised, reliable and sensitive assessment method for the evaluation of perineal trauma in women following childbirth, especially since the additional use of a non-touch linger measurement technique by the midwife assessors helped to resolve any uncertainties in evaluation. This tool was used to determine the levels of oedema and bruising by the midwife assessors only following a period of training. The evaluating tool and study design were piloted in 10 women who had recently given birth and this confirmed that the midwives were able to use the tool to detect and monitor all levels of severity for oedema and bruising. Structured protocols for the preparation and application of the three treatments were drawn up and discussed with the twelve midwife assessors. These protocols were used by all midwives involved in the care of the women in the trial at the study hospital. All the midwives were given copies of the structured protocols and asked to sign an attached form to confirm that they had read and understood the protocol procedures.

The clinical trial

The midwife assessors and the midwives supervising the treatment applications were blind to the inclusion/exclusion criteria apart from the inclusion of women who had undergone an instrumental delivery. No attempt was made to standardise the performance of the instrumental delivery.

Inclusions: women, aged 20-35 years, English speaking, primigravidae, terra fetus, cephalic presentation, instrumental delivery, episiotomy, sutured with vicryl.

Exclusions: women with any medical disorder, fetal anomaly, retained placenta, multiple pregnancy.

Treatment protocols

Both the ice pack and Epifoam treatment protocols followed the standard regimes used at the study hospital. Normal saline sachets were placed in a hospital freezer for between two and six hours (ice packs) and these were covered with a sterile gauze immediately prior to application to the episiotomy

wound. The Epifoam canister was shaken before use and the foam dispensed onto sterile gauze and applied directly to the injury. Maternity gel pads were labelled with the woman's name, date and time arid placed in the freezer for between two and six hours prior to use. The pads were re-useable for an individual woman's use and safely approval was obtained from the COSHH and Control of Infection departments at the study hospital. Instructions from these departments were included in the treatment protocol and in the event of a gel pad being punctured, the pad was immediately withdrawn from use.

Cleansing of the gel pads was the responsibility of the midwives supervising the treatment applications and they were advised that only warm soapy water was required as other cleansing agents may cause deterioration to the soft plastic covering. It was emphasised that the gel pads should be thoroughly dried before re-freezing and re-use. A series of challenge tests were conducted by the Control of Infection Department at the study hospital 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. Midwives involved in the trial expressed some apprehension regarding the advice given by the Control of Infection Officer to the cleansing of the gel pads with only warm soapy water and drying them thoroughly. This was addressed by putting a small amount of chlorhexidine solution into the soapy water during the cleansing process.

All initial applications for the three treatments were supervised by a Delivery Suite midwife who explained the protocol to ensure that the treatments were applied correctly. The gel pads were covered with sterile gauze and moulded around the episiotomy wound, the right labia majora and extending over the anal sphincter. The women were free to choose the time of initial application (within four hours) and number of subsequent treatments up to 48 hours after suturing. The majority of repeat applications were unsupervised, although midwives were available to offer support and advice where necessary. The number and time of applications were recorded.

Assessments

Evaluation of perineal oedema and bruising was carried, out by the trained midwife assessors using the visual evaluating tool within the first four hours, at 24 hours and finally al 48 hours following suturing. A non-touch measurement technique, using the width of the little finger to represent 1 cm was used to support the visual tool as recommended by Steen and Cooper (1997). Every attempt was made to ensure that the midwife assessors were blind to the treatment the women received. The same midwife assessor undertook the evaluation of the perineum for each woman wherever possible. The inter-rater reliability between midwives has been reported to be highly statistically significant by Steen and Cooper (1997) and confirmed in the pilot study for both oedema and bruising (Cohen's kappa, $\kappa = 0.86$ and 0.93 respectively). Healing of the perineal wound was observed by monitoring the approximation of the skin edges at five and 10 days post delivery. Self-assessed pain was recorded within the first four hours, at 24 hours, at 48 hours by the midwife assessors and finally at five days by community midwives using a 10-point visual analogue scale to estimate the intensity of

pain. The number of treatment applications, baths, use of oral analgesia and length of 2nd stage of labour was also recorded. All women were asked to complete a 5-point ordered rating scale using the categories of poor, fair, good, very good and excellent to gain an overall view of the women's opinions as to the benefits of the three treatments at five days post-delivery by community midwives in the women's own homes. All assessments were entered onto a single record sheet for each woman which included both hospital and community derived data and was coded prior to computer analysis.

Statistical analysts

A range of descriptive and inferential statistical tests were carried out using Minitab and SPSS software packages. For the analysis of effect of treatment on oedema, bruising and self-assessed pain the χ^2 test, Cochran Q test, Kruskal-Wallis test, and the Jonckheere-Terpstra test (Siegel & Castellan 1988). The latter is an extension of the Kruskal-Wallis test for ordered categorical data. The Jonckheere-Terpstra test assessed whether the new treatment (maternity gel pad) was superior to the standard regimes (ice packs and Epifoam), taking into account initial assessment levels. The women identified as exclusions, refusals and non-returns were removed prior to analysis. The non-return of complete record sheets from the community midwives which contained all the hospital and community data for each woman meant that these could not be entered into the analysis even as partial data. All subsequent analyses were carried out on a basis of intention to treat. All *p*-values were calculated using SPSS Exact Tests where possible, using a Monte-Carlo simulation based on 10 000 trials, as well as using the more familiar azymptotic form of calculation.

FINDINGS

The mean age in years and (standard deviation) of the women in each group was 26.5 (4.8), ice pack; 25.1 (4.5), Epifoam; and 26.6 (4.3), gel pad. Of the 77 women entered for analysis 64 were recorded as white UK/Irish, four as Afro-Caribbean, four Asian, two Mediterranean and three undeclared. The number of women in each group following randomisation is shown in Table 1. The data demonstrate that randomisation to treatment groups was effective since there were no statistically significant differences in the numbers assigned to the three groups (χ^2 test, $p = 0.92$, df = 2). The exclusion of non-returns from the analysis could potentially bias the findings. The number of non-returns and exclusions, however, were evenly distributed among the three treatment groups and the mean age (standard deviation) of the non-return group of women at 25.9 (4.2) years was similar to the other treatment groups. Twenty-one of the 30 non-returns were from outside the study hospital midwifery service area. There was no statistically significant difference using a χ^2 test between groups in the proportion of spontaneous/induced labour ($p= 0.94$, df = 2), the use of epidurals ($p<0.44$, df = 2) or in forceps/ventouse deliveries ($p<0.13$, df = 2). There was no statistically significant difference in the number of treatment applications between groups (ice pack 10.4 (4.3), Epifoam 9.4 (2.5), Gelpack 8.0 (5.0); one-way ANOVA $p= 0.12$, df = 2). Haemorrhoids and extended episiotomies were observed in some women.

The number and percentage of women with some oedema (mild, moderate or severe) at initial assessment, 24 hours and 48 hours following suturing is shown in Table 2. The findings demonstrate that the majority of women (56-77%) already had recognisable perineal oedema within four hours post-delivery, although there was no significant effect of treatment effect either within four hours or at 24 hours. The proportion of women with some oedema, however, was significantly lower in the gel-pad group at 48 hours when compared with the two standard regimens (χ^2 test, p=0.01, df = 2). As is shown in Table 2, only 26% of the women exhibited any oedema at this time compared to 60 and 64% in the Epifoam and ice-pack groups.

The number and percentage of women with some mild-to-severe bruising is shown in Table 3 for the three treatment groups. This was seen to be between 26 and 43% at initial assessment, mainly in the mild category, although there was no significant effect of treatment (χ^2 test, p=0.43, 0.22, 0.13, df = 2). The proportion of women across all groups having some perineal bruising, however, increased significantly from initial assessment over the next 48 hours, irrespective of treatment (Cochran Q test, p<<X0005, df = 2).

The effect of treatment on the number and percentage of women with self-assessed moderate/severe pain is shown in Table 4. Between 52 and 61% of women reported pain in this category at day one despite oral analgesia (paracetamol for mild pain and co-proxamol for moderate/severe pain). There was no statistically significant effect of treatment at any time-point of assessment (χ^2 test, df=2), although the level of moderate-to-severe pain was generally lower in the gel-pad group from day one onwards.

An ordered comparison of treatment effects was carried out using the Jonckheere-Terpstra test at 48 hours. This showed that there was a statistically significant change in the medians of oedema, bruising and pain across the treatment groups for starting levels of mild oedema (Table 2), no bruising (Table 3) and moderate-to-severe pain ('Table 4), (p=0.017, p= 0.021, p=0.048), respectively in favour of the maternity-gel-pad group. None of the other initial levels of severity showed a statistically significant trend across treatment group medians of the three outcomes at 48 hours and neither were statistically significant differences found at 24 hours or five days.

Maternity gel pads were more highly rated by the women when compared with ice packs and Epifoam (Table 5). In the control groups, women's opinions centred around a median for the category 'fair', whereas the median for the maternity-gel-pad group was in the 'good' to 'very good' category. This difference was highly significant (Kruskal-Wallis test, p<0.0005, df = 2). The Kruskal-Wallis test was used because we had no prior assumption about the ordering of the median rating of the three treatments.

DISCUSSION

Since the pilot study showed that the gel pad was at least as effective as ice packs or Epifoam in relieving perineal trauma, ethical approval was granted to carry out a comparison study of these three treatments. One unavoidable

limitation in the design of this study was the absence of a no-treatment group, so that absolute rather than comparative improvements could not be assessed. This would- have required withholding either one of the two standard localised treatments readily available at the study hospital and was considered unethical, even though this reduced, the power of the trial. In addition, the distinctive shape, size and composition of all three treatments made it: impossible to disguise the type of treatment each woman received, although the midwife assessors were, as far as possible, blind to treatments. Some difficulty was experienced in implementing the initial Study design which was intended to standardise the timing and number of treatment applications because it did not promote a responsive and individualised approach to care. As a consequence, the women were free to choose the number and timing of applications.

It is not standard midwifery practice to provide localised treatments to alleviate perineal trauma outside the hospital setting, therefore, no treatments were available for women to use in their own home. It is, therefore, not possible to confirm from the findings of this study whether there is a need for localised applications after leaving hospital. The levels of pain, oedema and bruising seen in all groups at 48 hours and the continuing level of pain at five days, however, indicate that localised treatment should be provided for use in the woman's own home. The larger than expected number of non-returned record sheets from, the community, which contained all the information for each woman, reduced the amount of data available for statistical analysis. The impact of this loss of data on the findings is impossible to calculate. The majority (70%) of the missing data was from women who resided outside the midwifery service area for the study hospital and this limits the generalisability of the findings to inner city areas. Every effort was made to retrieve this data to no avail, which indicates that future clinical trials will ideally require both a community and hospital-based study co-ordinator to ensure that all record sheets are returned for analysis.

The timing of the first treatment was decided by the individual women, provided this occurred within four hours of delivery. The high level of oedema and pain seen at: initial assessment indicates that localised treatment should be applied as soon as possible after suturing. Since 80% of the women received epidural anaesthesia, these women would be unlikely to experience the full extent of the pain caused by the perinea! trauma within the first: four hours, although perineal oedema was visible. Earlier application of treatment would probably have reduced this initial oedema and contributed to a lower level of pain during the following 48 hours.

The pattern of perineal oedema, bruising and pain seen in this study is consistent with the normal physiological processes associated with wound healing (Mera 1997, Steen & Cooper 1997).

Cold therapy has been shown to attenuate the level of pain, by numbing the superficial tissue surrounding the injury through its action on local nerve fibres and by reducing the level of oedema of soft tissue damage (McMasters 1977). Epifoam has been reported to reduce the levels of perineal oedema and pain,

but will not have the immediate effect of localised cooling through numbing of traumatised tissue. The maternity gel pad has been shown in this study to have a greater effect on perineal oedema, bruising and pain than the comparison treatments. This may be explained by the closer approximation to the traumatised tissues resulting from the use of a specially shaped gel pad. In addition, the gel composition was designed to have a higher thermal capacity than ice and to remain pseudo-plastic at temperatures down to -30°C. This allowed the pad to be moulded around the vulval and perineal regions even at the point of removal from the freezer, unlike the ice packs. It is also likely that the larger surface area of the gel, pads will ameliorate the pain associated with hyperalgesia of the area surrounding the episiotomy wound.

Some women not in the trial and who were suffering from perineal trauma asked midwives if they could use a gel pad. This caused an ethical dilemma and refusing these women made the midwives feel very uncomfortable. It was reported that one Asian woman who spoke limited English had asked for a 'Mary pad'. She had overheard the overall co-ordinator's first name and this in turn was interpreted as the name of the new device.

The movement towards the woman having an informed choice has promoted less intervention during childbirth and this may reduce the severity of perineal trauma (DoH 1993). However, as one midwife stated in the National Childbirth Trust survey concerning the perineum in childbirth, 'No matter how good delivery technique becomes there will always be women who need extra support and care' (Holme & Greenshields 1993). A letter by Jane Hatt published in the New Scientist as recently as 1991 advised. 'A handful of frozen peas placed in a polythene bag and held gently against a bruised and battered perineum post-childbirth, is most soothing and effectively reduces swelling'. The apparent reduction in perineal oedema, bruising and pain found with the maternity gel pad and its higher rating in women's opinions support the need for further investigation of this new form of treatment in both instrumental and non-instrumental delivered women. A large clinical trial to extend this initial study to these groups in both the hospital and home setting has been funded by the NHS Executive in the form of a research fellowship to one of the authors (MPS).

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Table 1 : Characteristics of Treatment Groups

	Ice pack	Epifoam	Gel pad
Original randomisation	38	42	40
Non-returns	10	11	9
Exclusion	4	3	4
Refusals	2	0	0
Final numbers	22	28	27
Spontaneous labour	18	23	21
Induced	4	5	6
Epidural	14	22	21
Forceps	13	23	22
Ventouse	9	5	5
Episiotomy extended	4	1	4
Haemorrhoids	5	5	3

χ^2 test (df=2) for testing the equality of binary proportions for each of the three treatments

Table 2 : Treatment effect on the number (percentage) of women with oedema

	Group 1 (ice pack)		Group 2 (Epifoam)		Group 3 (gel pad)		Statistical significance
	n	%	n	%	n	%	
< 4 hours	17	77	21	75	15	56	*p*=0.19
24 hours	16	73	20	71	19	70	*p*=1.0
48 hours	14	64	17	61	7	26	*p*=0.01

χ^2 test (df=2)

Table 3 : Treatment effect on the number (percentage) of women with bruising

	Group 1 (ice pack)		Group 2 (Epifoam)		Group 3 (gel pad)		Statistical significance
	n	%	n	%	n	%	
< 4 hours	7	32	12	43	7	26	*p*=0.43
24 hours	17	77	26	93	21	78	*p*=0.22
48 hours	18	82	25	89	18	67	*p*=0.13

χ^2 test (df=2)

Table 4 : Treatment effect on the number (percentage) of women with self-assessed moderate/severe pain

	Group 1 (ice pack)		Group 2 (Epifoam)		Group 3 (gel pad)		Statistical significance
	n	%	n	%	n	%	
< 4 hours	6	27	9	32	13	48	*p*=0.29
Day 1	13	59	17	61	14	52	*p*=0.84
Day 2	9	41	10	36	7	27	*p*=0.59
Day 3	10	48	10	39	6	24	*p*=0.25

χ^2 test (df=2)
Note: There was 1 missing value at Day 2 and 5 missing values at Day 5

Table 5 : Women's opinion's on treatment effects

	Poor		Fair		Good		Very good		Excellent	
	n	%	n	%	n	%	n	%	n	%
Group 1 (ice pack)	3	14	13	59	4	18	2	9	0	
Group 2 (Epifoam)	8	29	11	39	5	18	1	4	3	11
Group 1 (gel pad)	1	4	4	15	8	30	9	33	5	19

Kruskal-Wallis test (p<0.0005, df=2)