Paracervical Block Diminishes Cramping Associated with Cryosurgery

Diane M. Harper, MD, MPH
Kansas City, Missouri

BACKGROUND. The choice of treatment method for cervical intraepithelial neoplasia can be dictated by the lesion size, by comfort of the operator with the technique, by the cost of the procedure, and by patient comfort with the procedure. The purpose of this research was to compare the usual method of cryosurgery (no anesthetic block) with a method using a paracervical block to reduce the pain and cramping associated with cryosurgery.

METHODS. A prospective trial was designed and conducted in a colposcopy clinic. Of the 85 women enrolled in the study, all were immediately given 550 mg of naproxen sodium orally; 40 received no block and 45 received a paracervical block before the cryosurgery procedure. After the procedure, a trained interviewer elicited pain and cramping scores using a visual analog scale. Chi-square, Fisher's exact test, Mann-Whitney *U*, Wilcoxon signed-ranks test, Friedman's two-way analysis of variance, and mutivariate analysis of variance with covariates were used to analyze the data.

RESULTS. Each part of the double-freeze cryosurgical procedure was ranked according to the participants' perceptions of pain and cramping. The cramping after the first freeze was significantly less for women receiving the paracervical block than for the women undergoing the usual procedure (z = -2.44, P=.014). Including the discomfort from the injection itself, the women who received a paracervical block perceived less cramping overall during cryosurgery than the women with no block (z=-2.35, P=.019). The paracervical block did not decrease the pain from cryosurgery according to the participants' rankings of perceived pain.

CONCLUSIONS. A paracervical block is effective in reducing the cramping from cryosurgery.

KEY WORDS. Cryosurgery; pain measured; anesthesia, local; cervical intraepithelial neoplasia. *(J Fam Pract 1997; 44:71-75)*

The choice of a therapeutic modality for cervical intraepithelial neoplasia depends on three factors: the extent of disease in the lower genital tract, the comfort and success of the physician with the procedure, and the woman's ability to tolerate the procedure.

Various methods of cryosurgery have been reported as effective treatment of cervical intraepithelial neoplasia (CIN).[1-13] One of these methods, the 5-minute double freeze with 5-mm lateral extension of freeze, demonstrates superior morphologic and histologic evidence of efficacy,[11,14] but produces significantly more pain and cramping than the other cryosurgical methods.[15] Reducing the pain and cramping associated with this method would allow women to tolerate and to undergo this ablative procedure more comfortably.

The purpose of this study was to compare the pain and cramping perceived by women undergoing the usual practice of cryosurgery with that of women who received a paracervical block before the cryosurgery. Both cohorts of women were pretreated with a nonsteroidal anti-inflammatory drug.

METHODS

Women with the following characteristics were identified as candidates for this study: (1) willing-

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From the Department of Community and Family Medicine and the Department of Obstetrics and Gynecology, University of Missouri-Kansas City School of Medicine, Kansas City, Missouri. Requests for reprints should be addressed to Diane M. Harper, MD, MPH, Dartmouth-Hitchcock Medical Center One Medical Center Dr, Lebanon, NH 03755.

ness and competence to participate; (2) satisfactory colposcopy with biopsy diagnosis of CIN I to CIN III (carcinoma in situ) and a negative endocervical curettage; (3) a cervical transformation zone that could be visualized and covered by the cryoprobe tip; (4) biopsy results that were concordant with the cytology findings; (5) the entire lesion could be covered by the cryoprobe tip and occupied no more than two quadrants of the cervix; and (6) fluency in the English language. Exclusion criteria were: (1) evidence of invasion or microinvasion on the biopsy report; (2) endocervical curettage that was positive for squamous or glandular dysplasia or lesion extending more than 4 mm into the canal; (3) previous conization, electrosurgical loop excision procedure, laser therapy, or hysterectomy; (4) presence of any other genital tract neoplasia; (5) pregnancy; (6) allergy to nonsteroidal anti-inflammatory drugs; (7) known drug abuse; or (8) known central or peripheral neurologic deficit.

Of the 108 women with abnormal cytology seen during the study period, 85 women met the study criteria and completed all parts of the pain and cramping evaluation. The remaining 28 women did not qualify because of their cervical lesion size and were offered a different method of treatment.

To have a power of 80% to detect a difference of 20 mm on the visual analog scale at the .05 level of significance (assuming a standard deviation of 30 mm), the power analysis a priori showed that 35 women would be needed in each cohort. The first 35 women who met the inclusion and exclusion criteria for cryosurgery were treated in the usual manner with no anesthetic block given before cryosurgery. The variances of the actual responses were greater than anticipated in the a priori power analysis, leading to the subsequent enrollment of the next five women qualifying for the study for a total of 40 women in the usual treatment group. This increase in enrollment maintained the power of the study.

The first 40 women given a paracervical block again had variances greater than originally anticipated, leading to a final enrollment of 45 women in this cohort. In this study it was important to make the power calculations both a priori and a posteriori, and to adjust the sample size to ensure large enough cohorts to declare no difference in women's perceptions of pain and cramping block type, ie, no block vs block. Each woman was given 550 mg of naproxen sodium at least 30 minutes before the cryosurgery procedure.

The paracervical block was placed at 9 and 3 o'clock at the cervicovaginal junction to infiltrate the paracervical branches of the uterosacral nerve. The amount of 1% lidocaine with 1:100,000 epinephrine injected in those women receiving a paracervical block was 3.1 cc ± 0.3 cc on each side. This quantity of lidocaine provides up to 70 mg of lidocaine that can be absorbed systemically. Five minutes after the last injection, freezing was initiated.

The cryosurgeries were performed with nippled cryoprobes (Cryomedics, Cabot Medical Group, Langhorne, Pa) cooled with nitrous oxide in large "D" tanks maintained above 40 kg/cm^2 of pressure. Large 25-mm probe surfaces were used in 69.6% of the women; small 19-mm probe surfaces in 25.3%; and a combination of large and small probes in 5.1%. The first freeze took 5 minutes, accomplishing a 5-mm lateral extent of freeze. The cervix was allowed to thaw (usually taking 5 to 7 minutes) to complete pinkness immediately following the 5-minute freeze. The second freeze was immediately initiated for another 5 minutes after cervical thawing.

Within 10 minutes of completion of the cryosurgical procedure, a trained interviewer recorded the woman's perception of pain and cramping associated with four subsections of the procedure. The intensity of pain and cramping were assessed on a 100-mm visual analog scale (VAS), where the 0 anchor represented no pain or cramping and the 100 anchor represented the most severe pain or cramping. The four subsections of the procedure were: (1) the injection itself; (2) the first freeze; (3) the second freeze; and (4) the composite procedure. The patient was also asked to indicate the intensity of cramping of her normal menses as a marker for pain and cramping tolerance. The same wording was used for each patient. No reaffirmation or suggestion of pain or cramping was made beyond acknowledgment of these discomforts.

Statistical Analysis

The categorical demographic and clinical descriptors for women in the two cohorts were performed with chi-square statistics and Fisher's exact test using a one-tailed χ^2=.05 as the level of significance: race, financial classification, gravidity, parity, abortions, birth control method, severity of screening cytology, number of biopsied specimens, severity of histologic diagnosis, and probe size. Chi-square sta-

tistics were also used to detect a difference in women who experienced neither pain nor cramping during the procedure for each cohort. Mann-Whitney *U* statistics were used to compare age, time in the menstrual cycle, and pain and cramping scores between the two block type cohorts. The pain and cramping scores were linearly adjusted for the severity of menstrual cramps usually experienced. Finally, a power analysis for two samples of unequal size was calculated a posteriori to determine that there was a 80% power to detect a difference of 20 mm on the VAS at the .05 level of significance; or a 70% power to detect a difference of 15 mm on the VAS at the .05 level of significance.

The Wilcoxon signed ranks test for matched pairs was used to compare the adjusted intensity of pain and cramping for each subsection of the procedure as univariate analyses. Friedman's two-way analysis of variance by ranks was used to compare the adjusted intensity of pain and cramping across all procedural subsections for each block type. A multivariate analysis of variance with covariates (MANCOVA) was performed to assess whether parity, menstrual pain and cramping, time in the menstrual cycle, or the size of the probe used during cryosurgery affected the differences detected between the two cohorts for the adjusted pain and cramping scores.

RESULTS

Forty women were treated in the usual manner, and 45 received a paracervical block. There was no difference between the two cohorts in the woman's age, gravidity, parity, number of abortions, method of birth control, race, financial classification, time of cryosurgery in menstrual cycle, probe size, or intensity of cramping during menses. The severity of Papanicolaou screening smear, the histologic confirmation, and the number of biopsied specimens taken at colposcopy also did not differ between cohorts.

Over 95% of the women in the study were white; the remainder were African American. Socioeconomic status, based on method of payment, was described as self-pay (57%), Medicaid/Medicare (38%), or commercial insurance (5%). The women's pregnancy histories were 13.1% nulligravid, 23.8% nulliparous, and 39.3% with at least one abortion, induced or spontaneous. Fifty-seven percent of the women were using a combined oral contraceptive and 43% used a progesterone-only contraceptive.

No Pain and No Cramping Scores

A very small percentage of women were completely free of pain and cramping during the cryosurgery procedure (2.6% with no block, 6.7% with the paracervical block). There were significantly more women with no pain and no cramping during the second freeze of the cryosurgery procedure who received the paracervical block compared with no block (χ^2=7.96; *df*=3; *P*=.047 [Table I]). There was, however, no difference between block cohorts in the number of women free of pain and cramping during the first freeze of the procedure and for the overall composite evaluation of the cryosurgery procedure.

Pain and Cramping Scores by Procedural Subsection and Anesthetic Method

The separate pain and cramping scores for each cohort are detailed by procedural subsection in Table 2. Women with a paracervical block had significantly less cramping during the first freeze of the cryosurgery procedure than women with no block (37 vs 50, respectively [*z*=–2.62; *P*=.014]). Overall,

TABLE 1

The Number of Women Without Pain or Cramping, by No Block or Block for Subsection Evaluations

	No Block			Paracervical Block		
Patient Report	**1st Freeze**	**2nd Freeze***	**Composite**	**1st Freeze**	**2nd Freeze***	**Composite**
No pain, no cramping	1	2	1	3	7	1
Pain, no cramping	1	1	1	3	6	4
No pain, cramping	4	6	3	4	2	1
Pain, cramping	34	31	35	35	30	39

*The women with a paracervical block have no pain and no cramping during the second freeze significantly more often than those women with no block (χ^2=7.96; *df*=3; *P*=.047).

TABLE 2

Pain and Cramping Scores Reported by Women After Cryosurgery Procedures

	Pain and Cramping Scores		
	No Block	Paracervical Block	*P* Value*
Pain of injection median (25%ile-75%ile)		21(7-35)	
Cramping with injection median (25%ile-75%ile)		7 (0-19)	
Pain with first freeze median (25%ile-75%ile)	37 (14-59)	26 (5-59)	NS
Cramping with first freeze median (25%ile-75%ile)	50 (30-69)	37 (8-50)	.014
Pain with second freeze median (25%ile-75%ile)	14 (3-38)	19 (1-42)	NS
Cramping with second freeze median (25%ile-75%ile)	25 (10-49)	18 (0-47)	NS
Pain of total procedure median (25%ile-75%ile)	43 (22-66)	44 (9-58)	NS
Cramping from total procedure median (25%ile-75%ile)	50 (32-73)	32 (7-57)	.019

*Mann-Whitney *U* test for comparison between block types.

the composite score indicated that the women with a paracervical block also perceived less cramping than women with no block (32 vs 50, respectively [z=–2.46; P=.014]). The paracervical block offered no other significant pain or cramping relief over the usual method of cryosurgery.

Pain scores by procedural subsection. The pain of the first freeze was significantly worse than the pain of the second freeze for women with no block (37 vs 14, respectively [z=3.98; P<.001]), whereas women with a paracervical block perceived the same amount of pain for the two freezes.

Cramping scores by procedural subsection. The cramping of the first freeze was significantly worse than the cramping of the second freeze for women with no block (50 vs 25, respectively [z=3.35; P<.001)), whereas there was no difference in cramping scores for women with a paracervical block between the first and second freezes of the cryosurgery procedure.

Discomfort of the injection. The injection, placed bilaterally, did cause significantly more pain than cramping (21 vs 7, respectively [z=2.87; P=.004)).

Cramping Scores Compared with Pain Scores by Procedural Subsection and Anesthetic Method

Women who had no block perceived significantly more cramping than pain during the first freeze (50 vs 37, respectively [z=2.25; P=.024]) and during the second freeze (25 vs 14, respectively [z=2.94; P=.003), whereas women with the paracervical block perceived the same amounts of pain and cramping.

Analysis of Variance

An analysis of variance with parity, intensity of menstrual pain and cramping, time in the menstrual cycle, and the size of the probe as covariates was done. None of these variables affected the results of the block type on the pain or cramping perceived by women. The block types accounted for the entire variance.

DISCUSSION

Cryosurgery is associated with pain and uterine cramping.[14, 16] Physiologically, this pain and cramping is mediated through adrenergic parasympathetic pathways terminating at the cervical os as very small myelinated Aδ fibers and larger unmyelinated C fibers which can be stimulated by mechanical, thermal, chemical, or electrical stimuli.[17-19] Cryosurgery causes thermodestruction of cervical tissue, which, in turn, releases prostaglandins and endoperoxides, both of which sensitize such nerve afferents. The feelings of pain and cramping are distinctly different for a majority of women..[15-16]

This research was undertaken because of the increased amount of cramping and pain associated with the 5-minute double freeze compared with other cryosurgery procedures.[15] Because the 5-minute double freeze has been demonstrated to be superior in morphometric destruction of the transformation zone, it is important to make this procedure as tolerable as possible. Other ablative, excisional, and dilational procedures of the cervix generate less pain and cramping when a cervical block has been placed before the procedure.[20-22]

It was not the intent of this study to determine

whether the agent used in the paracervical block was effective, but rather whether a known block type was better than the usual medical practice of no anesthesia. The paracervical block with lidocaine and epinephrine has been effectively documented in multiple gynecologic and obstetrical procedures,[16, 20, 21] and the paracervical block has been shown to be effective even if the anesthetic is only saline.[23] The volume of anesthetic needed to produce an effective block has been driven by the concentration of the lidocaine, so that lidocaine toxicity does not develop.[23] The amount of anesthetic used in this study is well within the range reported by the literature, from 1 to 10 cc on each side.

The cost of the lidocaine anesthetic is regionally variable, but at our institution is less than $1.00 for a 30-mL vial. Thus, the cost of adding comfort to an uncomfortable procedure is minimal for cryosurgery.

One limitation of the study is that it was not a randomized controlled trial. It did, however, allow a comparison of two very similar cohorts of women in a manner that minimized the initial possible prejudicial influence that thinking about block type may have had on the participants' perceptions of the pain and cramping while undergoing the cryosurgery procedures. The power analyses were reviewed throughout the study to ensure that if there was no difference between the paracervical block and no block, the sample size would be adequate.

The paracervical block did decrease participants' cramping during the cryosurgery procedure. This is, in part, because cryosurgery causes more cramping than pain. The pain associated with cryosurgery is minimally perceived. Thus, the paracervical block is more effective than no block in diminishing the cramping perceived during the 5-minute double-freeze procedure of cryosurgery.

Future work by the author will use these perceptions of pain and cramping in a decision model to formally address the decision of choosing whether or not to have a paracervical block prior to cryosurgery.

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