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TREATMENT OF EPISIOTOMY PAIN WITH COLD PACKS

BY

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Abstract

Pain is a common outcome of episiotomy, a surgical procedure to enlarge the vaginal orifice for delivery. Treatment of episiotomy pain is compromised because new mothers are often reluctant to take analgesics, and topical agents, although readily available, vary widely in effectiveness. Cryotherapy is a commonly used non-pharmacologic method of pain relief. Factors affecting the efficacy of cryotherapy include temperature, method of application, timing and duration of the treatment. The pattern of cold application, that is, whether cold is applied continuously or intermittently for a fixed time interval, may also be an important factor in treatment success. The purpose of this investigation was to examine the effects of continuous and intermittent cold application on episiotomy pain.

Subjects were randomly assigned to either an intermittent or a continuous treatment group. Treatment commenced 30 minutes after arrival in the postpartum unit. Subjects in the continuous group (n=32) received a continuous cold pack for 60 minutes. Subjects in the intermittent group (n=32) received two treatments of 30 minutes duration separated by 30 minutes of no treatment. Subjects in both groups rated their pain five times at intervals during and following treatment. The last pain measure was obtained 26 hours after delivery. All pain scores were recorded on a Visual Analogue Scale with "no pain" and "extreme pain" as anchors on either end of a 10 cm line.

A 2 X 5 ANOVA was employed to test the hypotheses. Neither the main effect of group nor the interaction effect of group by time was significant. The main effect of time was, however, significant. The greatest pain occurred 24 hours after the initial pain measure. The lowest pain occurred during treatment. Post-hoc analyses demonstrated that cold packs provided effective short term pain relief for both groups. Cold packs may have provided a long term effect but this could only be ascertained with a no-treatment control group.

It was also concluded that the same effect could be obtained with continuous or intermittent applications. Use of intermittent cold packs probably accommodates postpartum activities better than continuous application. Intermittent cryotherapy should be provided in conjunction with analgesics during the early postpartum period to prevent the rise in pain evidenced at 24 hours in this study.

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Treatment of Episiotomy Pain with Cold Packs

Episiotomy has been described as the most common operation in obstetrics with the exception of the cutting and tying of the umbilical cord (Pritchard & MacDonald, 1980). The incidence of episiotomy ranges from 14% (Sleep, Grant, Garcia, Elbourne, Spencer, & Chalmers, 1984; Thacker & Banta, 1983) to 90% (Conn, Vant, & Cantor, 1941; Harrison, Brennan, North, Reed & Wickham, 1984; Willmott, 1980).

One of the consequences of episiotomy is mild to severe pain (Bloomfield & Hurwitz, 1970; Kitzinger, 1984; Reading, Sledmere, Cox & Campbell, 1982; Sleep, 1990; Thacker & Banta, 1982). Episiotomy pain may last from several days to months (Kitzinger, 1984; Larsson, Platz - Christensen, Bergman & Wallstersson, 1991; Reading et al., 1982; Sleep, 1984; Sleep et al., 1984; Thacker & Banta, 1983).

During the immediate postpartum period, episiotomy pain is often minimized by both staff and patients (Kitzinger, 1984). While analgesics are widely prescribed during this period, new mothers are reluctant to take them, fearing harm to their infants (Kitzinger, 1984; Reading et al., 1982). Furthermore, nurses are known to administer analgesics sparingly because of inadequate knowledge about pain and fears about addiction (Lander, 1990; Marks & Sachar, 1973).

Medicated or herbal sprays, gels, solutions and creams, which are alternatives to centrally acting analgesics, are available for postpartum use (Rhode & Barger, 1990; Sleep, 1990). These topical agents vary widely in effectiveness, however. As for non-pharmacologic alternatives for pain control, use of heat (heat lamps, hot packs, warm sitzbaths), and cold (cold packs and cold sitzbaths) are the most common treatments.

Decreased nociception through both heat and cold can be explained by the Gate Control Theory of pain. The mechanism of action as proposed by the Gate Control Theory is described in detail in Appendix A.

Proponents of warm perineal treatments suggest that heat provides comfort and healing (Hodgson & Day, 1951; Hodgson & Smith, 1965). During heat application, bloodflow may be increased through dilated arterioles with a resultant increase in the local rate of metabolism. Others argue the initial increase in bloodflow may promote

edema formation with subsequent increase in nociception from pressure on surrounding tissue (Lehmann & deLateur, 1984).

Proponents of cold perineal treatments suggest that cryotherapy causes initial constriction of arterioles which may lead to relief of vascular stasis. This then would result in a decreased rate of fluid formation and improved fluid reabsorption near the site of trauma (Lee & Warren, 1978; Lehmann & de Lateur, 1990; Michlovitz, 1990). Edema and pressure on adjacent tissues would be reduced, resulting in decreased nociception. Despite the logic of this view, the relationship between perineal edema and perineal pain remains controversial (Boutselis & Sollars, 1964; LaFoy & Geden, 1989).

Both clinical and laboratory research have been conducted about the use of cold therapy. Factors found to influence efficacy of cryotherapy treatment include temperature, timing, method of application as well as duration and frequency of treatment.

Comparisons have been made between warm and cold perineal treatments for post-episiotomy pain (Barclay & Martin, 1983; Droegemueller, 1980; Hill, 1989; LaFoy & Geden, 1989; Ramler & Roberts, 1986) as well as cold versus no treatment (Pinkerton & Beard, 1961). Of these, cold treatments have been reported to be the most efficacious in decreasing nociception (Barclay & Martin, 1983; Droegemueller, 1980; Pinkerton & Beard, 1961; Ramler & Roberts, 1986).

Further conclusions about cold therapy cannot be arrived at with confidence as there are many methodological variations among the studies. One variation is the use of a wide range of temperatures for therapeutic cold application. Although temperatures near 0^0 C have been used in most research, 17^0 C has been used for cold therapy (Ramler & Roberts, 1986). Indeed, 17^0 C is considered to be within the therapeutic range, depending on the method of application (Lee & Warren, 1978). However, cold sitz baths seemed to be aesthetically unappealing as most researchers had trouble recruiting subjects (Barclay & Martin, 1983; Droegemueller, 1980; LaFoy & Geden, 1989; Ramler & Roberts, 1986).

Timing of cold application is also an important factor. The most effective treatments were started within hours of delivery and repeated for the first few days (Barclay & Martin, 1983; Droegemueller, 1980; Pinkerton & Beard, 1961). These findings support

the notion that cryotherapy is most effective if started immediately after tissue trauma has occurred (Kalenak, Medlar, Fleagle, & Hochberg, 1975; Lehmann & deLateur, 1990; Schaubel, 1946).

Another factor which is important to the effectiveness of cold treatment is the type of application. Cold applications include immersion in a cold bath, ice packs, and cold packs. Ultimately, the type of application chosen depends on the area to be treated, condition of the person, and the reaction to the treatment (Lee & Warren, 1978). The most common method used is immersion in a cold bath (Lee & Warren, 1978; Lehmann & deLateur, 1990).

Indeed, sitz baths have been suggested as the method of choice for the perineal area (Droegemueller, 1980). As mentioned, ice water sitz baths have little appeal. Alternatively, ice packs and cold packs have been used in the treatment of episiotomy pain (Hill, 1989; Pinkerton & Beard, 1961). While ice and cold packs are more acceptable, one criticism is that they do not mold to ensure contact with perineal tissues (Droegemueller, 1980).

More recently, soft, pliable, sterile cold packs have been made available (Cohn, Draeger & Jackson, 1989). Benefits of these packs include ability to conform to the perineal area, and stability of temperature. These factors allow direct contact of the pack with perineal tissues for a prolonged period ensuring cooling of the deeper tissues.

Besides inflexibility, another disadvantage of the ice and cold packs is that they must be wrapped to prevent tissue damage from extreme cold. However, a thick wrapper may not allow the cold to penetrate the deeper tissues within the allotted treatment time (Hill, 1988).

Whether or not the wrapper is wet or dry is another factor. Covering an ice pack with a wet cloth before applying it to the skin produces a more consistent and pronounced decrease in skin temperature than when it is wrapped in a dry cloth (LaVelle & Snyder, 1985). While the ice and cold packs require a wrapper, soft pliable packs do not.

Duration of treatment also influences effectiveness of cold therapy. Application of cold may be continuous when temperatures are above freezing (Cohn et al., 1989;

McCoy, Selby, Keeping, Lawlis, Gill, & Henderson, 1987). When using ice however, tissues must be prevented from having prolonged contact with ice to avoid skin burn, frost bite, and tissue necrosis. These risks increase significantly with prolonged treatment time (Lehmann & de Lateur, 1990). Generally, ice is applied from 15 to 20 minutes (Lee & Warren, 1978; Lehmann & de Lateur, 1990; McMaster, 1977; Michlovitz, 1990), but ice application for up to 25 minutes is accepted as safe practice (Hillman & Jarman, 1986; Landen, 1967; Lee & Warren, 1978; Michlovitz, 1990).

Sitz baths are recommended to continue for about the same time as ice and cold packs (LaFoy & Geden, 1989; Ramler & Roberts, 1986). Although ice water sitz baths of 10 minute duration have been reported to lower perineal pain perception (Barclay & Martin, 1983), it has been suggested that treatment time for cold sitz baths be at least 20 minutes (Droegemueller, 1980). Neither duration of cold sitz baths nor duration of cold packs have been systematically investigated.

Nor does past research provide definitive answers regarding the optimum frequency of treatment, which is another factor in cold applications. Few sources specifically address frequency of treatment and when they do, frequency seems to be related to the underlying reasons for cryotherapy. Even under the same conditions, recommendations for cryotherapy intervention vary (Basur, Shephard, & Mouzas, 1976; Kalenak et al., 1975). The same inconsistency occurs with cold treatments for post-episiotomy pain (Barclay & Martin, 1983; Droegemueller, 1980; Pinkerton & Beard, 1961).

It is possible that other timing factors (besides overall duration of application) are important factors in the success of cold for reduction of pain. The pattern of cold application, that is, whether cold is applied continuously or intermittently for a fixed time interval, may be an important factor in success. The purpose of this investigation was, therefore, to examine the effects of continuous and intermittent cold application on episiotomy pain.

Methods

Sample

The target population consisted of women who gave birth at a large city hospital and who experienced episiotomy during the birth process. Women who, in addition to

episiotomy, experienced lacerations of the labia, vagina or cervix were also eligible to participate in this study.

As data collection was limited to the hours from 0700 until 2130, to minimize disruption in rest, women who did not deliver between 0600 and 1800 hours were excluded. Women whose medical condition was unstable were also excluded from participating in this study.

Equipment

The Hot/Ice machine supplies and controls hot or cold therapy via flexible packs (Appendix B). This device has been used to apply continuous cold packs after surgery with no ill effects (Cohn et al, 1989; McCoy et al, 1987).

The machine is primed with a mixture of alcohol and sterile water, which circulates from the pump to a pack via rubber tubing. Temperatures of the packs can be adjusted from 3.9^0 C to 40.5^0 C with a variation of plus or minus 1^0 C. The temperature of the perineal packs was set at the lowest setting of 4^0 C in this study.

Packs used in this study measured five inches by ten inches. This was the most appropriate sized pack available for perineal cooling. The pliability of the pack helped to ensure maximum contact with perineal tissues. One sterile perineal pack was provided for each subject in the study.

Instruments

The measurement instrument for pain perception was a visual analogue scale (VAS) (appendix C). This instrument provides a simple yet useful technique for measuring the subjective experience of pain (McCormack, Horne & Sheather, 1988; Reading, 1980). The VAS is a 10 cm horizontal line anchored by descriptive words for minimum and maximum extremes of pain (Scott & Huskisson, 1976). The VAS was placed horizontally in this study.

The VAS has been widely used and its reliability is well established (Huskisson, 1974; McGuire, 1984; Ohnhaus & Adler, 1975). Sensitivity of the VAS has been demonstrated in comparisons with a simple descriptive pain scale (Scott & Huskisson, 1976), and a five point rating scale (Ohnhaus and Adler, 1975).

Procedure

The study was explained to potential subjects who were asked for consent to participate (appendix D). Consent was normally obtained from women who were in active labor and admitted to the labor and delivery unit. Only those who eventually had an episiotomy were included, others were dropped from the study.

Immediately following consent, eligible subjects were trained on the VAS. McGrath's affective faces pain scale has been used successfully to help train subjects and assess their use of the VAS (cited in McGrath & Unruh, 1987). Each subject was shown three randomly ordered faces representing a range of expressions (Appendix E). Each subject was asked to rate the amount of pain perceived in each of the three faces. Correct ranking of the faces on a VAS indicated comprehension of the VAS.

Randomly ordered, sealed envelopes containing the treatment assignments had been prepared prior to the study with the requirement that the two groups would be of equal size. One was drawn for each subject as she was enrolled. With this procedure, subjects were randomly assigned to one of two treatment groups (continuous or intermittent cold treatment).

Thirty minutes after admission to the postpartum unit (following delivery), subjects reported their perineal pain on the VAS (Pain 1). The initial treatment was begun using a Hot/Ice machine after this first pain rating. After 30 minutes of treatment each subject was asked to complete a VAS (Pain 2) at which time the envelope was opened to reveal the treatment group. Thus a partial blind was included in the study as all subjects were similarly treated up to this point.

Subjects assigned to the continuous treatment group continued the cold pack treatment for an additional 30 minutes. Thus the treatment period consisted of 60 minutes of uninterrupted cold pack treatment. Pain was assessed at the end of the 60 minute treatment time (Pain 3). Subjects were also asked to complete a VAS 60 minutes after the cold treatment was concluded (Pain 4) and 24 hours later (Pain 5).

Subjects assigned to the intermittent treatment group were treated in an identical manner except their 60 minute cold pack treatment was interrupted. Their treatment

period consisted of two 30 minute intervals separated by a 30 minute no treatment interval. Pain was assessed prior to (Post-interlude Pain) and at the end of the second 30 minute treatment time (Pain 3). Subjects were also asked to complete a VAS 60 minutes after the cold treatment was concluded (Pain 4) and 24 hours later (Pain 5). Appendix F illustrates the timing of cold on-off and VAS pain measures.

Data were obtained from the patient charts on the following variables: gravida, para, previous perineal surgery, presence of hemorrhoids, obstetrical history, and use of sitz baths and anesthesia and analgesia during this hospitalization (Appendix G).

Research Design

The design employed for this study was a mixed factorial experimental design (Craig & Metze, 1979). There were two independent variables: time (at five intervals - the within subject factor) and type of cold application (intermittent, continuous - the between group factor). The dependent variable was pain perception as measured by a visual analogue scale.

Hypotheses

It was hypothesized that:

(1) Subjects would report significantly less pain at 24 hours than prior to the treatment (main effect of time).

(2) Subjects receiving a continuous cold pack would report significantly less episiotomy pain post treatment than subjects receiving intermittent cold packs (main effect of group).

(3) All subjects would report similar pain at Pain 1 and 2 but subjects receiving a continuous cold pack would report significantly less episiotomy pain at the completion of treatment and 1 and 24 hours after treatment (at Pain 4, 5, 6) compared to subjects receiving intermittent cold packs (interaction of group and time).

Results

Data Preparation

The VAS were scored by measuring, in millimeters, from the 'no pain' end of the VAS to the mark made by the subject. All data were coded and stored in the computer. Data were examined and corrected for coding and key punch errors prior to analyses. Descriptive statistics were computed for all variables and distributions examined.

Sample Characteristics

In total 218 women, admitted to the labor and delivery area were assessed for participation in this study. Sixty-six percent (n = 145) did not meet the criteria for inclusion. Thirty-four percent (n = 73) met the criteria and were invited to participate. Three declined to participate; one had an ice pack applied by a staff member; and five started but did not complete the study. Thus, 64 were enrolled and completed the study (32 per treatment group). Figure 1 illustrates enrollment. The results presented in this paper relate to the 64 subjects who completed the study.

Table 1 describes pertinent obstetrical characteristics of the sixty four subjects by treatment group. Sixty-six percent (n = 42) had carried at least one previous pregnancy to viable gestation. Of those, 35 had experienced perineal sutures during a previous confinement. The mean gestational age at time of this delivery was 39 weeks (standard deviation (SD) = 1.3 weeks).

Length of labor varied among the subjects. Most births occurred spontaneously (n = 41, 64%), while forceps and ventouse deliveries accounted for the remainder. Mean infant birthweight was 3477 grams (SD = 471 grams). Midline episiotomy was done for most subjects. Perineal damage, further than episiotomy, was experienced by 27% (n = 17) of subjects. Typically, repair of the perineum was accomplished only using 3-000 chromic (n = 56). Other sutures used were 2-00 Dexon and 3-000 Dexon.

On postpartum assessment 22% (n = 14) of subjects were found to have hemorrhoids. Sitz bath were used by the majority of subjects (n = 52, 81%) following completion of cold pack treatment but during the twenty-four hour data collection time.

Figure 1

Details About Subject Enrollment

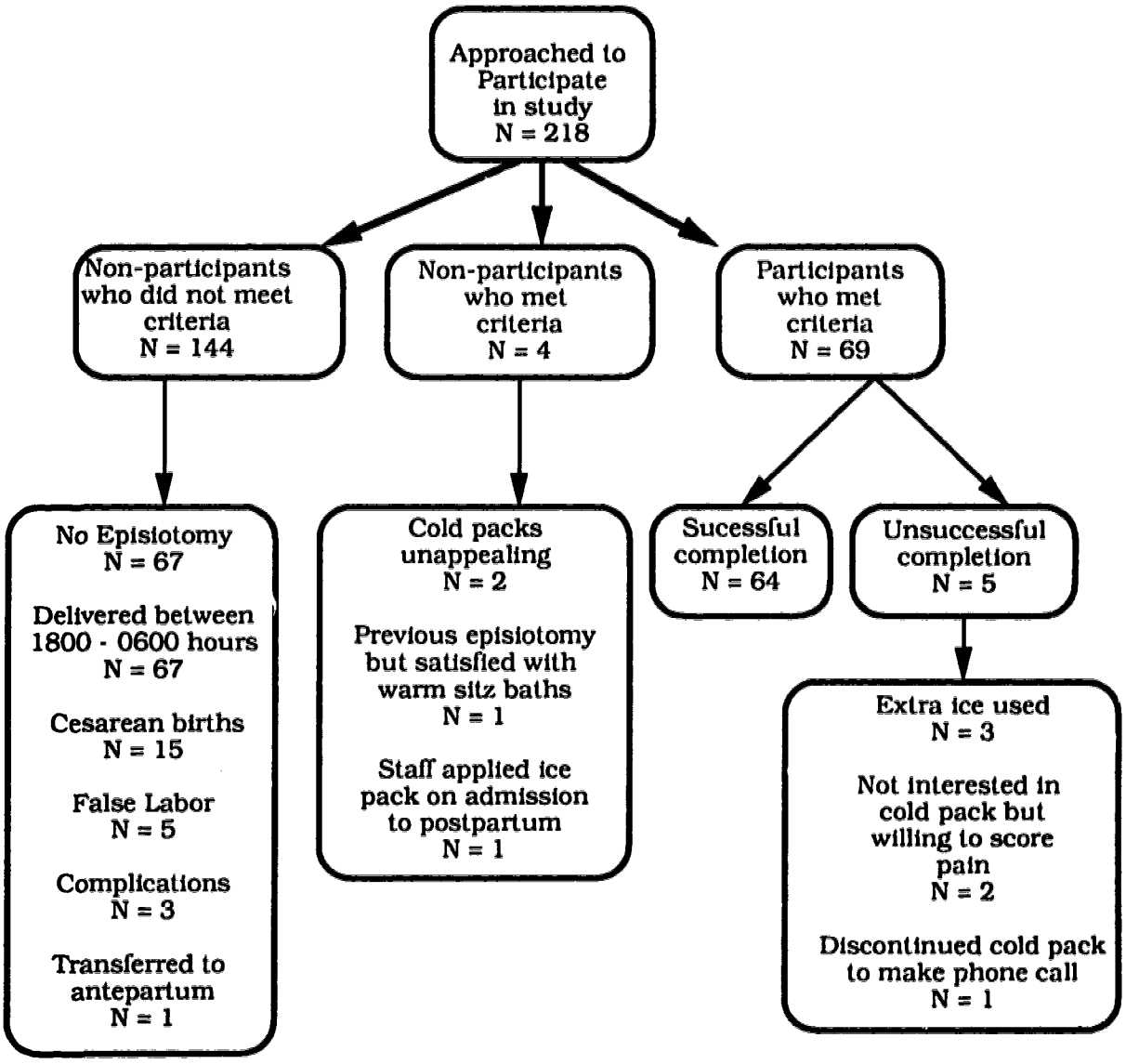


Table 1
Characteristics of Subjects by Group

		Continuous	Intermittent	All Subject
I Frequencies:*				
Gravida	1	12 (18.8)	10 (15.6)	22 (34.4)
	2	7 (10.9)	8 (12.5)	15 (23.4)
	3	7 (10.9)	7 (10.9)	14 (21.9)
	≥4	6 (9.4)	7 (10.9)	13 (20.3)
Para	1	18 (28.1)	14 (21.9)	32 (50.0)
	>1	14 (21.9)	18 (28.1)	32 (50.0)
Gestational age				
in weeks	≤38	10 (15.6)	8 (12.5)	18 (28.1)
	39	11 (17.2)	12 (18.8)	23 (35.9)
	≥40	11 (17.2)	12 (18.8)	23 (35.9)
Previous perineal				
sutures	Yes	13 (20.3)	16 (25.0)	29 (45.3)
	No	19 (29.7)	16 (25.0)	35 (54.7)
Delivery method				
Spontaneous		19 (29.7)	22 (34.4)	41 (64.1)
Operative		13 (20.3)	10 (15.6)	23 (35.9)
Episiotomy type				
Midline		28 (43.8)	28 (43.8)	56 (87.5)
Mediolateral		4 (6.3)	4 (6.3)	8 (12.5)
Perineal Trauma				
Yes		10 (15.6)	7 (10.9)	17 (26.6)
No		22 (34.4)	25 (39.1)	47 (73.4)
Sutures				
3-0 Chromic		30 (46.9)	26 (40.6)	56 (87.5)
2-0/3-0 Dexon		2 (3.1)	6 (9.4)	8 (12.5)
Hemorrhoids				
Yes		8 (12.5)	6 (9.4)	14 (21.9)
No		24 (37.5)	26 (40.6)	50 (78.1)
Sitzbaths				
Yes		25 (39.1)	27 (42.2)	52 (81.3)
No		7 (10.9)	5 (7.8)	12 (18.8)

Table 1

Continued

	Continuous	Intermittent	All Subject
II Means:**			
Length of Labor			
First Stage	416 min. (265)	340 min. (409)	407 min. (342)
Second Stage	48 min. (42)	39 min. (42)	43 min. (36)
Third Stage	6 min. (5)	8 min. (5)	7 min. (5)
Birth Weight	3395 grams (539)	3558 grams (383)	3477grams (471)
Time Elapse from Confinement to First Treatment	132 min. (22)	137 min. (24)	134 min. (23)

* Percent of total in parenthesis

** Standard deviation in parenthesis

Cold pack treatment was started about 2 hours after delivery (mean = 134 minutes, SD = 23). Temperatures of the cold packs were recorded every thirty minutes during treatment. The mean temperatures are reported in Table 2.

Data for certain low frequency categories (gravida, para, and gestational age) were combined in order to compare the treatment groups for equivalence. Chi square analysis was used to compare the treatment groups for gravida, para, gestational age, method of delivery, type of episiotomy, the presence of tears, suture material used, incidence of hemorrhoids and use of sitzbaths. There were no significant differences. Analysis of variance (ANOVA) was used to compare the two groups on length of labor, birthweight, time of starting cold pack treatment, and pump temperature. No significant differences were found.

Effect of Cold Treatment on Episiotomy Pain

A 2 X 5 analysis of variance was used to assess time, treatment and the interaction of time and treatment on episiotomy pain (Table 3). Neither the main effect of group (hypothesis 2), nor the interaction of group by time (hypothesis 3) were found to be significant. The main effect of time (hypothesis 1) was significant ($F = 6.63$, $df = 4$, $p < .001$). Power was computed for each main effect and for the interaction effect. These are reported in Table 3. Mean pain for each time interval and treatment group are reported in Table 4.

As 13 subjects reported no pain prior to their assigned treatment and could, therefore, not have a reduction in pain, the analysis of pain over time was completed without them. The reduced sample size was 51. Significant differences were found for pain over time (as also occurred in the 2 X 5 ANOVA described above). This ANOVA symmary table is presented in Table 5 ($F = 4.55$, $df = 4$, $p < .002$). Post-hoc comparisons indicated that Pain 1 was significantly greater than Pain 3, and Pain 3 was significantly less than Pain 5 (Table 6: Tukey's HSD $p = .05$). Figure 2 illustrates the progression of episiotomy pain over time.

For the intermittent group, an additional pain score had been obtained immediately prior to commencing the second 30 minutes of treatment (Post-interlude Pain). Analysis

Table 2

Mean Pump Temperatures at Time of Pain Assessment for Continuous and Intermittent Groups*

Time	Continuous Group	Intermittent Group	All Subjects
Pain 1 Prior to treatment	4.8 (0.4)	4.8 (0.6)	4.8 (0.5)
Pain 2 After 30 minutes treatment	5.0 (0.7)	5.1 (0.6)	5.0 (0.6)
Post-interlude Pain Prior to second 30 minutes treatment (intermittent group only)	____	4.8 (0.4)	____
Pain 3 After 60 minutes treatment	4.8 (0.5)	4.8 (0.4)	4.8 (0.5)

* Standard deviation in parenthesis, temperatures are in degrees Celsius

Table 3

Analysis of Variance of Time and Treatment on Pain*

Summary Table

Condition	Sum of Squares	Degrees of Freedom	Mean Square	F	*p*	Power (1 - beta)
Main Effect:						
Time	6426.72	4	1606.68	6.63	.001	.99
Group	5.23	1	0	0	.951	.03
Interaction:						
Group by Time	341.20	4	8530.10	.35	.842	.13
Error:						
(within cells)	242.27					

*N = 64

Table 4

Mean Pain * for Time by Continuous and Intermittent Groups

Time	Continuous Group	Intermittent Group	All Subjects
Pain 1 Prior to treatment	21.3 (26.7)	22.4 (26.1)	21.8 (26.2)
Pain 2 After 30 minutes treatment	15.7 (24.2)	17.5 (18.8)	16.6 (21.8)
Post-interlude Pain Prior to second 30 minutes treatment (Intermittent group only)	———	21.9 (24.3)	———
Pain 3 After 60 minutes treatment	14.2 (20.8)	15.3 (15.7)	14.8 (18.3)
Pain 4 60 minutes following treatment	19.5 (20.6)	20.5 (20.9)	20.0 (20.6)
Pain 5 24 hours following treatment	29.6 (20.2)	25.7 (20.5)	27.6 (20.3)

* in millimeters, standard deviation in parenthesis

Table 5

Analysis of Variance of Time on Pain*

Summary Table

Condition	Sum of Squares	Degrees of Freedom	Mean Square	F	*p*	Power (1 - beta)
Main Effect:						
Time	4795.52	4	1198.88	4.55	.002	.94
Error:						
(within cells)	263.46					

* excluding cases with no recorded pain at Pain 1, N = 51

Table 6

Paired Comparisons of Differences Among Means for Five Times+

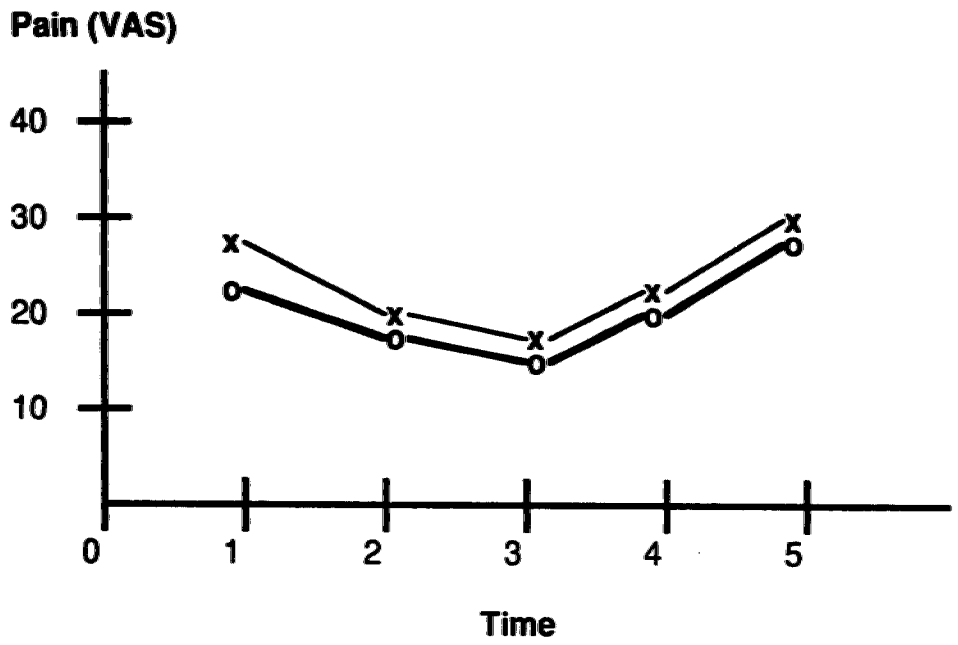
	$\overline{\text{Pain 3}}$	$\overline{\text{Pain 2}}$	$\overline{\text{Pain 4}}$	$\overline{\text{Pain 1}}$	$\overline{\text{Pain 5}}$
$\overline{\text{Pain 3}}$ = 17.3	———	3.3	5.0	10.1*	11.6*
$\overline{\text{Pain 2}}$ = 20.6	———		1.7	6.8	8.4
$\overline{\text{Pain 4}}$ = 22.3		———		5.1	6.7
$\overline{\text{Pain 1}}$ = 27.4			———		1.6
$\overline{\text{Pain 5}}$ = 29.0				———	

+ excluding cases with no recorded pain at Pain 1, N = 51

*Tukey's HSD Test $p < .05$

Figure 2

Mean Pain Over Time



o —— o = all subjects, N = 64

x —— x = excluding cases with no reported pain at Pain 1, N = 51

of variance was used to assess time on episiotomy pain for the intermittent group only. This was not significant (power = .64).

Analysis of variance was used to determine what factors influenced pain at Pain 5. The 24 hour pain measure was chosen because anesthesia effects would no longer be present. Subjects with perineal trauma in addition to episiotomy reported significantly higher pain (mean = 39.9, SD = 20.1) at Pain 5 ($F = 9.56$, $df = 1$, $p \leq .003$), compared with those who experienced episiotomy only (mean = 23.2, SD = 18.6). Other factors which were compared included parity, spontaneous or operative delivery, use of epidural anesthesia , type of episiotomy, previous perineal sutures, additional trauma to the perineum, type of sutures used and sitzbaths use. No significant differences were found in pain scores for subjects grouped by these variables.

Use of Pain Medications

Various kinds of drugs, dosages and routes were used both during labor and during the postpartum period. Medication during labor was administered by nurses, residents, obstetricians and anesthetists. Documentation of route and dosage of medication, especially epidural anesthesia was unsatisfactory. It was not always possible to ascertain whether epidural anesthesia was administered continuously or intermittently. It was also difficult to assess when and how much epidural 'top - up' was given. Consequently, drugs used during labor and delivery were categorized by dosage and route with the total number of people who received each drug, dosage, and route combination. These are presented in Table 7.

Most subjects required analgesics post delivery. The types and frequencies of these analgesics are presented in Table 8. Eleven subjects used no analgesics during the postpartum period. The drug Tylenol #3 was the most common analgesic used by subjects in the postpartum period. Frequencies of use of Tylenol #3 for each group can be found in Table 9.

Information on route and dosage of drugs administered was insufficient to allow conversion of drugs to morphine equivalents for the purpose of statistical analysis. Therefore, analysis of group pain scores with analgesic intake as a covariate could not be undertaken.

Table 7

Frequencies of Drugs Taken Prior to Delivery for Continuous and Intermittent Groups*

Drug	Group	
	Continuous	Intermittent
Epidural with Marcaine	5	5
Epidural with Marcaine and epinephrine	2	2
Epidural with Marcaine and Fentynal	3	5
Epidural with Xylocaine CO2	1	1
Epidural with Xylocaine CO2 and epinephrine	1	1
Epidural with Xylocaine CO2 and Fentynal	2	1
Epidural with Marcaine and Fentynal continuous	1	—
Pudendal anesthesia	5	2
Local anesthesia	20	21
Morphine 2.5 mg I.V. push	—	—
Morphine 7.5 mg I.M.	3	2
Morphine 10 mg I.M.	6	4
Morphine 15 mg I.M.	2	1
Demerol 50 mg I.M.	4	8
Demerol 75 mg I.M.	8	9
Demerol 100 mg I.M.	1	1

*N does not equal 64 because one person may be counted under several different drugs/dosage/route categories.

Table 8

Frequencies of Drugs Taken After Delivery for Continuous and Intermittent Groups*

Drug name	Group	
	Continuous	Intermittent
Morphine 2.5 mg I.V. push	—	1
Morphine 10 mg I.M.	1	1
Demerol 25 mg I.V. push	1	—
Demerol 75 mg I.M.	—	1
Demerol 100 mg I.M.	—	1
Tylenol plain tabs ii	1	1
Tylenol #3 tab i	—	2
Tylenol #3 tabs ii	26	23
Darvon tabs ii	—	2
Codeine 60 mg p.o.	—	1

*N does not equal sixty-four because one person may be counted under several different drugs/dosage/route categories.

Table 9

Frequencies of Administration of Tylenol #3 for Continuous and Intermittent Groups

	Group	
Frequency	Continuous	Intermittent
1	4	5
2	7	6
3	6	9
4	4	1
5	3	2
6	1	1

Discussion

Effect of Cold Pack Treatment

Cold packs provided short-term reduction in post-episiotomy pain as evidenced by a significant decrease in pain after 60 minutes of cold application. The effect in both groups was short-lived as mean pain scores returned to their pre-treatment level one hour after the cold treatment. Indeed, there is evidence that the effect may not last longer than 30 minutes. When the intermittent group was examined separately, there was a trend for pain to increase within 30 minutes of removal of the first cold pack further supporting the notion of a short-term effect.

From the examination of trials, it was found that pain at 24 hours had surpassed pre-treatment pain. This finding was contrary to the prediction that pain would be lower at 24 hours compared to any other time. Since a no-treatment control group was not included in this study, it is impossible to determine if early application of cold did or did not provide long-term benefit. An untreated group may have had significantly more pain than either of the two groups which were treated with cold. A no-treatment control group was not included in this study because ice application is common practice and could not be withheld for this study.

It was predicted as well that early application of continuous cold packs would cause a greater reduction in episiotomy pain at 24 hours compared with intermittent cold. The absence of significant group and group by time effects indicates there was no difference in benefit for continuous and intermittent cold application. Because power was low, several assumptions can be made. One is that the low power led to an incorrect rejection of the null hypotheses (for group and group X time); a Type II error. A second assumption is that any effect identified with a larger sample would be very small as sample size was established on the basis of a forecasted medium effect. A substantial increase in numbers of subjects would be required for power to be adequate. If support were found for the hypotheses with a larger sample size, it seems unlikely that the findings would suggest a clinically relevant difference for continuous compared to intermittent cold application, as the effect would be rather small. Our conclusion, therefore, is that there are no clinically relevant, short-term benefits for early application

of continuous cold packs compared to intermittent cold packs. Either approach will produce similar benefits.

Nevertheless, practical issues may make intermittent cold treatment the preferred approach for episiotomy pain. Several subjects in this study asked to suspend treatments while they attended to personal matters. Thus, post-partum activities are likely to place some restrictions on the pattern of cold pack applications. Intermittent cold packs are less likely to interfere with self care and infant care activities than are continuous cold packs.

Since warm sitz baths were not withheld by nursing staff during this study, most subjects received these treatments following the early application of cold (but only after the 60 minute pain assessment, Pain 5). These occurred equally among subjects in the two groups. The timing of these warm sitz baths were not controlled and the benefits not recorded. Hence, these additional treatments likely would inflate error variance. This source of error could not be extracted and may have resulted in a less sensitive test of the hypotheses related to the benefits at 24 hours.

In future research there should also be an examination of the pattern of discomfort following delivery, including long-term discomforts. The time of greatest discomfort in this study occurred 24 hours after the cold treatment. This suggests the need to apply ice at later intervals in the postpartum period. Cold packs were applied early in this study because early application has been reported to be the best strategy for relieving pain.

The inclusion of a placebo control group would have permitted an assessment of the contribution of subject bias (especially suggestion) to the treatment effect. A placebo-cold treatment was, however, not viable.

There certainly was opportunity for subject bias in this study. Hospital personnel were found sharing favorable comments about cold pack treatments with potential subjects. As well, subjects described the cold packs as soothing and comforting and many asked to have the treatment repeated following completion of the protocol. The apparent popularity of the cold packs may have influenced subjects to score pain lower during cold pack treatment compared to before treatment. However, a similar benefit from suggestion could be expected if cold therapy were used in clinical practice. The

absence of a placebo-control group merely makes it impossible to determine how much of the effect is due to the treatment compared to suggestion.

Influence of Analgesia on Treatment Effect

All subjects received analgesia or anesthesia or both prior to or during the data collection period. The potential influence of these drugs on pain scores remains unclear particularly since no correlation has been reported between amount of analgésia consumed and reported pain (Duggleby, 1990; Finlay, 1990).

Nonetheless, because of incomplete records, drugs could not be used as a covariate. Nine subjects who experienced epidural anesthesia and three subjects who did not experience epidural anesthesia reported no pain prior to the treatment. Therefore, short-term benefit could not be assessed (they had no pain to be reduced). These subjects were not deleted from the study because long-term as well as short-term effects were assessed. However, the no-pain scores likely contributed to low power and/or inflated error variance.

Although analgesic orders were written on all postpartum charts, only three subjects received the maximum amount of analgesics within the 24-hour data collection period. A number of subjects seemed to need reassurance that it was acceptable to use analgesics for pain. Adequate pain relief may be realized if nurses advocate liberal use of pharmacological as well as non-pharmacological methods of pain relief.

Other Factors Influencing Pain

Data were examined to determine if specific variables influenced pain. Findings support earlier research that subjects with additional trauma experienced considerably more pain as compared to subjects who sustained no additional perineal trauma. Whether increased pain is caused by additional perineal trauma or by other factors related to perineal trauma cannot be determined in this study.

Conclusions

Cold packs significantly decrease post-episiotomy pain during treatment and for an indeterminate, but short, period thereafter. No greater benefit was obtained for continuous compared to intermittent cold packs. Nonetheless, an intermittent cold

treatment regime is recommended for its practicality; it interferes less with self and infant care activities than a continuous cold therapy.

Future research may provide more specific answers to the most effective cold pack regime. For now, it is clear that cold packs effectively decrease perineal pain. Therefore, frequent use of intermittent cold packs is recommended for the treatment of perineal pain in the early postpartum period.

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Appendix A

Review of the Literature

The phenomenon of pain has been studied, described and treated for centuries. Pain continues to be experienced universally, yet treatment to date often only serves to minimize rather than alleviate the pain. Postpartum women require a non-pharmacologic method of pain relief because of the potential of pharmacologic preparations to harm the newborn. Personal hygiene and warm sitz baths have been used to promote comfort in healing of traumatized perineal tissues following child birth. More recently, the use of cold temperature treatments have been studied.

Literature pertinent to the treatment of episiotomy pain with cryotherapy is reviewed in this paper. Topics presented in this review include incidence and effects of episiotomy, experience of post-episiotomy pain, the Gate Control theory of pain, and use of cryotherapy following tissue trauma.

Incidence and Effect of Episiotomy

Episiotomy was first described in the mid 18th century. More frequent use of this procedure was advocated throughout the early to mid 1900s when childbirth moved from the home to the hospital and medical intervention became the norm (Simkin, 1989; Thacker & Banta, 1983). In recent years, the routine use of episiotomy has been widely questioned as perceived benefits of this procedure are scrutinized (Kitzinger, 1984; Larsson, Platz-Christensen, Bergman, & Wallstersson., 1991; McGuiness, Norr & Nacion, 1991; Rockner, Wahlberg & Olund, 1989; Sleep et al., 1984; Thorp & Bowes, 1989).

Episiotomy rates vary among practitioners as well as among institutions (Bromberg, 1986; Graham, Catanzarite, Bernstein, Varela - Gittings, 1990; Roberts & Kriz, 1984; Thacker & Banta, 1982, 1983). Some institutions have policies to perform episiotomy routinely while others leave this decision up to the birth attendant. However, even the strongest opponents of episiotomy advocate discriminate use of episiotomy.

Most studies which focus on incidence of perineal trauma, episiotomy and lacerations, are retrospective studies depending on chart information and recall for their

data. Therefore, there are many methodological problems and limitations in these studies. As well, the high rate of episiotomy and lacerations precludes employment of a control group consisting of women who deliver over an intact perineum. Consequently, causal relationships are difficult to establish. However, variables that influence perineal outcome at delivery have been identified and include use of analgesics and anesthetics during labor and delivery, progress of labor, length of labor, paternal distress, presentation, position and birthweight of infant, fetal distress, and expertise of attendant at the birth.

More specific results suggest operative deliveries such as forceps and vacuum extraction may lead to an increased risk of perineal lacerations (McGuinness, et al., 1991; Thacker & Banta, 1983; Walker, Farine, Rolbin & Ritchie, 1991). Epidural anesthesia has been found to result in a higher rate of episiotomy (Larsson et al., 1991; Nodine, & Roberts, 1987) as well as a higher rate of operative deliveries (Harrison, Brennan, North, Reed, & Wickham, 1984). Some found rates of episiotomy and/or perineal lacerations correlate significantly with duration of second stage (McGuinness et al., 1991), while others did not find this association (Thranov, Kringelbach, Melchior, Olsen & Damsgaard, 1990). Findings on whether episiotomy predisposes to lacerations are equivocal. Some studies determined that episiotomy leads to a greater risk of major perineal lacerations (Bek, & Laurberg, 1992; Rockner et al., 1989; Walker et al., 1991; Yancey, Herpolsheimer, Jordan, Benson, & Brady, 1991), but other findings do not corroborate (Larsson et al., 1991; Sleep et al., 1984). There is agreement that primigravidae tend to experience a higher rate of episiotomy and that the underlying causes that lead to perineal trauma are multifactorial.

Research findings are also equivocal in regards to perineal edema and its contribution to perineal pain. Some investigators suggest that the perineal edema correlates with perineal pain (Droegemueller, 1980; Goldstein, Lipman, & Luebehusen, 1977) yet, others report persistence of perineal pain even though perineal edema has decreased (Boutselis & Sollars, 1964; LaFoy, & Geden, 1989). One study reported increased edema and bruising in patients who underwent epidural anesthesia (Harrison et al, 1984). These patients also recorded the highest pain scores for the first two days postpartum.

Part of the difficulty with these studies is lack of a reliable tool to measure perineal edema. Perineal assessment tools have been developed for postpartum use (Davidson, 1974; Hill, 1989). However, additional testing of these tools found them unreliable for use in research (Hill, 1990).

Dyspareunia and perineal insufficiency have been addressed in some studies. Urinary incontinence is the most common measure of postpartum insufficiency and was found to occur in large numbers irrespective of perineal trauma (Sleep, 1984). Others found that long term insufficiency symptoms occurred more frequently in primiparous subjects and in older subjects irrespective of episiotomy (Thranov et al., 1990).

Dyspareunia is reported to occur frequently, in 50 percent of subjects, at some time postpartum with 20 percent of subjects reporting symptoms at three months postpartum (Sleep, 1984). Increased risk of dyspareunia is reported often in subjects who have experienced episiotomy (Kitzinger, 1984), following vaginal tear, and following forceps delivery (Abraham, Child, Ferry, Vizzard, & Mira, 1990).

Several studies have addressed perineal pain during the postpartum period. It is generally accepted that a consequence of episiotomy is pain. This pain is acute in nature (Abraham et al, 1990; Kitzinger, 1984; Harrison et al., 1984; Larrson et al., 1991), with intensity ranging from mild to severe and duration ranging from three days to more than three months (Kitzinger, 1984; Reading, Sledmere, Cox, & Campbell, 1982, Thranov et al., 1990). The trend for higher pain scores in primigravidae is well documented (Adoni & Anteba, 1991; Khan & Lilford, 1987; Larsson et al., 1991; Sleep et al., 1984). It is unclear why this occurs although a longer second stage may be part of the cause. Intensity of perineal pain has been correlated with length of second stage of labor (McGuiness et al., 1991; Thranov et al., 1990), with epidural anesthesia (Harrison et al, 1984; Khan, & Lilford, 1987) and with operative deliveries (Abraham et al., 1990; Reading et al., 1982).

It is clear that women who experience episiotomy as well as lacerations experience more pain. However findings that laceration causes less pain than episiotomy (Kitzinger, 1984; Thacker, & Banta, 1983) have been questioned (Abraham et al, 1990; Harrison et al., 1984; Sleep et al., 1984; Thranov, 1990).

Experience of Postpartum Perineal Pain

The pain experience is more than a simple straight forward response to nociception. The experience of pain is a complex phenomenon involving physiological, psychological and sociocultural factors. Our understanding of pain has changed over the centuries. The origin of the word 'pain' comes from the Greek word 'poine' which means payment or penalty (Mish, 1989). This definition reflects the belief that pain was a punishment for sins (Mersky, 1980). A more contemporary definition: "pain is whatever the experiencing person says it is, existing whenever he says it does" (McCaffery, 1979, p. 11) reflects a more tolerant position. It places responsibility for reporting pain on the individual experiencing pain, the only person who can accurately report pain. Although technology allows for measurement or observation of some aspects of the pain experience in a laboratory setting, these measurement techniques do not transfer well into a clinical setting.

Acute pain, as experienced by postpartum women limits mobility, encourages guarding of the affected area and increases anxiety (Luckmann & Sorenson, 1987; McCaffery, 1979). Reduced mobility caused by pain increases risks of thrombophlebitis and interferes with self and infant care activities. Postpartum mothers are reluctant to take analgesics because they are unsure of their reaction to the medication. They do not wish to be sleepy while holding or feeding their infants, and they fear excretion of drugs through the breastmilk. The extent to which a drug is excreted in the breastmilk and the potential effects on the newborn are legitimate concerns for both mothers and care givers (Kitzinger, 1984; Reading et al., 1982; Sleep, 1990). Perineal pain experienced in both the sitting and lying positions has been found to negatively influence the new mother's sense of general well-being as well as her enjoyment of breastfeeding (Kitzinger, 1984). Anxiety, arising in part due to pain, may interfere with the let-down reflex leading to negative breastfeeding experience with subsequent early cessation of breastfeeding (May & Mahlmeister, 1990).

Postpartum women are discharged home within 24 to 48 hours following delivery. These new mothers are often the primary caregiver and take responsibility for home and family. If pharmacological methods of pain relief are unacceptable to them, then non-

pharmacological methods must be investigated. Reduction of postpartum pain potentially benefits mother, infant and the family.

The Gate Control Theory of Pain

Treatment of pain has been influenced, over time by theories of pain. Each new theory helps create new strategies to deal with the pain experience. The most contemporary and most integrated theory of pain was proposed by Melzack and Wall in 1965. According to the Gate Control theory of pain (Melzack & Wall, 1965, 1988; Wall, 1984) nociceptive stimuli are received by the substantia gelatinosa, located in the dorsal horn of the spinal cord, the cerebrum and the thalamus, the latter two are referred to as central control system. Nociceptive stimuli may be transmitted by both large and small diameter neuron fibers. Large diameter fibers are rapidly conducting, myelinated fibers which modify and inhibit pain transmission in the substantia gelatinosa. At the same time, they transmit directly to the central control system. Small diameter fibers are slow conducting unmyelinated fibers which decrease the inhibitory effect of the substantia gelatinosa on pain transmission and allow impulses to the T cells.

Cells within the substantia gelatinosa have the ability to inhibit nociceptive impulses so that subjective pain perception is decreased or absent. This is known as the gating mechanism. It occurs when cells within the substantia gelatinosa receive more input from large diameter fibers than from small diameter fibers in conjunction with descending inhibiting impulses from the central control system.

The central control system, when triggered, activates both the brain stem reticular formation and the cortex. These brain areas function as subsystems in pain perception and incorporate past experiences, memories, expectations and emotions in the subjective perception of pain. Thus, the central control system identifies and evaluates sensory stimuli received via the large diameter fibers and feedback from the reticular formation and cortical regions and then controls the gating mechanisms in the substantia gelatinosa through descending inhibiting impulses.

If summation of impulses from small diameter fibers, excitatory impulses, is greater than from large diameter fibers, inhibitory impulses, gating does not occur and sensory impulses reach the T cells within the dorsal horn. When the output of the T cells reaches a critical level, the action system is activated. The action system and the central control

system interact with one another and are ultimately responsible for the response elicited by noxious stimuli (Melzack & Wall, 1965; Kim, 1980; Wolf, 1980). Such a response might consist of visually focussing on the stimulus, withdrawing from it and vocalizing one's discomfort.

The major criticism of this theory has focussed on the assumptions made in regards to human neurophysiology (Nathan, 1976; Wall, 1978). Although further research is needed to test assumptions inherent in the Gate Control theory, this theory incorporates the many aspects of the pain experience.

Cryotherapy

Non-pharmacologic pain relief measures are supported by the Gate Control theory. Various new treatments have been employed to aid perineal healing and decrease perineal pain. Ultrasound and pulsed electromagnetic energy have been used with some success (Frank, 1985; Sleep, 1990; Sleep, & Grant, 1988; Ultrasound/PEME for perineal pain, 1989) as well as jet hydrotherapy (Aderhold, & Perry, 1991). The main disadvantage of these treatment modes is that they are not meant for home use. Treatments for postpartum perineal pain must be convenient and safe for use in the home. Ice packs are portable and potentially safe. Instruction must be provided to cover the ice pack to prevent direct contact of ice with the skin.

Application of cold to the skin is said to produce nerve impulses that block deeper impulses originating from the damaged site, thereby decreasing nociception (Melzack & Wall, 1988). In addition, cold application is thought to activate the central control mechanism, thereby closing the gate within the substantia gelatinosa, and inhibiting further transmission of nociceptive stimuli (Melzack, Guite & Gonskor, 1980). Application of cold may also reduce the nociceptive impulses by directly affecting free nerve endings (Bonica, 1990; Michlovitz, 1990). The direct effect of cold on the skin afferents is to decrease their diameter (Lee & Warren, 1978) causing decreased nerve conduction (Lehmann & de Lateur, 1982). Consequently, nociceptive impulse transmission may be completely inhibited leading to a transient peripheral nerve block or it may lead to lessened sensitivity through an elevated pain threshold (Lee & Warren, 1978; Lehmann & de Lateur, 1990; Michlovitz, 1990). Finally, local cooling of tissues causes initial constriction of arterioles leading to relief of vascular stasis, which results

in improved tissue fluid reabsorption together with a decrease in the rate of fluid formation (Lee & Warren, 1978; Lehmann & de Lateur, 1990; Michlovitz, 1990). The end result is minimal blood loss and edema formation with subsequent minimal pressure exerted on tissues adjacent to the injury, thus decreased nociception.

Thus, the use of cold is advocated when nociceptive stimuli and tissue edema are anticipated. Consequently, intermittent application of cold and ice has been used extensively and successfully following sports injuries, in the mobilization of arthritic joints and in the management of spasticity (Basur, Shephard, & Mouzas, 1976; Hartviksen, 1962; Lehmann & de Lateur, 1990; McMaster, 1977; McMaster, Liddle & Waugh, 1978; Michlovitz, 1990). Prolonged cold application has also been used effectively following sports injuries (Basur et al., 1976), knee surgery (Cohn, Draeger & Jackson, 1989), lumbar surgery (McCoy et al., 1987), and other orthopedic surgery (Schaubel, 1946). Findings from these studies suggest that continuous cold therapy increases mobility and decreases analgesic intake during the post-operative and rehabilitation periods.

Droegemueller (1980) compared pathophysiology of perineal trauma following vaginal birth to soft tissue trauma injuries incurred by athletes. Since sports injuries were treated with cold therapy, he deduced that postpartum perineal trauma may benefit from cold therapy as well. Cold therapy in the form of cold packs, ice packs and cold water sitz baths have been used to promote healing and comfort in the early postpartum period with varying degrees of success.

Several studies report no significant decrease in perineal pain following cryotherapy. These results are attributed to several factors: (1) offering a one time treatment (LaFoy, & Geden, 1989), (2) the thick wrapper around the cold pack (Hill, 1988), and (3) the temperature of the water (Ramler, & Roberts, 1986). A one time treatment is not an unusual occurrence in postpartum research. Cold treatments are fairly new in postpartum and little research is available specific to perineal cooling following delivery. In addition, recruitment of potential subjects proved challenging for several investigators using ice water sitz baths post-partum (Droegemueller, 1980; LaFoy & Geden, 1989; Ramler & Roberts, 1986).

The actual time required to cool tissues depends on the thickness of the cutaneous tissues and , when applicable, the cover used to wrap the cold pack. Cold must be applied in a manner that will promote cooling of the deeper tissues for a sufficiently long period of time. Tissues must be exposed to cryotherapy for a minimum of 10 to 20 minutes to ensure cooling of the deeper tissues. Covering an ice pack with a wet cloth before applying it to the skin resulted in more consistent and pronounced decrease in skin temperature than when ice was wrapped in a dry cloth (LaVelle and Snyder, 1985). Despite the advantage of a wet cover, ice is frequently wrapped in a dry towel or dry gauze (LaVelle & Snyder, 1985; Lee & Warren, 1978; Schaubel, 1946).

Temperature of the cold treatment must be cool enough to penetrate the subcutaneous tissues. Although temperatures up to 18^0 C are considered therapeutic in the treatment of soft tissue injuries (Kalenak et al., (1975), ice packs may be used safely with some precautions.

Tissues must be protected from prolonged and direct contact with ice. Although severe adverse effects are rare, cryotherapy is not without side effects (Lehmann, & de Lateur, 1982). Prolonged exposure to ice increases the incidence of frost bite, skin burns, and tissue necrosis (Lehmann & de Lateur, 1990; Michlovitz, 1990). Prolonged ice and cold packs (10 degrees celcius) over or near superficial nerves have been associated with transient nerve palsy in some cases (Drez, Faust & Evans, 1981; Cohn et al., 1989). As well, cryotherapy causes marked vasoconstriction and should not be used in areas where circulation is compromised. Contraindications for cryotherapy include, but are not limited to, presence of peripheral vascular disease, known hypersensitivity to cold, rheumatic diseases, Raynauds disease, and Buerger's disease. Cold hypersensitivity syndromes, although rare have been demonstrated and side effects may be serious (Lehmann, & de Lateur, 1990; Michlovitz, 1990).

Conclusion

There is much interest in the practice of episiotomy. Some long held beliefs about benefits of episiotomy are being questioned. Research is readily available addressing incidence of episiotomy, but scientific evidence is lacking in identifying advantages and disadvantages of this procedure. Some variables have been identified that influence perineal trauma. However, few are able to establish causal relationships. Sound clinical

trials are required to provide answers, albeit these studies are sometimes difficult to execute.

Studies to date have differed in the way episiotomy and lacerations are grouped. Consequently, results are difficult to compare. Clinical studies on perineal outcome are needed that differentiate various types of anterior and posterior lacerations of the perineum and vagina from no episiotomy and episiotomy only. As well, research is needed comparing perineal outcome following medial and mediolateral episiotomies.

Continuing investigation into the pain phenomenon may bring about more effective and acceptable treatments for postpartum pain relief. Few published studies focus on perineal pain relief measures. Although some success has been reported with ice water sitz baths, this method is unappealing to many individuals. Ice packs have also been used successfully but little is known, as yet, what constitutes optimum frequency and duration of treatment.

A review of the literature has provided evidence that much is yet to be learned. Increased knowledge based on sound clinical research is required to improve obstetrical practice thereby improving the outcome for new mothers and their families.

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Appendix B

Hot/Ice Machine

InCare™

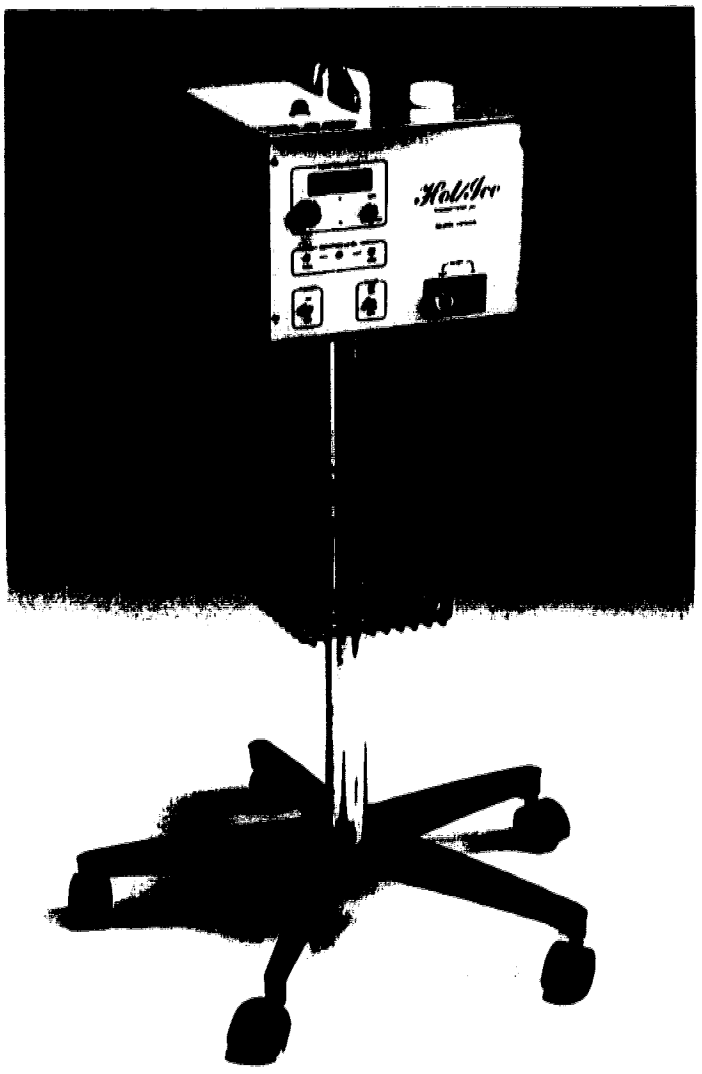
InCare Medical Products offers the innovative Hot/Ice® System for the treatment of various post-surgical and traumatic conditions.

These products utilize state-of-the-art technology with solid state electronics and are designed to deliver predictable, controlled performance for hot or cold therapy.

Hot/Ice® Equipment

The Hot/Ice® Equipment is designed to apply hot or cold therapy. Insulated hoses and blankets ensure controlled, even temperature delivery. Sterile and non-sterile blankets in a variety of shapes and sizes are available to accommodate different applications.

Suggested Uses
Orthopedics
General Surgery
Obstetrical/Gynecologic Procedures
Urology
Plastic Surgery



Features and Benefits

Controlled Cold Therapy
Reduces post-operative pain

Eliminates side-effects associated with pain medications

Decreases swelling

Controls blood loss

Encourages earlier restoration of range of motion to reduce length of hospital stay

Controlled Hot Therapy
Accurate neonatal temperature control

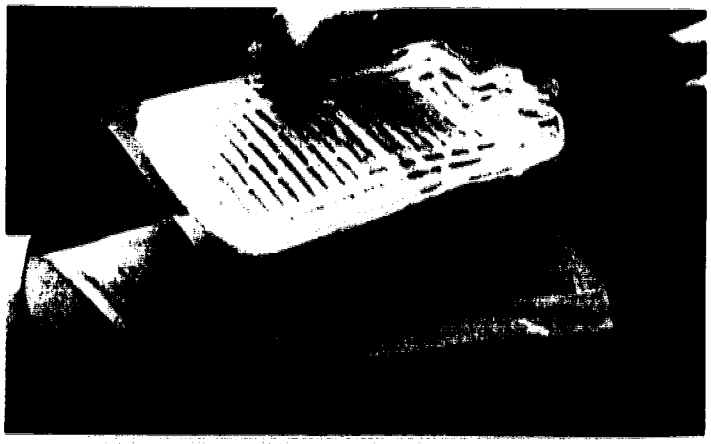
Chronic pain therapy delivered to specific sites

Portable, Lightweight Dual-function Equipment
Easily moved with patient from recovery room to patient's room

Conveniently supplies and controls hot or cold therapy from 40° to 105°F

Accurately controls solution temperature to ±2°F

Easy-to-read digital L.E.D.



Insulated Hoses and Blankets
Ensure controlled temperature delivery

Prevent condensation; affected area stays dry

Accommodate a variety of applications

Flexible, Vinyl Blanket Construction
Conforms to a variety of body parts

Comfortable

May be incorporated into standard post-surgical dressing

Dual Connector Hose
Allows use of 2 blankets simultaneously to maximize cooling of joints

Product Specifications

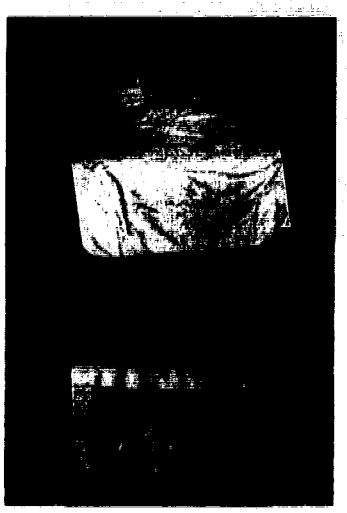
Weight: 21 lbs.

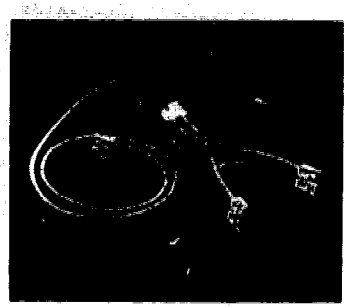
Electrical Rating: 115V, 50/60HZ, 3 Amps
230V, 50/60HZ, 1.5 Amps

Current Leakage: Less than 50 Micro Amps

Reservoir: 16 oz.

Power Cord: 10' Hospital Grade Plug





Blankets and Hoses with Automatic Shut-off Connectors
Allow quick, easy, no leak disconnections

Appendix C

Visual Analogue Scale for Pain Perception

no pain _____ **worst pain imaginable**

Appendix D

Consent for Participation

Name of Study - Treatment of Episiotomy Pain with Cold Packs

Investigator
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Master of Nursing Candidate
Faculty of Nursing
University of Alberta
Phone: (home) 469-7187
(Beeper) 445-1506

Advisor
Dr. Janice. Lander
Professor
Faculty of Nursing
University of Alberta
Phone: 492-6317

Purpose of the Study

To find out how long and how often cold packs should be used on the episiotomy (the cut made to make the birth opening larger).

1. Treatment
   After the baby is born a cold pack will be placed inside your pad against your skin.
   To make sure the cold pack stays at the same temperature it will be connected to a machine which will stand beside the bed.
   The cold pack can be thrown away so that you will be the only person to use it.
   The cold pack will be left on between 20 and 60 minutes and may be put on several times.

2. Collecting information
   You will be asked to mark the amount of pain you have on paper.
   It will take only a minute to mark the amount of pain.
   You will be asked to mark the amount of pain you feel 5 times in the first few hours after you have your baby.
   You will be asked to mark the amount of pain you feel 24 hours later.
   All this information will be collected during the day or evening.

3. Information from the chart

   I will look at your chart to see:

   1) how many times you have been pregnant

   2) how your labor and birth went this time

   3) how you have been doing since the birth

Confidentiality
The records from the study will not have your name on them.
When talks are given about this study, you will not be identified.
Except for your nurse and doctor, no one will know you were in this study unless you tell them.

Risks

There are no risks to you.

Normal care will be given to you during this study.

Being in this study may help you and may help patients in the future.

Voluntary Participation

You do not have to be in this study. Your care will not change if you do not want to be in this study.

If you decide to be in this study you can drop out any time. Just tell me or the nurse looking after you.

You can ask me any questions now or if you have questions later you can call me at 469-7187 or leave a message at 445-1506.

Consent

I, _____, have read this information, and agree to be in the study called, 'Treatment of Episiotomy Pain with Cold Packs'. I have had the opportunity to ask questions about the study and my part in it. I have been given a copy of this paper.

_____ _____

signature of participant date

_____ _____

signature of researcher date

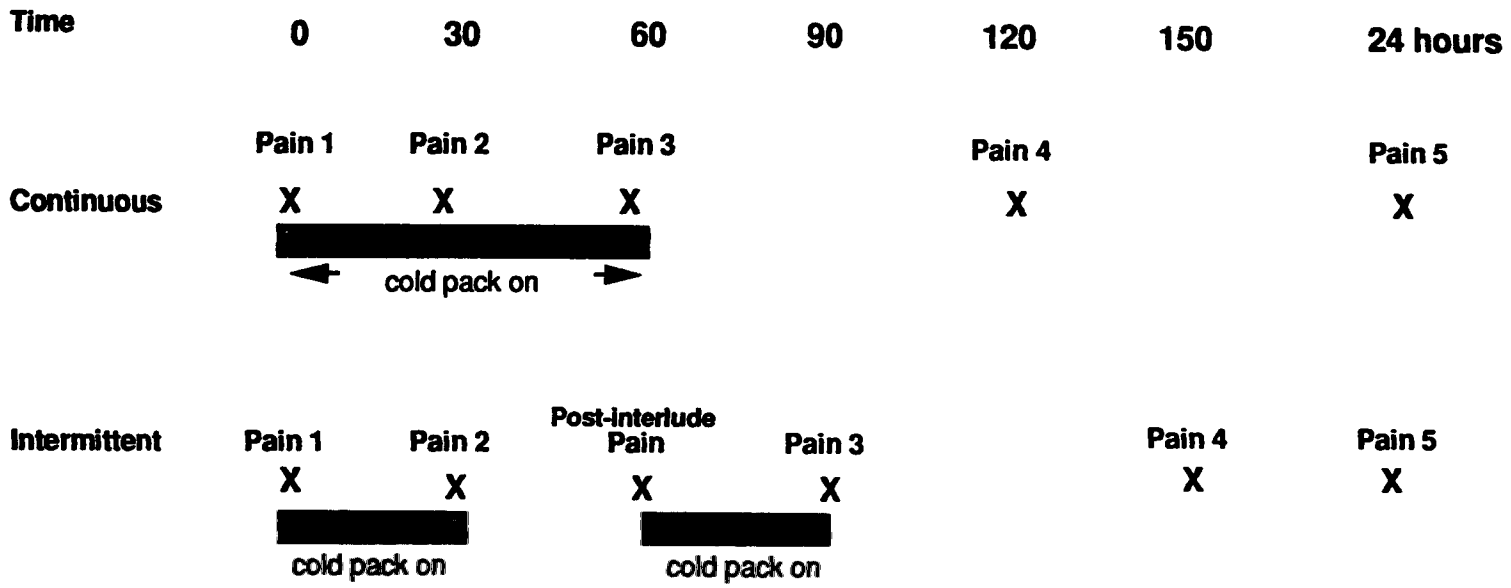
Appendix E

McGrath Affective Faces Pain Scale

Appendix F

Timing of Data Collection and Treatments:

Continuous and Intermittent Groups



Time is the elapsed time from the beginning of treatment. Time is in minutes unless noted otherwise

Intermittent is the cold application regime of 30 minutes with a cold pack and 30 minutes without a cold pack

Continuous is the 60 minutes continuous cold pack

X is the VAS measure of pain perception

Appendix G

Chart Data To Be Collected

DEMOGRAPHICS

Code Number_____ Treatment Group: Continuous / Intermittent.

General History

Gravida

Para

Previous perineal surgery

Pre-existing Medical conditions

Pregnancy related High risk conditions

Length of Gestation

Labor and Delivery

Length of 1st Stage_____ 2nd Stage_____ 3rd Stage_____

Time of full dilatation of cervix_____ Time of delivery_____

Type of delivery_____ Birthweight_____

Type of episiotomy

Presence of laceration Yes_____ No_____

Presence of hemorrhoids Yes_____ No_____

Suture material used to repair perineum

Analgesics/anesthesia used during labor

Time of analgesics/anesthesia