# Cervical Mucosal Block Effectively Reduces the Pain and Cramping from Cryosurgery

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**BACKGROUND.** Cryosurgery is an effective treatment for squamous intraepithelial lesions, but causes pain and cramping regardless of the particular method of cryosurgery used. The purpose of our study was to determine how effective a four-quadrant cervical mucosal block is in reducing the pain and cramping of cryosurgery.

**METHODS.** Of the 112 women presenting for cryosurgery at the teaching clinics of the University of Missouri-Kansas City School of Medicine at Truman Medical Center-East between September 1995 and September 1996, 87 completed the study. The first 39 women were given the standard treatment of no block with the cryosurgery procedure. The subsequent 48 women were given a four-quadrant submucosal block of 1% lidocaine with 1:100,000 epinephrine 5 minutes before cryosurgery. The intensity of pain and cramping of each part of the procedure was measured on 100-mm visual analog scales.

**RESULTS.** The pain and cramping of cryosurgery were significantly reduced ($P < .05$) with the mucosal block for all measured parts of the cryosurgery procedure, including pain of the first freeze (39 mm vs 12 mm), cramping of the first freeze (49 mm vs 13 mm), pain of the second freeze (24 mm vs 12 mm), cramping of the second freeze (32 mm vs 18 mm), pain of the total composite procedure (44 mm vs 28 mm), and cramping of the total composite procedure (51 mm vs 21 mm).

**CONCLUSIONS.** A four-quadrant mucosal block effectively reduces the amount of pain and cramping associated with cryosurgery.

**KEY WORDS.** Cryosurgery; mucosal block; pain; cramping; vaginal smears. *(J Fam Pract 1998; 47:285-289)*

Cryosurgery is an effective method of treating cervical squamous intraepithelial lesions[1-3] and has been used for almost three decades. The actual method of performing cryosurgery has undergone many changes through the years, from single to double freezes, and from a timed 2- to 7-minute procedure to one in which the color change of treated tissue indicates cellular death.[3-17] Regardless of the method of cryosurgery performed, patients will experience pain and cramping during this procedure.[8-20]

The paracervical block has been shown to diminish the cramping associated with a double-freeze cryosurgical procedure.[21] Specifically, the paracervical block effectively diminishes the cramping during the first of two freezes; and over the course of the entire procedure (speculum insertion, block placement, double freezing, and speculum removal), it diminishes total procedure cramping. A submucosal block has been shown to decrease the perception of pain during cryosurgery.[19] The perceptions of cramping associated with the procedure, and the pain and cramping associated with the separate freezes have not been evaluated in previous literature.

The primary purpose of this study was to determine how well a mucosal block diminishes both the pain and cramping of a double-freeze cryosurgical procedure.

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## METHODS

Between September 1995 and September 1996, 112 women presented for cryosurgery after a colposcopic examination to the teaching clinics of the University of Missouri-Kansas City School of Medicine at Truman Medical Center-East campus. To be included in our study, a woman had to meet the following criteria: (1) age 18 years or older; (2) willingness to participate in the study; (3) satisfactory colposcopy with biopsy diagnosis of cervical intraepithelial neoplasia stage I (CIN I) to CIN III and a negative endocervical curettage; (4) a cervical transformation zone that could be visualized and covered by the cryoprobe tip; (5) biopsy results that were concordant with the cytologic findings; and (6) a lesion of less than two quadrants. A woman was excluded if: there was evidence of invasion or microinvasion on the biopsy report; the endocervical curettage biopsy result was positive for squamous or glandular dysplasia; there was a lesion extending more than 4 mm into the canal; she had undergone a previous coniza-

tion, electrosurgical loop excision procedure, laser therapy, or hysterectomy; there was any presence of other genital tract neoplasia; she was pregnant; she had a known central or peripheral neurological deficit; she was allergic to any nonsteroidal anti-inflammatory drugs; or she had a history of drug abuse.

Of the 112 women who were eligible, 3 women had neurological deficits that excluded them from the study; 3 women assigned to the block arm of the study declined to participate in the study; and 19 women had lesions inappropriate for cryosurgical treatment and were referred for excisional procedures. The remaining 87 women were separated according to the date on which they presented for their cryosurgery into two cohorts: treatment with a block and treatment without one.

The standard of care in the clinic was to provide no anesthesia during cryosurgery. The first 39 women enrolled in the study underwent cryosurgery in the standard manner, without any anesthetic block. The following 48 women underwent cryosurgery with an anesthetic mucosal block. The nursing staff personnel changed from the first cohort to the second. The importance of impartiality was stressed and role-played for the second nursing staff. Local institutional review board approval was expedited for this study. One physician, an expert in gynecologic block placements and cervical procedures, performed all cryosurgery procedures.

The cryosurgery was performed with large- (74%) and small-nippled (26%) probes (Cryomedics, Cabot Medical Group, Langhorne, Pa) cooled with nitrous oxide in large "D" tanks maintained above 40 kg/cm$^2$ of pressure. The first freeze took 5 minutes, accomplishing a 5- to 7-mm lateral extent of freeze. The cervix was allowed to thaw to complete pinkness (usually 5 to 7 minutes) before the second 5-minute freeze was initiated.

Each woman received 550 mg of naproxen sodium at least 30 minutes before the cryosurgical procedure. Each woman in the treatment group received a mucosal block of 1.5 mL of 1% lidocaine with 1:100,000 epinephrine in each of four quadrants (12, 3, 6, and 9 o'clock), injected with a 27-gauge needle. The mucosal block was placed submucosally into the superficial stroma. Five minutes elapsed to allow full anesthetic benefit before commencing cryosurgery. Four sites were chosen for injection after a small pilot study indicated superior pain relief with a four-quadrant injection as compared with a two-quadrant injection.

The intensity of the pain and cramping for each part of the cryosurgical procedure was assessed using a 100-mm horizontal visual analog scale anchored on the left side by "no pain or cramping" (0) and on the right side by "most severe pain or cramping" (100). There were nine tick marks between each extreme to indicate each decile. Within 15 minutes of completing the cryosurgery, a trained interviewer presented eight visual analog scales about the cryosurgical procedure for the patient to complete. Each woman marked the intensity of the pain of injection (if applicable), the pain of the first freeze, the second freeze, and the overall procedure. She then indicated the intensity of the cramping associated with each part of the cryosurgical procedure. Each woman also marked on a separate visual analog scale the intensity of cramping experienced during her usual menses. The same interviewer was used for each patient. No reaffirmation or suggestion of pain or cramping was made by the interviewer beyond the acknowledgment of these discomforts.

### Statistical Methods

Thirty-six subjects were needed in each cohort to have a power of 80% to detect a difference of 20 mm of pain or cramping on the visual analog scale with a two-sided .05 level of significance and a standard deviation of 30 mm.

Categorical demographic and clinical variables (gravidity, parity, abortion history, method of payment, severity of cytologic screening results, severity of histologic diagnosis, colposcopic impression, and probe size) were compared between the two groups by chi-square test and Fisher's exact test. Age, number of days since last menstrual period (LMP), the usual amount of menstrual discomfort, and all pain and cramping measures were compared for the two groups using *t* tests. The two-sided significance level was set at .05. Analyses were repeated with nonparametric methods and yielded similar results.

To evaluate whether perceptions of pain and cramping differ according to the menstrual cycle, women were classified into four groups on the basis of days since LMP: days 1 through 7, days 8 through 14, days 15 through 21, and days 22 through 35 of the cycle. Pain and cramping scores were then compared in the menstrual cycle groups and anesthetic block groups using analyses of variance. Women whose LMP was more than 35 days previous were assumed not to be cycling regularly and thus were not included in these analyses. The frequency of experiencing no pain or cramping during the procedure was compared for the two anesthetic block groups by chi-square test and Fisher's exact test.

## RESULTS

Eighty-seven women were enrolled in this study; 39 received no block and 48 received an anesthetic mucosal block. The two groups did not differ significantly in age, gravidity, parity, abortion history, method of payment, or usual amount of menstrual discomfort. The mean menstrual discomfort was 33.2 (standard deviation [SD] = 33.2) for both cohorts combined. The severity of cytologic screening results, the severity of histology, colposcopic impression, and size of probe tip also did not differ significantly between the two groups. Table 1 summarizes the demographic, clinical, and histologic characteristics of the study population.

The mean pain and cramping scores associated with

the mucosal injection were 35.8 (SD = 27.4) and 19.8 (SD = 25.1), respectively, on a visual analog scale of 0 to 100. The mean pain and cramping scores for each individual part of the procedure and the composite scores are shown in Table 2. All comparisons were significant ($P \leq .05$), with the mucosal group consistently reporting less pain and cramping throughout the procedure.

Significantly more pain and cramping were associated with the first freeze than with the second freeze for women with no block ($P = .017$ and $P = .011$, respectively). This difference was eliminated in women with the mucosal block.

The frequency of women reporting no pain or no cramping is shown in Table 3. More than five sixths of the women who did not receive an anesthetic block experienced pain and cramping. Significantly more women in the mucosal block group reported no pain or cramping (22.9%) than in the standard care group (2.6%) (Fisher's exact test, $P < .001$).

Because there is a large standard deviation for both pain and cramping scores regardless of block, two cutoff values for intensity of pain and cramping were used to quantify the decrement in pain and cramping of cryosurgery when the mucosal block was used. A visual analog scale score greater than 50 mm would indicate perception of more severe pain or cramping, and a score of greater than 75 mm would indicate perception of most severe pain or cramping. The frequency of women reporting severe or most severe pain or cramping composite scores (more than 50 mm and 75 mm on a visual analog scale) is shown in Table 4. Significantly fewer women in the mucosal block group reported scores greater than 50 mm for both pain and cramping and greater than 75 mm for cramping ($P = .006$, $P = .005$, and $P = .02$, respectively).

As a secondary goal, we investigated the role of the menstrual cycle in the perceived pain and cramping associated with cryosurgery. Of the total study sample of 87 women, 20 (23%) had their LMP more than 35 days before the cryosurgery procedure and thus were considered not to be cycling regularly. In evaluating total pain and cramping scores according to week of menstrual cycle, no significant differences were found. There was a suggestion of a trend toward higher mean pain scores for women both with and without a block in the first week of the menstrual cycle; but there were insufficient numbers to prove this trend.

**TABLE 1**

**Demographic, Clinical, and Histologic Characteristics of Participants in Cervical Mucosal Block Study (N=87)**

| Characteristic | Participants Who Received No Block (n=39) | Participants Who Received Mucosal Block (n=48) |
|---|---|---|
| Mean age, years (SD) | 26.0 (7.0) | 26.3 (7.2) |
| Nulligravid, % | 10.3 | 12.5 |
| Nulliparous, % | 20.5 | 16.7 |
| One or more abortions, % | 35.9 | 39.6 |
| White, % | 97.4 | 95.8 |
| Mean menstrual cramping, VAS score (SD) | 33.3 (34.8) | 33.1 (32.8) |
| Histologic confirmation, no. (%) | | |
| HPV | 8 (20.5) | 4 (8.3) |
| CIN I | 18 (46.2) | 29 (60.4) |
| CIN II/CIN III | 12 (30.8) | 15 (31.3) |
| Other | 1 (2.5) | 0 |
| Method of payment, % | | |
| Medicaid | 33.3 | 41.7 |
| Self-pay | 61.5 | 54.2 |
| Commercial insurance | 5.1 | 4.2 |

Note: There are no statistical differences between the women with a mucosal block and women without a block.
VAS denotes visual analog scale from 0 (no pain or cramping) to 100 (most severe pain or cramping); HPV, human papillomavirus; CIN, cervical intraepithelial neoplasia.

## CONCLUSIONS

Cryosurgery is associated with pain and uterine cramping.[21] The visual analog scale is one method to assess pain and cramping. This measure, a horizontal scale from 0 to 100 mm, has been successfully used in many areas of medicine for both immediate and past recall of pain and discomfort; it is reliable, easily understood and implemented, and reproducible.[22-30] Without any anesthetic block, 97% of women felt either pain or cramping; and approximately 50% of women without any block reported more than 50 mm of pain or cramping intensity during the procedure. The pain and cramping are mediated through the adrenergic parasympathetic pathways terminating at the cervical os as very small myelinated Aδ fibers and larger unmyelinated C fibers that can be stimulated by mechanical, thermal, chemical, or electrical stimuli.[27-29]

Cryosurgical treatment has evolved as our understanding of the association of human papillomavirus (HPV) with cervical cancer has evolved. At the time of this study, it was appropriate to treat CIN I or HPV disease. This practice is undergoing scrutiny as we learn more about whether there are any benefits to treating CIN I or HPV disease.

The mucosal block dramatically reduced the amount of both pain and cramping associated with cryosurgery in all phases of the procedure. In the literature, a study measuring only the pain of cryosurgery showed that a

**TABLE 2**

**Intensity of Pain and Cramping Associated with Cryosurgery Measured on a Visual Analog Scale From 0 (No Pain or Cramping) to 100 (Most Severe Pain or Cramping)**

| | No Block, mm mean (SD) | Mucosal Block, mm mean (SD) | *P* Value |
|---|---|---|---|
| First freeze | | | |
| Pain | 38.8 (28.7) | 12.2 (21.6) | < .001 |
| Cramping | 48.5 (28.0) | 11.7 (19.9) | < .001 |
| Second freeze | | | |
| Pain | 23.8 (26.1) | 13.3 (23.1) | .05 |
| Cramping | 32.1 (28.1) | 17.8 (29.3) | .02 |
| Total procedure | | | |
| Pain | 43.5 (29.1) | 27.9 (27.5) | .01 |
| Cramping | 51.4 (28.1) | 21.1 (26.7) | < .001 |

SD denotes standard deviation.

**TABLE 3**

**Frequency of Pain and Cramping Occurrence, by Composite Score for Total Procedure**

| | No Block no. (%) | Mucosal Block no. (%) |
|---|---|---|
| No pain, no cramping | 1 (2.6) | 11 (22.9) |
| No pain, cramping | 3 (7.7) | 1 (2.1) |
| Pain, no cramping | 1 (2.6) | 5 (10.4) |
| Pain, cramping | 34 (87.2) | 31 (64.5) |

Note: Scores according to Fisher's exact test comparing block types for no pain and no cramping; $P < .001$.

**TABLE 4**

**Frequency of Pain and Cramping Intensity Levels, by Composite Score for Total Procedure**

| Intensity Level* | No Block no. (%) | Mucosal Block no. (%) | *P* Value |
|---|---|---|---|
| > 50 mm | | | |
| Pain | 21 (54) | 9 (19) | < .001 |
| Cramping | 19 (49) | 7 (15) | < .001 |
| > 75 mm | | | |
| Pain | 6 (15) | 2 (4) | .07 |
| Cramping | 12 (31) | 2 (4) | .02 |

*Greater than 50-mm intensity indicates severe pain or cramping; >75 mm intensity indicates the most severe pain or cramping associated with cryosurgery.

submucosal block placed only at 2 and 10 o'clock showed a similar decrease in pain.[19] Average scores for the intensity of the residual pain and cramping perceived after the mucosal block were less than 18 mm for the individual procedural components and less than 28 mm for the overall procedural pain and cramping. Parts of the residual intensity may be explained by the speculum placement and removal, often commented on by women during their examination and commensurate with the minimum discomfort a score of 18 mm would represent.

The four-site mucosal block appears to be more effective than a paracervical block to reduce the pain and cramping of cryosurgery,[21] and appears to be at least as effective as the literature-supported two-site–injection mucosal block.[19]

Since the 1% lidocaine solution used in this study was so effective, a physician choosing to use a 2% lidocaine solution should see similar results, but should be aware of the total dose of lidocaine available for systemic absorption. If 6 mL of 2% lidocaine is used, rather than the 1% used in this protocol, there will be 120 mg of lidocaine, a cardioresuscitative dose, available for systemic absorption.

The mean recorded pain score of the injections delivering the mucosal block was 36 mm, yet was perceived as more than 50 mm in one third of the women receiving the block. Of this third, 80% reported the first cryosurgery procedure as less painful than 50 mm, showing that the block was quite effective despite the initial high pain intensities of the injection; and 20% of this one third experienced less than 50 mm of pain during the second cryosurgery procedure. To describe to a woman how painful she can expect the injections to be, a physician may state that the mean pain of the injections is similar to the mean discomfort the woman experiences with her menses (36 mm vs 33 mm).

Dentists use a topical benzocaine to prepare the gingival mucosa for injection. Topical benzocaine gels have been tested to reduce the pain of cervical biopsies and endocervical curettages[20] and have been found not effective. The aerosol form of benzocaine anecdotally causes vaginal burning. At this time, there is no evidence to support the use of a topical agent to reduce the pain of the cervical mucosal injections.

## Study Limitations

The population of women undergoing cryosurgery in this study was more than 97% white. Perceptions of pain and cramping can be specific to racial and ethnic cultures, limiting the generalizability of these results to other population groups.

This study was designed to test the current method of standard of care for cryosurgery against the mucosal block. A specific randomization scheme would have made the comparison between the two groups methodologically tighter, eliminating possible intergroup differences in nursing-physician-patient interactions. This study did not have a placebo control group, such as a saline mucosal injection

group; therefore, it is not possible to state whether it was the anesthetic properties of lidocaine or the volume bolus that produced the decrease in pain and cramping.

## SUMMARY

Providing excellent women's health care means not only being technically proficient at treatment procedures, but also being sensitive to the comfort of the woman during the procedure. The mucosal block provides significant pain and cramping relief during cryosurgery.

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