A Randomized Controlled Trial of Nonpharmacologic Approaches for Relief of Low Back Pain During Labor

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BACKGROUND. Low back pain is common during labor. Our randomized controlled trial compared the effectiveness of 3 nonpharmacologic approaches for relief of back pain.

METHODS. A total of 34 women suffering from low back pain during labor were randomly assigned to receive 1 of 3 treatments: (1) intracutaneous sterile water injections (ISW); (2) transcutaneous electrical nerve stimulation (TENS); and (3) standard care, including back massage, whirlpool bath, and liberal mobilization. Women self-evaluated both intensity and affective dimensions of pain using visual analog scales. Their evaluations of control and satisfaction were assessed using adapted versions of the Labour Agentry Scale and the Labor and Delivery Satisfaction Index.

RESULTS. Women in the ISW group rated the intensity and unpleasantness of pain during the experimental period significantly lower than women in the standard care group or the TENS group, ($P = .001$ and $P = .003$, respectively). Similar results were observed for intensity ($P = .01$) and unpleasantness ($P = .03$) of pain assessed just before delivery or request for an epidural. Mean pain intensity at 15 and 60 minutes after randomization was significantly reduced in the ISW group compared with the 2 other groups. There was no significant difference in the 3 groups in the level of control and satisfaction with labor and delivery, but less women in the ISW group indicated that they would like to receive the same treatment for back pain during another delivery.

CONCLUSIONS. Intracutaneous sterile water injections are more effective than standard care (back massage, bath, and mobilization) or transcutaneous electrical nerve stimulation for relieving low back pain during labor.

KEY WORDS. Randomized controlled trials; low back pain; labor; transcutaneous electric nerve stimulation.
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Approximately one third of women suffer from severe low back pain during labor.[1,2] Epidural analgesia, when available, is often the preferred method for relieving this pain. Although very effective, epidural analgesia, particularly when given at a cervical dilatation of 5 cm or less, is associated with an increase in cesarean sections.[3-5] Narcotics are effective in relieving pain but are associated with side effects and potentially deleterious consequences for the newborn.

Nonpharmacologic approaches for pain relief developed in accordance with the Gate Control Theory[1] have been suggested as alternatives. One of these techniques consists of stimulating skin nociceptors by injecting sterile water intracutaneously in the lower back. Intracutaneous sterile water (ISW) injections have been shown to be an effective pain reliever in 4 experimental studies,[6-9] of which 2 were double-blinded placebo-controlled randomized trials.[6,7] Transcutaneous electrical nerve stimulation (TENS) is another approach to pain relief. In a meta-analysis including 6 randomized placebo-controlled trials,[10] TENS received favorable evaluations from women whom reported they would use it during other pregnancies. However, it does not appear to decrease the intensity of the pain or preclude the use of other forms of analgesia. This finding was confirmed in a recent trial.[11]

No previous study has compared ISW with TENS for relieving low back pain during labor. Therefore, we carried out a randomized controlled trial in a rural hospital to compare the effect of ISW, TENS, and standard care (low back massage, whirlpool baths, and liberal mobilization) on low back pain during labor. We also explored the effect of these approaches on requests for other forms of analgesia.

METHODS

Participants and Procedure

Participants were recruited between September 1995 and January 1997 at the Hôtel-Dieu de Montmagny, a rural hospital in Quebec, Canada. Only women considered at low risk were admitted for delivery (>36 weeks' gestation, no obstetric or medical complications). Women in active first-stage labor were informed about the study. Only

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those who subsequently spontaneously complained of low back pain during labor were considered eligible to participate. Of the 304 women informed of the study, 35 (12%) were recruited.

After signing an informed consent form, participants were randomly assigned to 1 of 3 intervention groups: (1) ISW (n = 11); (2) TENS (n = 12); or (3) standard care, including back massage, whirlpool bath, and liberal mobilization (n = 12). The randomization design was developed using a table of random numbers, and balanced in blocks of 6 or 9. A set of sealed, sequentially numbered, opaque envelopes was used for study group assignment.

The following baseline characteristics were collected before randomization: obstetric and sociodemographic characteristics, intensity and affective dimensions of back pain using 10-cm visual analog scales (VAS),[12] and self-efficacy[13] to tolerate labor-related back pain for 15, 60, 90, 120, and 180 minutes, using an 11-point numerical rating scale.

Interventions

Standard care consisted of an initial 15-minute back massage with a moisturizing cream, performed by either a nurse or the woman's partner, followed by continued massage, whirlpool baths, or liberal mobilization (walking or frequent change of position), according to the woman's preference.

For women assigned to the TENS group, the attending nurse or the physician installed 2 pairs of disposable electrodes connected to a 3M portable TENS unit (London, Ontario) on the skin of the lower back. Units were set in normal mode. Initial current intensities from each of the 2 channels were adjusted according to tolerance, starting with a rate of 80 to 125 pulses per second and a pulse width of 60 to 100 μsec. The women were instructed to proceed with subsequent adjustments according to their needs.

Women in the ISW group received 4 intradermal injections of 0.1 cc sterile water in the lumbosacral area in accordance with the technique described by Reynolds.[14] The injections were administered by either the attending nurse or the physician and were repeated on request. They were given during a contraction, to counteract the short duration stinging pain produced by each injection. In the TENS group and the ISW group, women were permitted to use any component of the standard care approach 15 minutes after receiving their assigned interventions. All participants were informed that if, at any moment, they considered their pain relief to be insufficient, they could request any other form of analgesia, including an epidural injection.

Outcome Measures

The main outcome measures were the intensity and unpleasantness of back pain at 15, 60, 90, 120, and 180 minutes after the initial intervention, assessed using a 10-cm VAS. Time and cervical dilatation were recorded if epidural analgesia or narcotics were requested. A research nurse extracted data on other obstetric outcomes from the medical records. Participants completed the French-Canadian

TABLE 1

Baseline Characteristics of the Participants According to Treatment Group (N = 34)

Characteristic	Treatment Group*		
	Standard Care (SD)	TENS (SD)	ISW (SD)
Mean age, years	27 (±6)	27 (±5)	29 (±6)
Nulliparous, %	67	67	60
Mean education level, years	13 (±2)	11 (±2)	13 (±3)
Mean gestational age, weeks	40 (±1)	39 (±3)	40 (±1)
Mean cervical dilatation, cm	3 (±2)	3 (±2)	3 (±1)
Mean intensity of back pain, mm	81 (±14)	77 (±14)	75 (±15)
Mean unpleasantness due to back pain, mm	80 (±15)	70 (±23)	79 (±15)
Back pain worse than abdominal pain, %	50	67	50
Mean ability to tolerate back pain more than 180 minutes, %	54 (±18)	36 (±26)	39 (±32)
Mean time to less then 50% self-efficacy, minutes	98 (±43)	51 (±66)	70 (±69)
Mean birth weight, g	3406 (±425)	3563 (±326)	3387 (±422)
Baby's head in occipito-posterior position, %	33	38	50

Note: All women were French Canadian. Standard care included back massage, whirlpool bath, and liberal mobilization.
TENS denotes transcutaneous electrical nerve stimulation; ISW, intracutaneous sterile water injections; SD, standard deviation.
*Standard care, n = 12; TENS, n = 12; ISW, n = 10.

short version of the Labour Agentry Scale (LAS)[15] and an adapted version of the Labor and Delivery Satisfaction Index (LADSI) within a few days of delivery. These self-administered questionnaires addressed their feelings of control and satisfaction with the delivery. Higher scores on these scales indicated higher levels of perceived control or satisfaction.

Data Analysis

Differences between the 3 groups in terms of sociodemographic and obstetric variables, ability to tolerate pain, and back pain before randomization were examined using a 2-tailed Fisher exact test and analysis of variance for categorical and continuous variables, respectively.

Differences among the treatment groups in both the intensity and unpleasantness of back pain were evaluated by analysis of variance using 2 models: one using the last rating of back pain attained immediately before delivery or a request for epidural analgesia, and the other using the average pain rating during labor before delivery or an epidural injection. A mean difference of 20 mm or more between the groups was considered clinically significant. Baseline intensity of back pain, baseline unpleasantness of back pain, and baseline characteristics not equally distributed among the treatment groups were used as covariables in the models. We simultaneously compared total mean scores of the LAS and the LADSI among the groups using a multivariate analysis of variance. All post-hoc analyses comparing each group with one another were done using Tukey-Kramer tests. Factors predicting the time interval between randomization and the request for epidural analgesia were explored using a stepwise multiple linear regression analysis.

TABLE 2

Outcome Variables According to Treatment Group (N = 34)

Outcomes	Treatment Group* Standard Care (SD)	TENS (SD)	ISW (SD)	P
Primary				
Mean pain intensity during intervention period, mm	79 (±6)	66 (±6)	32 (±6)	.001
Mean pain unpleasantness during intervention period, mm	73 (±7)	78 (±7)	30 (±7)	.003
Last pain intensity before delivery or epidural, mm	82 (±9)	68 (±9)	40 (±9)	.01
Last pain unpleasantness before delivery or epidural, mm	78 (±9)	68 (±9)	41 (±10)	.03
Secondary				
Mean Labour Agentry Scale score	2.6 (±06)	3.4 (±10)	3.5 (±12)	.06†
Mean Labor and Delivery Satisfaction Index score	5.1 (±07)	5.3 (±04)	5.4 (±04)	
Would choose to receive the same treatment for back pain at another delivery, %	92	83	40	.03
Would recommend the same treatment for back pain to a friend, %	92	92	70	.40
Delivery by cesarean section, %	8	33	0	.10
Epidural requested, %	58	83	80	.39
Epidural received, %	33	75	60	.14
Mean cervical dilatation when epidural requested, cm‡	6 (±2)	6 (±2)	6 (±2)	.96
Mean time interval between randomization and request for epidural injection, min‡	103 (±94)	145 (±80)	130 (±68)	.57

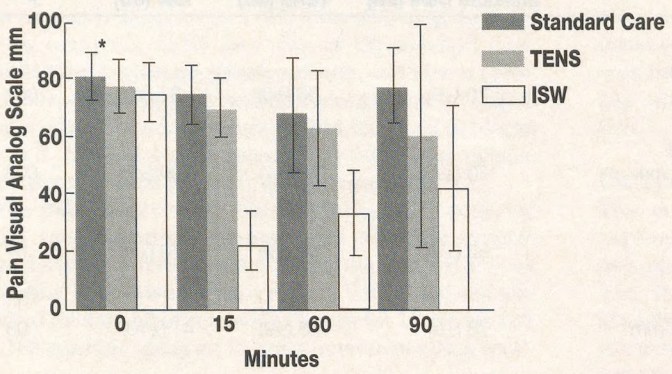
Standard care included back massage, whirlpool bath, and liberal mobilization.
TENS denotes transcutaneous electrical nerve stimulation; ISW, intracutaneous sterile water injections; SD, standard deviation.
*Standard care, n = 12; TENS, n = 12; ISW, n = 10.
†With multivariate analysis of variance model including the Labour Agentry Scale and the Labor and Delivery Satisfaction Index.
‡In the 25 women who requested epidural analgesia.

RESULTS

Of the 403 women admitted for delivery, 304 (75%) were informed of the study; of those women, 45 (15%) complained of low back pain, and 35 (12%) were recruited. One woman randomized to the ISW group was excluded from

FIGURE

The mean intensity of pain (± 95% confidence interval) at 0, 15, 60, and 90 minutes after beginning intervention, by treatment group.



*95% confidence interval.
TENS denotes transcutaneous electrical nerve stimulation; ISW; intracutaneous sterile water injections.

the analysis, as she did not receive the injections because of a precipitate delivery. Table 1 shows the characteristics of the 34 participants according to study group. Although none of the differences among the groups were statistically significant ($P > .05$), mean age was higher in ISW group, education level was lower in the TENS group, and perceived ability to tolerate pain was higher in the standard care group.

Comparison of average pain ratings during the experimental period indicated significant differences among the 3 groups for intensity and unpleasantness (Table 2). Tukey-Kramer test results showed that the women in the ISW group rated the intensity and unpleasantness of pain significantly lower than women in the standard care group or the TENS group. Similarly, comparison of the last pain rating before delivery or the request for an epidural showed significant difference for intensity and for unpleasantness (Table 2). Again, women in the ISW group rated the intensity and unpleasantness of pain significantly lower than women in the standard care group and the TENS group. When controlling for baseline pain (intensity or unpleasantness), age, education level, and mean pain tolerance, all pain rating differences between the groups remained statistically significant.

A reduction of pain intensity in the ISW group was rapidly achieved and was maintained during the first hour of intervention (Figure). After the first hour, the number of subjects was too small for reliable estimation of effect.

Although our results show that women in the ISW group gave lower pain intensity and unpleasantness ratings than women in the TENS group or the standard care group, this intervention may still be less attractive in terms of treatment satisfaction. The multivariate analysis of variance failed to show significant difference in the level of control and satisfaction among the 3 groups as assessed by the LAS and the LADSI, respectively (Table 2). However, the proportion of women who reported that they would like to receive the same treatment for relief of low back pain during another delivery was significantly lower in the ISW group. In the ISW group, the 4 women who *would* receive the same treatment tended, on average, to have more pain before the injections (84 vs 69 mm) and to be better relieved at 15 minutes (17 vs 26 mm) and 60 minutes (15 vs 42 mm) than the other 6 women in the same group. The proportion of women who would recommend the same treatment to a friend was not statistically different among the groups.

No significant differences were found between the 3 treatment groups regarding the proportion of women undergoing cesarean section, the proportion requesting and receiving epidural analgesia, the mean dilatation at the time of the request for an epidural injection, and the mean time interval between randomization and request for an epidural (Table 2). Only 1 woman, in the standard care group, received narcotics during labor.

Finally, we explored which factors predicted the delay before requesting epidural analgesia using multiple linear regression analysis. Variables in the model included treatment group, age, education level, mean self-efficacy to tolerate pain, pain intensity at randomization, mean pain intensity during the experimental period, last pain intensity rating before epidural request, dilatation at randomization, and dilatation before epidural request. The results indicated that that the only significant predictor of time delay was perceived ability to tolerate pain ($F_{[1,19]} = 5.26$, $P = .033$).

DISCUSSION

Our study was the first to compare 3 nonpharmacologic approaches for the relief of low back pain during labor. ISW rapidly and effectively reduced low back pain compared with standard care and TENS, neither of which had any significant analgesic effect.

Blinding the women to the intervention was not possible. A potential bias exists because of differences in expectations of pain relief in the 3 treatment groups; we did not measure this baseline variable. All 3 groups, however, were submitted to at least 1 form of intervention for back pain relief, thereby reducing the difference among the groups due to an active placebo effect. Furthermore, the magnitude of the mean reduction of pain with ISW in the present study (-55 mm at 15 minutes and -45 mm at 60 minutes) is comparable with previous reports by Trolle and colleagues[6] (-53 mm at 60 minutes) and Ader and cowork-

ers[7] (-42 mm at 10 minutes and -35 mm at 45 minutes). The absence of significant effect on low back pain observed with TENS is also similar to earlier studies demonstrating no effect of this approach on labor pain.[10,11] Women in the standard care group, which integrated liberal mobilization as a component of the approach, did not show any benefit in pain reduction. A decrease in back pain of 83% during early labor has been reported with the standing position,[17] but as we did not record the time each woman spent lying down or standing, we cannot compare these results with our own.

Perceived control and overall satisfaction toward labor and delivery do not seem to be influenced by any of the interventions studied, but failure to observe a difference between the groups may be due to a lack of statistical power. Women in the ISW group, however, did appear to be less satisfied with the treatment received. Only 4 of 10 women indicated that they would request ISW again during another delivery. ISW administration is associated with a sharp injection pain lasting 20 to 30 seconds. Although the ISW injections are usually done during a contraction, some women may find the short high-intensity pain of this treatment less acceptable than suffering low back pain. In earlier studies, 68%[6] to 81%[8] of participants said they would request ISW during a future delivery. Cultural disparities and participant selection may account for differences between our subjects and other populations studied. Nevertheless, women should be informed of this isolated[6-9] but bothersome side effect.

We did not observe any statistically significant difference among the groups in the frequency of requests for epidural analgesia, the proportion receiving epidurals, or any other birth characteristics and outcomes. However, this study was primarily designed to evaluate the effect of the 3 treatment approaches on pain and did not have the statistical power to rule out effects on other labor and delivery characteristics. Epidural analgesia may be associated with a higher risk of cesarean section delivery,[3-5] especially if it is administered at a cervical dilatation of 5 cm or less.[3,4] Analgesia with ISW could potentially help to decrease the use of epidural injections or delay their administration. Further studies with larger sample sizes are needed to verify this hypothesis. Our results are consistent with those of Manning and Wright,[18] however, and show that the only significant predictor of time delay of epidural injection was perceived self-efficacy to tolerate pain. This suggests that rather than decreasing back pain levels, a better strategy to delay administration of epidural analgesia would be to increase perceptions of self-efficacy.[13]

According to previous reports, up to one third of women suffer low back pain in labor.[1,2] We observed a lower incidence of this problem in the present study (15%). It was not possible to obtain data on low back pain from women who, at admission, refused involvement with the study. Although this limited generalizability, the internal validity of the data was not affected.

CONCLUSIONS

Among the 3 nonpharmacologic approaches studied for relief of low back pain among low-risk women in active labor (ISW, TENS, and standard care), only ISW proved effective. Back pain is rapidly reduced by ISW, and relief lasts for at least 1 hour. However, this approach may be unacceptable for some women. All patients should be informed of the short-duration stinging pain caused by the injections.

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