

Is it Cost-Effective to Use a Mucosal or Paracervical Block to Relieve the Pain and Cramping from Cryosurgery?

A Decision Model

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BACKGROUND. Cryosurgery is an effective treatment for cervical intraepithelial neoplasia, but it often causes pain and cramping. Both paracervical and mucosal blocks have been shown to provide relief from the pain and cramping associated with cryosurgery. The purpose of this article is to recommend the use of mucosal block, paracervical block, or no block on the basis of which procedure minimizes the costs of averting the pain and cramping that a woman experiences during cryosurgery.

METHODS. A decision model was constructed encompassing the options (mucosal block, paracervical block, or no block) that a physician has when performing cryosurgery. The 4 possible outcomes for a patient undergoing cryosurgery were diagrammed as: (1) no pain and no cramping; (2) only cramping; (3) only pain; and (4) both pain and cramping. Each of these outcomes was measured on a 200-mm horizontal visual analog scale. Costs were derived for cryosurgery from the office perspective. Sensitivity analyses were conducted to test the robustness of the analysis.

RESULTS. The base case analysis showed that the lowest cost per pain and cramping averted was for women who had a mucosal block before cryosurgery (\$153.87), compared with women with a paracervical block (\$183.24) and women with no block (\$218.83).

CONCLUSIONS. A mucosal block is the most cost-effective method to avert the pain and cramping from cryosurgery in women who have taken a nonsteroidal anti-inflammatory drug before the procedure.

KEY WORDS. Decision analysis; cryosurgery; cervical intraepithelial neoplasia; pain; cost-effectiveness. (*J Fam Pract* 1999; 48:285-290)

Cryosurgery is one of many effective treatment modalities for cervical intraepithelial neoplasia. The intent of the freeze is to kill the cells of the cervical transformation zone to a depth of at least 5 mm.^{1,3} Cellular death is accomplished by 2 rapid freezes separated by a natural unaccelerated thaw. This double freeze can cause pain or cramping or both.⁴

Several studies have shown that topical anesthetic agents do not control this pain and cramping.^{5,8} Two studies have been published addressing the pain and cramping of the 5-minute double-freeze cryosurgery method. Both studies concluded that some type of block provided more relief from the pain and cramping than no block at all when the patient has been pretreated with a nonsteroidal anti-inflammatory drug (NSAID). The mucosal block provided significantly more relief from pain and cramping after each freeze of the procedure than was

experienced with no block⁹; and the paracervical block provided relief from cramping after the first freeze and after the entire procedure.¹⁰ There were no adverse reactions, such as hypotension, vasovagal seizures, or uncontrolled bleeding from the block site during the cryosurgery procedures in any of the women.

Women were clearly able to distinguish the difference between pain and cramping associated with the block placement, the first 5-minute freeze, the second 5-minute freeze, and the whole procedure. It is the woman's experience of the entire cryosurgery procedure that is most relevant to reducing the overall pain and cramping associated with it.

The physician needs to know from the office perspective the cost of averting the woman's pain and cramping due to cryosurgery before he or she can decide whether it is worthwhile to place the block. The purpose of this paper is to discuss the block option (mucosal, paracervical, or none) most useful for minimizing the cost of averting the pain and cramping of cryosurgery.

METHODS

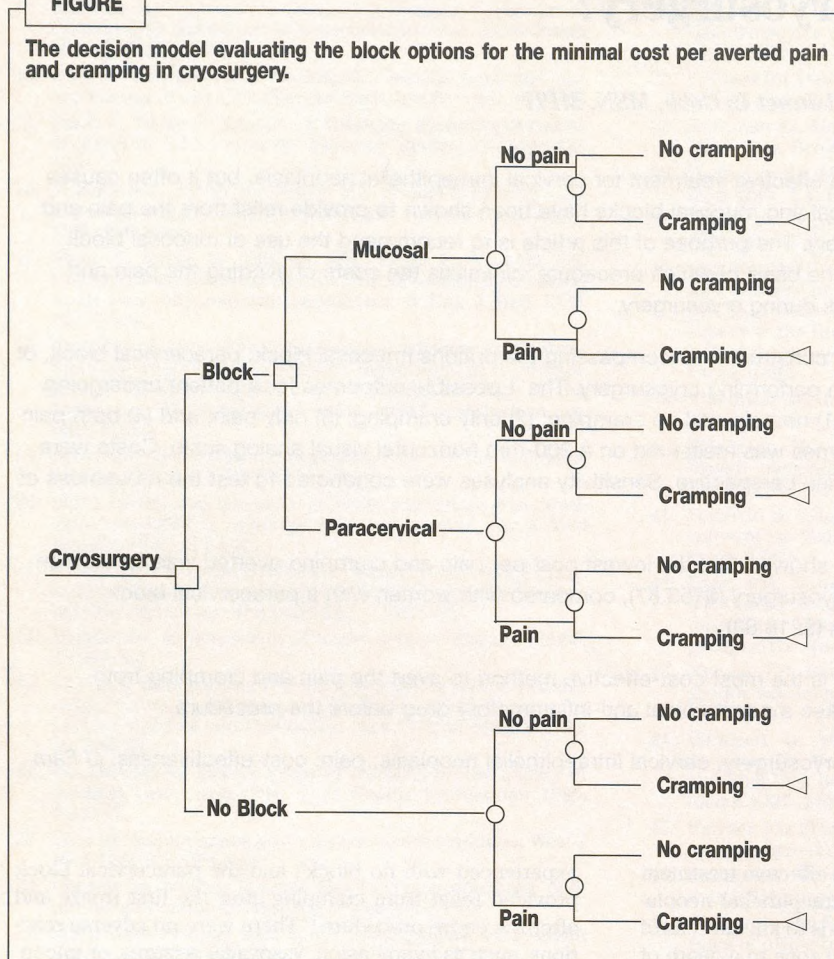
A cost-effectiveness analysis was undertaken with a decision model created using DATA software (version 3.0.17, TreeAge, Williamstown, Mass). All decision choices

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FIGURE

The decision model evaluating the block options for the minimal cost per averted pain and cramping in cryosurgery.



assumed that the patient would receive an NSAID before cryosurgery. One arm of the model represented each block option. The subtree, which is repeated for each arm, details the 4 possible pain and cramping outcomes: no pain and no cramping; only cramping; only pain; and both pain and cramping. A diagram of the model is shown in the Figure. We calculated the costs per pain and cramping averted for the 2 block types, mucosal and paracervical, and compared them with those of no block. We evaluated the 5-minute double-freeze method from the cost perspective of the physician's office.

THE SCORES FOR AVERTED PAIN AND CRAMPING

In our previous work,^{9,10} a trained interviewer evaluated the separate experiences of pain and cramping immediately after the entire cryosurgery procedure. Each patient was asked to separately evaluate the pain and cramping of the entire procedure, including any caused by the injection, using 2 visual analog scales (VASs). Each VAS is a 100-mm linear scale anchored by 0 (no pain or cramping)

and 100 (the worst pain or cramping). The outcome measurements for the combined score for pain and cramping were units along each VAS. These outcome measurements were derived in 2 steps. The individual pain and cramping scores of each patient were summed for a pain and cramping score on a 200-mm scale. This combined score was averaged over those women in each of the 4 separate outcomes: no pain and no cramping; only cramping; only pain; and both pain and cramping. For women who experienced neither pain nor cramping, the mean of the sum of the rankings was always 0. For women experiencing only cramping, the mean of the sum was the mean of the cramping scores on a 200-mm scale. For those experiencing only pain, the mean of the sum was the mean of the pain scores. For women experiencing both pain and cramping, the mean of the sum of the separate pain and cramping scores was a score between 0 and 200.

These scores were transformed into a score of averted pain and cramping by dividing the mean VAS pain and cramping score by 200 and subtracting the ratio from 1. A score of 1 means that 100% of the pain and cramping due to cryosurgery was averted; a score of 0 means that no

pain and cramping was averted. The base case outcome values derived from data from the previous studies, as well as the scores of averted pain and cramping used in the base case, are listed in Table 1.

PROBABILITIES OF PAIN AND CRAMPING DURING CRYOSURGERY

The probabilities of each of the 4 outcomes (no pain and no cramping, only cramping, only pain, and both pain and cramping) occurring for the base case scenario were also derived from data from the previous studies and are presented in Table 2. The majority of women, regardless of block or type of block, experienced a combination of pain and cramping: 65% of women with a mucosal block, 87% of women with a paracervical block, and 87% of women with no block.

COSTS ASSOCIATED WITH CRYOSURGERY

The costs included in this model are only those pertaining to an ambulatory clinic for performing cryosurgery. No indirect costs were included, because they would be

TABLE 1

Mean Pain and Cramping Scores for Each Outcome on a 200-mm Scale and the Mean Averted Pain and Cramping Scores Used in the Base Case

	Mucosal Block		Paracervical Block		No Block	
	Pain and Cramping Score	Averted Pain and Cramping Score	Pain and Cramping Score	Averted Pain and Cramping Score	Pain and Cramping Score	Averted Pain and Cramping Score
No pain and no cramping	0	1	0	1	0	1
Only cramping	29	0.855	45	0.775	50	0.750
Only pain	22	0.890	19	0.905	7	0.965
Pain and cramping	72	0.640	83	0.585	105	0.475

Note: The mean averted pain and cramping scores were calculated as: $1 - \left(\frac{\text{mean pain and cramping score}}{200 \text{ mm}} \right)$

A final score of 1 indicates that 100% of the pain and cramping was averted; 0 indicates that none of the pain and cramping was averted.

equally distributed across all arms of the model. No discount rate was included because the time frame of the analysis is only the time required to perform cryosurgery. The costs used in the base case analysis are presented in Table 3.

The costs of the cryosurgery equipment system included the cryogen regulator, the 4 classic cryosurgery tips, and the maintenance agreement. This equipment was given the standard 5-year accounting life, and its cost was calculated on a per-procedure basis. The ongoing cost of the nitrous oxide tanks was modeled as a function of the cost per liter of nitrous oxide, the number of liters of nitrous oxide per full tank, the average number of cryosurgeries performed per full tank, and the number of cryosurgeries performed per year. The additional time needed to place the blocks was modeled as a function of the salary and fringe benefits of the clinician performing the cryosurgery.

SENSITIVITY ANALYSES

The lowest expected cost to avert pain and cramping during cryosurgery was calculated for the base case. One-way sensitivity analyses were run to determine whether the results of the analysis were dependent on any of the pain and cramping scores, any of the probabilities of the pain and cramping outcomes, or any of the costs. The pain and cramping scores were varied by the standard deviation of

the mean pain and cramping outcome score. The probabilities were varied by 500% of the base case value to robustly approximate the 95% confidence intervals of the probabilities. The costs were varied individually as follows. The cost of the cryosurgery system was varied

TABLE 2

Probabilities Used in the Base Case Analysis

	Mucosal Block	Paracervical Block	No Block
No pain (regardless of cramping)	.250	.111	.103
No pain, no cramping	.917	.200	.250
No pain, cramping	.083	.800	.750
Pain (regardless of cramping)	.750	.889	.897
Pain, no cramping	.139	.025	.029
Pain and cramping	.861	.975	.971

TABLE 3

Cost Assumptions for the Base Case Analysis

Process	Cost
Cryosurgery system, in dollars	1500
Nitrous oxide cryogen, per liter, in dollars	2.50
Yearly salary and fringe benefits of the clinician performing cryosurgery, in dollars	150,000
Lidocaine and syringe, in dollars	0.28
Time to place the block by clinician performing cryosurgery, in minutes	1
Time cryosurgery system is functional, in years	5
No. of liters of nitrous oxide per tank	20
No. of cryosurgeries performed per year	30
No. of cryosurgeries performed per tank	15

TABLE 4

Block Option that Gives the Lowest Cost per Averted Pain and Cramping for Cryosurgery

Variable	Range of Values Incorporated in Sensitivity Analysis	Block Option with Lowest Cost per Averted Pain and Cramping
Intensity of Pain and Cramping		
<i>Mucosal block</i>		
No pain and no cramping	0	
Only cramping	0 to 120	Mucosal block
Only pain	2 to 42	Mucosal block
Pain and cramping	19 to 115	Mucosal/Paracervical
<i>Paracervical block</i>		
No pain and no cramping	0	Mucosal block
Only cramping	20 to 65	Mucosal block
Only pain	0 to 52	Mucosal block
Pain and cramping	33 to 133	Mucosal/Paracervical
<i>No block</i>		
No pain and no cramping	0	
Only cramping	0 to 100	Mucosal block
Only pain	0 to 200	Mucosal block
Pain and cramping	50 to 160	Mucosal/No block
Probability of Outcome		
<i>Mucosal block</i>		
No pain (regardless of cramping)	0 to 1.0	Mucosal block
No pain, no cramping	0.6 to 1.0	Mucosal block
Pain, no cramping	0 to 0.70	Mucosal block
<i>Paracervical block</i>		
No pain (regardless of cramping)	0 to 0.555	Mucosal block
No pain, no cramping	0 to 1.0	Mucosal block
Pain, no cramping	0 to 0.150	Mucosal block
<i>No block</i>		
No pain (regardless of cramping)	0 to .515	Mucosal block
No pain, no cramping	0 to 1.0	Mucosal block
Pain, no cramping	0 to 0.145	Mucosal block
Costs		
Cryosurgery system	\$0 to \$3000	Mucosal block
Nitrous oxide cryogen	\$0 to \$5	Mucosal block
Salary and fringe benefits of the clinician performing cryosurgery	\$30,000 to \$250,000	Mucosal block
Lidocaine and syringe	\$0 to \$15	Mucosal block
No. of minutes to place the block by clinician performing cryosurgery	0.5 to 5	Mucosal block
No. of years cryosurgery system is functional	0.25 to 20	Mucosal block
No. of liters of nitrous oxide per tank	0.5 to 100	Mucosal block
No. of cryosurgeries performed per year	1 to 400	Mucosal block
No. of cryosurgeries performed per tank	1 to 400	Mucosal block

from 0% to 200% of the base case value to account for regional cost differences in cryosurgery units. The lifetime of the cryosurgery unit was varied from 3 months to 20 years to simulate office practices in the United States. The number of cryosurgeries performed per year was varied from 1 to 400 to simulate the differences in small private practice sites and large residency training programs. The cost of the nitrous oxide was varied from no cost to 200% of the base cost to reflect different price agreements. The number of liters of nitrous oxide per tank was varied from 0.5 liters to 100 liters to reflect all possible tank sizes used by practices throughout the country. The number of cryosurgeries that the clinician is able to perform per tank of nitrous oxide was varied from 1 to 400, as this number is tightly correlated to the size of the tank used for cryosurgery. The clinician's salary and fringe benefits were varied from \$30,000 per year to \$250,000 per year to consider the effect of midlevel providers or residents-in-training, as well as the established gynecologist, on the cost-effectiveness analysis. The number of minutes that the clinician takes to place the block was varied from 0.5 to 5 minutes to reflect the possible additional time added to the procedure by clinicians with varying skill levels. The onset of action of lidocaine placed either submucosally or paracervically is less than 30 seconds, so the time to administer the blocks would encompass the time to effectiveness of the lidocaine. The cost of the lidocaine and syringe was varied from no cost to \$15. These ranges allowed the robustness of the model to be tested in all possible clinical situations.

RESULTS

The base case analysis shows that the lowest expected cost per averted pain and cramping was with patients who had a mucosal block placed before cryosurgery (\$153.87), followed by \$183.24 for those who had a paracervical block and \$218.83 for women who had no block.

The results of the one-way sensitivity analyses show that the mucosal block dominated all analyses except 3, as seen in Table 4. In these 3 other analyses, the mucosal block was effective for most of the ranges tested, but thresholds for the paracervical block and no block were reached. As the intensity of the pain and cramping experienced by women with the mucosal block surpassed 98.5 mm, the cost per averted pain and cramping for those women surpassed the cost per averted pain and cramping for women with a paracervical block.

As the intensity of the pain and cramping experienced by women with a paracervical block decreased below 57.7 mm, the cost per pain and cramping averted remained the lowest for women with the paracervical block (from \$153.87 to \$114.67).

As the intensity of the pain and cramping experienced by women with no block dropped below 59.9 mm, the cost per pain and cramping averted remained lowest for women with no block (from \$153.87 to \$112.97).

In the base case population, 27.5% of pain and cramping scores from cryosurgery for women with the mucosal block exceeded 98.5 mm. Of the pain and cramping scores from cryosurgery for women with a paracervical block, 38.6% of the scores were less than 57.7 mm; of the pain and cramping scores from cryosurgery for women with no block, 21.2% were less than 59.9 mm.

DISCUSSION

The previously published prospective randomized trials described the lessening of the pain and cramping experienced by women undergoing a 5-minute double-freeze cryosurgery procedure when a mucosal or paracervical block was used, compared with the effect of no block.^{4,9,10} The decision analysis presented in our work allows the physician to prescriptively determine whether the decrease in pain and cramping of cryosurgery with the use of a cervical block is worth the additional costs.

The decision model provides a structure from which the costs and the intensity of pain and cramping can be weighted for each of 4 possible outcomes: no pain or cramping; only pain; only cramping; and both pain and cramping. This will give an expected cost per averted pain and cramping for any one patient experiencing cryosurgery with a mucosal block, with a paracervical block, and with no block. The expected costs per averted pain and cramping for women with each type of block can then be directly compared. It is assumed that the lowest cost per averted pain and cramping of the 3 options should be the desired procedure before cryosurgery. This assump-

tion is based on the von Neumann-Morgenstern maximum expected value theory,¹¹ which states that the highest expected value is the preferred decision, when the highest value is most desirable. Or, conversely, the lowest expected value is the preferred decision when the lowest value is the most desirable, as in our study of costs per averted pain and cramping.

The cost outcome values are quality adjusted by utility measurements most often generated from standard gambles or time trade-off measurements. A rating scale, such as the VAS used for pain and cramping intensities in this study, does not have the mathematical properties of a true utility measurement,¹²⁻¹⁸ but does provide an inexpensive and reproducible method that can be used in certain settings in decision analysis. Pain assessment in dental literature has shown that there is no significant difference between the pain rating scores obtained from the VAS method and the standard reference gamble.^{19,20} The VAS method was chosen because this study focused entirely on the pain and cramping perceived during cryosurgery, a pain and cramping very similar to the acute pain of dental procedures, and not focused on other parameters of quality of life.

Decision analysis, which was used as the methodology, also assumes that the physician will make his or her decision on whether to use a block for cryosurgery in a manner consistent with expected value decision making. Under these assumptions, the physician has the choice to use a block, and both the paracervical block and the mucosal block may reduce pain and cramping during the entire cryosurgery procedure. Which women will be helped, however, and whether the block will relieve all pain and cramping, just pain, or just cramping in any particular woman is unknown. Expected value decision making assumes that the physician will make a choice that results in a patient's experiencing the least amount of pain and cramping on average,²¹ which would then result in the lowest cost per averted pain and cramping. A physician may have other reasons for the decision not included in this model that fall outside the assumptions of expected value decision making, such as the physician's skill at placing the block or the woman's insistence on or fear of the block.

Other studies have shown that the paracervical block is effective for cryosurgery.^{22,23} The data from these studies, using the 3-minute double-freeze procedure, were incorporated into the sensitivity analysis. The base case data led to the robust decision to use a mucosal block that will result, on average, in the lowest cost per averted pain and cramping. This outcome is stable over all cost considerations. The difference between the cost per averted pain and cramping for the mucosal block and the cost for no block is the incremental amount saved by using a mucosal block (\$64.96; a 30% decrease from using no block). The mucosal block is cost-effective for all levels of clinicians, whether they perform few or many cryosurgeries per year. When the time to place the paracervical block was halved

in comparison with the mucosal block (2 sticks rather than 4), the cost per averted pain and cramping was still lowest for women receiving the mucosal block.

The dominant variable surpassing the costs we used was the intensity of the pain and cramping experienced during the cryosurgery procedure, as well as the cost figures. A randomized controlled trial evaluating the intensity of pain and cramping during the cryosurgery procedure for all 3 block options could provide more accurate mean values with smaller standard deviations. This could more accurately direct the cost-effectiveness analysis for those instances where no block or a paracervical block may be more cost-effective, on average, than the mucosal block. But our model suggests that the mucosal block is amply robust to provide the least cost for the most pain and cramping averted. Since there is no predictor of the intensity of pain and cramping that a particular woman will experience while undergoing cryosurgery, the mean expected value from all women serves as the best guide.

CONCLUSIONS

Our analysis shows that a mucosal block is the most cost-effective method of averting the pain and cramping caused by cryosurgery in women who have taken an NSAID before the procedure. By providing a mucosal block, the physician can maximize the amount of pain and cramping averted in relation to the cost of the cryosurgery.

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