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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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of paracervical and mucosal blocks to relieve pain and cramping in 5-minute double-freeze cryosurgery for cervical intraepithelial neoplasia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of women undergoing a 5-minute double-freeze cryosurgery procedure who had taken a NSAID drug before the procedure.

Setting
The setting was an ambulatory clinic. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were collected from studies published between 1976 and 1998, whereas the dates relating to the cost data were not stated. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a literature review.

Modelling
A decision analytical model was used to determine the cost-effectiveness of paracervical blocks, mucosal blocks and no blocks for women undergoing a 5-minute double-freeze cryosurgery procedure.

Outcomes assessed in the review
The review assessed the probabilities of the four possible pain and cramping outcomes.

Study designs and other criteria for inclusion in the review
The effectiveness estimates were derived from two prospective, randomised controlled trials.
Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Mean scores from individual studies were used.

Number of primary studies included
At least two primary studies were included.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
With a mucosal block, the mean pain and cramping scores were 0 for patients experiencing no pain or cramping, 29 for those experiencing only cramping, 22 for those experiencing only pain, and 72 for those experiencing both pain and cramping.

The corresponding mean pain and cramping scores were: 0, 45, 19 and 83, respectively, with a paracervical block; and 0, 50, 7 and 105, respectively without a block.

The probabilities used in the base-case analysis were:
Mucosal block: no pain (regardless of cramping), 0.25; no pain and no cramping, 0.917; pain and no cramping, 0.139.
Paracervical block: no pain (regardless of cramping), 0.111; no pain and no cramping, 0.2; pain and no cramping, 0.025.
No block: no pain (regardless of cramping), 0.103; no pain and no cramping, 0.25; pain and no cramping, 0.029.

Measure of benefits used in the economic analysis
The authors derived a pain and cramping score using two visual analogue scales, with values ranging from 0 to 200. This score was then transformed into an averted pain and cramping score, where a score of 1 meant that 100% of the pain and cramping due to cryosurgery was averted, and a score of 0 meant that no pain or cramping was averted.

Direct costs
The direct costs were not discounted since the time horizon was less than one year. The quantities and unit costs were reported separately. The direct costs were the costs of the cryosurgery equipment system and clinician fees. The quantity/cost boundary adopted was that of the ambulatory clinic. The authors did not state the source of the data relating to the quantities and costs. The price year was not reported.
Statistical analysis of costs
No statistical analyses of costs were reported.

Indirect Costs
Indirect costs were not included because, according to the authors, they would be equally distributed across all groups.

Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses were conducted on the following:

- the pain and cramping scores,
- the probabilities of the pain and cramping scores,
- the lifetime of the cryosurgery unit,
- the number of cryosurgeries performed per year,
- the cost of the nitrous oxide,
- the number of litres of nitrous oxide per tank,
- the number of cryosurgeries that the clinician was able to perform per tank of nitrous oxide,
- the clinician's salary and fringe benefits,
- the number of minutes that the clinician took to place the block, and
- the cost of the lidocaine and syringe.

Estimated benefits used in the economic analysis
With a mucosal block, the mean pain and cramping scores were 0 for patients experiencing no pain or cramping, 29 for those experiencing only cramping, 22 for those experiencing only pain, and 72 for those experiencing both pain and cramping.

The corresponding mean pain and cramping scores were: 0, 45, 19 and 83, respectively, with a paracervical block; and 0, 50, 7 and 105, respectively without a block.

With a mucosal block, the mean averted pain and cramping scores were: 1 for patients experiencing no pain or cramping; 0.855 for patients experiencing only cramping; 0.890 for patients experiencing only pain; and 0.640 for patients experiencing both pain and cramping.

The corresponding mean averted pain and cramping scores were: 1, 0.775, 0.903 and 0.585, respectively, with a paracervical block; and 1, 0.750, 0.965 and 0.475, respectively without a block.

Cost results
The cost estimates for the three treatment alternatives were not reported.
Synthesis of costs and benefits
The cost per pain and cramping averted was lowest for women with the paracervical block, when the intensity of the pain and cramping experienced by women dropped below 57.7 mm with this block, or surpassed 98.5 mm with the mucosal block.

The cost per pain and cramping averted was lowest for women without a block, when the intensity of the pain and cramping experienced by women without a block dropped below 59.9 mm.

Authors' conclusions
"A mucosal block is the most cost-effective method to avert the pain and cramping from cryosurgery in women who have taken a NSAID before the procedure".

CRD COMMENTARY - Selection of comparators
Two of the comparators were justified on the basis that they were current treatment alternatives. You, as a user of the database, should decide if these health technologies are relevant to your setting and whether no block is appropriate.

Validity of estimate of measure of effectiveness
The authors' literature review to derive effectiveness estimates seemed appropriate, although there was no indication whether or not it was a systematic review. The validity of the results was enhanced by sensitivity analyses to account for any variability in the estimates.

Validity of estimate of measure of benefit
The estimation of benefits was modelled. The visual analogue scale used to derive the measure of health benefit, i.e. pain, seemed appropriate, although it was unclear how comparable it was with other measures of pain. Conversion of pain scores to a standardised score, perhaps in terms of quality of life, would permit easier comparison with the effects of other technologies.

Validity of estimate of costs
The cost analysis had several good features: all relevant direct cost categories were included; the validity of the cost results was enhanced by appropriate sensitivity analyses; and quantities and costs were reported separately, thus enhancing the generalisability of the results. However, the price year was not reported, which would make reflation exercises in other settings problematic; and the source of cost data and cost estimates of the three treatment alternatives were not reported. Unfortunately, the claims of the authors regarding cost-effectiveness cannot be supported due to the lack of incremental analysis. The lower cost to avoid pain and cramping for mucosal block could be due to lower cost and the same benefit, or even lower benefit, if the cost were proportionately lower. Similarly, it could be due to higher cost, if the benefit was proportionately higher. A judgement of cost-effectiveness requires knowledge of the change in cost for the change in benefit, between the different technologies.

Other issues
The authors made appropriate comparisons of their findings with those from other studies, and addressed the issue of generalisability to other settings through a sensitivity analysis. The authors did not appear to present their results selectively, although the costs and overall benefit for each group were not given. The study considered women undergoing a 5-minute double-freeze cryosurgery procedure who had taken a NSAID before the procedure, and this was reflected in the authors' conclusions.

Please note that correspondence with the authors has provided the following information additional to that contained in the main body of the abstract above:

1. Hypothesis and study question: the justification for the choice of comparator was that no block was the standard of
care at the time of the study.

2. Dates to which data relate: the cost data were from 1997. The price year was also 1997.

3. Sources searched to identify primary studies: Medline was searched.

4. Criteria used to ensure the validity of primary studies: RCTs were used as the source of data.

5. Method of combination of primary studies: studies were combined using meta analysis.

6. Investigation of difference between studies: there were no applicable differences between the studies.

7. Direct costs: the price year was 1997; Medicaid charges and ICD 9 clinic guide were used as the source of cost data

**Implications of the study**
The authors claim that a mucosal block is the most cost-effective method to avert the pain and cramping from cryosurgery in women who have taken a NSAID before the procedure. However, the information provided in the paper does not support this, despite appropriate analyses of cost and benefits. The authors also recommend a randomised controlled trial evaluating the intensity of pain and cramping during the cryosurgery procedure for all three treatment options, in order to provide more accurate mean values with smaller standard deviations.

**Source of funding**
Supported by the Robert Wood Johnson Foundation.

**Bibliographic details**

**PubMedID**
10229253

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Anesthesia, Obstetrical /economics /methods; Cervical Intraepithelial Neoplasia /surgery; Cost of Illness; Cost-Benefit Analysis; Cryosurgery /adverse effects /economics /instrumentation; Decision Trees; Female; Humans; Muscle Cramp /economics /etiology /prevention & control; Nerve Block /economics; Pain, Postoperative /economics /etiology /prevention & control; Treatment Outcome

**AccessionNumber**
22000000930

**Date bibliographic record published**
28/02/2002

**Date abstract record published**
28/02/2002