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The Effect Of Topical Lidocaine Anesthetic On Reported Pain In Women Who Undergo Needle Wire Localization Prior To Breast Biopsy

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ABSTRACT

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This study examined the effects of topical lidocaine on reported pain by patients who underwent needle wire localization (NWL) prior to breast biopsy. Patients typically report sensations of discomfort that range from moderate to intense pain. The purpose of this study was to compare a topical lidocaine anesthetic preparation with no topical substance in reducing reported pain by women undergoing NWL. There was one research question for this study: “Do women who receive topical lidocaine anesthetic report significantly less pain than those women who do not receive a topical substance?”

The research sample was limited to 40 female patients who were scheduled for needle wire

localization. Twenty women were assigned to the experimental group and 20 were assigned to the control group. The experimental group received a lidocaine cream; the control group received a similar cream without the active lidocaine ingredient. Pain levels were measured immediately after the procedure using the Visual Analog Scale. Data were collected and interpretation was based upon pain scores from the experimental group and the control group. Data analysis with one-tailed directional t-test ($p < 0.05$) produced a test statistic of -2.51, which was more than the critical t-value of -1.69. The null hypothesis was rejected suggesting that women who received the lidocaine cream reported significantly lower pain scores.

Key Words: needle wire localization, breast biopsy, pain, lidocaine cream, cancer, breast cancer

Introduction

A woman's lifetime risk of being diagnosed with breast cancer is 1:8; it is estimated that more than 750,000 women will undergo a breast biopsy of whom 192,000 will be positive for breast cancer.¹ Screening efforts directed at early detection have resulted in increased numbers of non-palpable mammographic lesions that warrant the use of the localization process with the hook wire technique known as needle wire

¹American Cancer Society. (1999). *Cancer facts and figures*. Atlanta.

²Papa, M., Klein, E., Davidson, B., Karni, T., Sperber, F., Koller, M., Ravid, M., & Ari, G. B. (1996). The effect of anesthesia type on needle localization breast biopsy: Another point of view. *The American Journal of Surgery*, 171, 242-243.

³Northouse, L. L., Tocco, K., & West, P. (1997). Coping with a breast biopsy: How health care professionals can help women and their husbands. *Oncology Nursing Forum*, 24(3), 473-480.

localization biopsy.² Needle wire localization is a procedure whereby a thin walled hollow core needle is inserted into the breast using mammographic visualization to identify the abnormality. After the needle is in place, a mammogram is done to confirm the needle position. Although approximately 80% of these women will learn that they do not have breast cancer, breast biopsy will be a stressful and painful event for them.³

The problem under investigation was that women who undergo needle wire localization (NWL) prior to excisional breast biopsy report sensations of discomfort that range from moderate to intense pain. At the institution where the author is employed, topical applied lidocaine is not used with this procedure. Injectable lidocaine is not used consistently with NWL and is at the discretion of the radiologist. Breast biopsy is a highly stressful experience for women because the procedure determines whether the suspicious area identified by prior mammogram is benign or malignant. There is a need to evaluate products that will lessen the discomfort and pain associated with this procedure. The purpose of the study was to compare a topical lidocaine anesthetic preparation with a topical placebo cream in

reducing reported pain by women undergoing NWL. There was one research question for this study: “Do women who receive topical lidocaine anesthetic report significantly less pain than those women who do not receive a topical anesthetic substance?” The research hypothesis was that women who use a topical lidocaine anesthetic would report significantly less pain than do women who did not use a topical anesthetic substance.

Relevant Literature

Theoretical Basis of the Study

In 1979, the International Association for the Study of Pain (ISAP) published a definition that is used to guide clinical practice and is used in research studying pain. The ISAP defined pain as follows:

An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Pain is always subjective and each individual learns the application of the word through experiences related to injury in early life... (p.250) ⁴

⁴International Association for the Study of Pain. (1979). Pain terms: A list of definitions and notes on usage. *Pain*, 6, 249-252.

Pain can be classified as acute, malignant, or chronic. Acute pain can result from a sudden insult such as injury, disease, and surgical or medical procedures. Montes-Sandoval⁵ draws on Melzack and Walls’ “Gate Control Theory of Pain”

⁵Montes-Sandoval, L. (1999). An analysis of the concept of pain. *Journal of Advanced Nursing*

Practice, 29(4), 935-941.

to outline complex neurophysical activities, located in the spinal cord, which function as a “gating mechanism.” Gate theory describes a mechanism that increases or decreases sensory impulses generated by injury-sensitive nerve receptors. These impulses are interpreted as pain in the brain’s cerebral hemisphere and are influenced by external factors that also include sensory and cognitive dimensions.

In 1990, the Agency for Health Care Policy and Research (AHCPR) established an interdisciplinary panel and set forth guidelines that became the standards used to treat and manage acute pain.⁶ This panel defines pain as “a complex, subjective response with several quantifiable features, which include intensity, time course, impact, and personal meaning.”⁷

⁶Acute Pain Management Guideline Panel. (1992). *Acute pain management: Operative or medical procedures and trauma*. Clinical practice guideline. AHCPR Publication no. 92-0032. Rockville, MD: Agency for Health Care Policy.

⁷ *ibid.*

Pain intensity is not always proportional to the type or extent of tissue damage and may be affected by many complex interactions at the cellular level. Intensity can be quantified using appropriate pain measurement tools that attempt to quantify the individual's experience of pain and convert the experience into meaningful data. This information can be used to develop pain reduction strategies for patients.

Perception, or *impact of pain* and *personal*

meaning, reflects complex phenomena that involve psychological, neurological, and emotional processes. Breast biopsy is a psychologically stressful procedure, in part because it is used to determine whether the woman has breast cancer. Even the term *cancer* often evokes feelings of fear and pain that affect the personal meaning of the experience.

During NWL, patients report pain at the time of the needle insertion and placement. These four variables of *pain intensity*, *time course* (duration), *impact*, and *personal meaning*, provide the framework underlying this research study. Although each of these variables can be quantified, the primary complaint of intense pain was addressed as the most clinically relevant variable associated with this procedure. Therefore, the focus of this study was *pain intensity* as reported by women who underwent NWL to test the effectiveness of a topical anesthetic in reducing pain associated with this procedure.

Literature on Pain

Pain is recognized as one of the most widely experienced and expressed phenomena in nursing practice and requires nurses to have a thorough and comprehensive understanding of its meaning and implications for nursing care.⁸ Pain is a physiologic process modified by the

⁸Montes-Sandoval, 1999.

⁹Dick, M. J. (1995).
Assessment and
management of acute pain.
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Gynecologic, and
Neonatal Nursing*, 24(9),
843-848.

human experience. It is also a unique experience with no two people experiencing pain in the same manner. In addition, no two pain experiences are identical for an individual. ⁹ This complexity poses a problem for the assessment of pain.

Pain measurement attempts to quantify the subjective nature of pain and convert the individual's experience into terms that can be scientifically meaningful and comparable across individuals. Instruments are used to describe the pain experience by drawing on the concepts of intensity, sensation, and effects of pain. Pain instruments must take into account the patient's cognitive ability as well as communication style to quantify pain as described by the patient. Self-reported pain by the patient is considered the most useful measure of pain. Pain assessment and measurement are similar but the end-points are different, therefore the process and instruments used may not be the same. "Pain assessment is a broader process which attempts to identify the occurrence, location, intensity, and meaning of pain to individual patients."¹⁰ This is subjective as compared to physiologic and behavioral indicators, and thus may be difficult to quantify.

¹⁰ibid.

¹¹Northouse, 1997

¹²Deane, K., & Degner, L.

During NWL, women have reported feelings of discomfort that range from mild discomfort to extreme pain.¹¹⁻¹⁴ The use of local anesthetic for

(1997). Determining the informational needs of women after breast biopsy procedures. *AORN Journal*, 65(4), 767-776.

¹³Kelly, P., & Winslow, E. H. (1996). Needle wire localization for nonpalpable breast lesions: Sensations, anxiety levels, and information needs. *Oncology Nursing Forum*, 23(4), 639-645.

¹⁴Florentine, B., Frankel, K., Raza, A., Cobb, C., Greaves, T., Carriere, C., & Martin, S. E. (1997). Local anesthesia for fine-needle aspiration biopsy of palpable breast masses: The effectiveness of a jet injection system. *Diagnostic Pathology*, 17(6), 472-476.

¹⁵Reynolds, H., Jackson, V. P., & Musick, B. (1993a). Preoperative needle localization in the breast: Utility of local anesthesia. *Radiology*, 187(2), 503-505.

¹⁶Reynolds, H., Jackson, V. P., & Musick, B. (1993b). A survey of interventional mammography practices. *Radiology*, 187(1), 71-73.

¹⁷ibid.

¹⁸Dean, 1997

¹⁹Florentine, 1997

extreme pain.¹¹⁻¹⁴ The use of local anesthetic for this procedure is an issue of debate.¹⁵ In a survey of 1,000 members of the American College of Radiology performed by Reynolds et al.,¹⁶ it was noted that 62% of radiologists administered local injectable anesthetic prior to NWL. Local anesthetics are often painful when administered because it requires a needle stick, and the lidocaine causes a burning sensation when injected.¹⁷

Deane and Degner¹⁸ interviewed women after NWL and found that women who did not receive local anesthetic reported pain with the insertion of the wire. In an effort to identify an effective topical preparation that would give adequate pain control, Florentine and colleagues¹⁹ examined pain levels of patients undergoing fine needle aspiration of the breast who received ethyl chloride spray, injectable lidocaine, eutectic mixture of local anesthetics (EMLA), and no preparation. They reported that the EMLA cream

²⁰ibid.

was effective in reducing pain with needle insertion.²⁰

Eutectic compounds are designed to enhance membrane transport of drugs through improved solubility and absorption. A eutectic mixture of local anesthetics (EMLA), applied topically, penetrates into the dermis after an application period of 1 to 2 hours. EMLA contains prilocaine 25g/L and lidocaine 25g/L in an oily base. This preparation has been shown to be effective in relieving pain from venous cannulation and minor surgical procedures²¹ and is convenient to use.²² Side effects of the cream include hypersensitivity, local skin reaction manifested by a typical allergic dermatitis, and asthma attack, which is rare.²³

²¹Love, G. (1998). Easing the discomfort of venipuncture. *Nursing*, 28(3), 30.

²²Leiser, C. (1995). Easing children's procedural pain. *American Journal of Nursing*, 95(11), 17.

²³Love, 1998

Methods

Design

The study used a quasi-experimental design and took place in an outpatient breast center of an acute care hospital in upstate New York. The hospital's Institutional Review Board approved the study and consent form. Patient confidentiality was maintained regarding medical record numbers and data collection. Women were recruited for the study during the time period of October 5, 1998 to January 31, 1999. Women who were scheduled for NWL were assigned to be in the experimental or control

group. Women who were in the experimental group received EMLA cream before the procedure. The women in the control group received a topical placebo cream. Immediately after the NWL, each woman was asked to rate the level of pain she experienced.

Sample

Two groups of patients were selected to serve as the sample for this study. Each group consisted of 20 women scheduled for NWL. Selection criteria included only: 1) women, 2) those 18 years of age or older, 3) ability to speak English, 4) ability to give informed consent, and 5) those with no prior NWL. The sample was selected in two steps. First, the nurse practitioner obtained the NWL schedule one week in advance of the procedure from the senior mammographer at the Breast Center. Second, the patients who were assigned an even medical record number were assigned to the experimental group, and the patients with the odd numbered medical record were assigned to the control group. The patient's age and race were recorded.

Instruments

Visual Analogue Scale: Pain was evaluated utilizing a horizontal Visual Analogue Scale (VAS). Visual analogue scales have been used in clinical research settings since the 1920's to measure a variety of subjective phenomena and

²⁴Wewers, M. E., & Lowe, N. (1990). A critical review of visual analogue scales in the measurement of clinical phenomena. *Research in Nursing and Health, 13*, 227-236.

²⁵Gift, A. (1989). Visual analogue scales: Measurement of subjective phenomena. *Nursing Research, 38*(5), 286-288.

²⁶ibid.

²⁷Wewers & Lowe, 1990

²⁸Dick, 1995

were used extensively in the 1980's to measure pain.²⁴ According to Gift,²⁵ numerous investigators have demonstrated reliability and validity of the VAS. Validity has been established for the VAS using a variety of techniques. For example, concurrent validity has been established with the use of the McGill pain questionnaire.²⁶ Reliability for the instrument has been demonstrated by the test-retest method, whereby subjects have been shown to be able to repeat measures of subjective sensations.²⁷ The instrument is easy to use and takes approximately 30 seconds complete. The VAS is usually depicted on a 100 mm horizontal straight line, and the end anchors are labeled as extreme boundaries of the sensation being evaluated. The anchoring adjectives commonly used for pain are “no pain” and “worst pain.” The intensity of the sensation is scored according to the mark placed by the patient. There are limitations to its use, which include: 1) inability of subjects to conceptualize the phenomena and define it on a horizontal line, 2) inability to photocopy the tool as it distorts the length of the line, and 3) perceptual/motor issues of the subject.²⁸

Treatment and Procedures

Informed consent was obtained from women after they were admitted to the ambulatory surgery unit approximately two hours before the scheduled procedure. The women were shown the

VAS and the instrument was explained to them at this time. The experimental group received the topical anesthetic and the control group received a placebo cream. The mammographer or nurse practitioner applied the anesthetic cream or placebo after consultation with the radiologist to obtain the location of needle insertion. This was applied approximately one-hour before the scheduled procedure. Maximum time for application prior to needle insertion was 75 minutes. Anesthetics were not the current standard of care for women undergoing the procedure. Immediately after the procedure, and before leaving the procedure room, each woman was asked by the mammographer, who was blinded to the treatment or placebo condition, to rate her pain on the VAS.

Assumptions

For this study, it was assumed that the patients in both groups were comparable and that they represented the typical woman who was scheduled for NWL.

Data Analysis

The scores obtained from the VAS were compared between the two groups. These data were subjected to a quantitative statistical analysis. A one-tailed independent group t-test of significance ($p < 0.05$) was used to determine if the mean pain scores of the two groups of

²⁹Data Most Corp., Salt Lake City, UT

patients differed. The statistical software program used was *StatMost* for Windows.²⁹ In the post-test-only design with equivalent groups, differences in post-test scores between groups can be caused by the inequities in the treatment or selection processes. To address this, women were selected by mammography results, which identified a non-palpable abnormality requiring biopsy. Then, women were randomly assigned to either the control or experimental group. Mammography is a routine screening exam performed after the age of 40, so all of the women in this study were 40 and older. The risk of making a critical decision based on this research was low, and because patients were not receiving any anesthetic prior to NWL, a 0.05 level of significance was considered acceptable.

Limitations

This study was limited in that it was specific to female patients who were scheduled for breast biopsy with NWL. Results could not be generalized to men having breast biopsies, nor to breast biopsies performed without NWL, nor to those performed using stereotaxis core biopsy. The study was also limited in that it used a small sample and the results may not be generalizable to other breast centers.

Results

The mean age of all subjects was 56.2 years.

Although not significantly different, the average age of the experimental group was 56.9 years, and the mean age of the control group was 55.5. One patient in the control group fainted after looking at the needle placement, even though she had rated her VAS pain score as 1.0 just seconds before this incident. Only one patient, a member of the experimental group, rated her pain as zero. Patients in both groups reported sensations of coolness or numbing associated with the cream. There were no adverse effects or skin changes associated with the use of either cream. The minimum amount of time the creams were applied prior to needle insertion was 60 minutes; the maximum was 75 minutes. The mean pain scores, standard deviation, degree of freedom, *p*-value, and test statistic for the two groups are presented in [Table 1](#).

The results produced a test statistic of -2.74, greater than the critical *t*-value of -1.68. Thus, the null hypothesis was rejected as there was sufficient evidence to support the research hypothesis that women who received the lidocaine cream would have significantly less pain than women who received the placebo cream.

Discussion

Research has shown that breast biopsy is a stressful event in a woman's life,³⁰ and that anxiety associated with the procedure has the

³⁰Friedman, S., Badere, B., & Fitzpatrick, S. (1992). The effects of television viewing on preoperative

anxiety. *Journal of Post Anesthesia Nursing*, 7(4), 243-250.

³¹Kelly, 1996

potential to exacerbate pain and increase the chance of complications.³¹ Most women report feelings of discomfort associated with NWL which range from mild discomfort to pain. The literature concludes that women who do not receive local anesthetic report pain with the insertion of the needle.

The use of locally injectable anesthetic prior to NWL has been an issue of debate among radiologists; only one half administer local injectable anesthetic prior to the procedure. Research findings show that women typically report sensations of burning and stinging with lidocaine injection of the breast.³² Only one prior study had evaluated topical anesthetics in NWL procedures; it found a significant reduction in pain.³³ Products such as lidocaine spray and eutectic mixture of lidocaine and prilocaine (EMLA) were found to be effective in providing anesthetic effect for a variety of minor surgical procedures.^{34,35}

³²Kelly, 1996

³³Florentine, 1997

³⁴Love, 1998

³⁵Leiser, 1995

This study was limited by the small sample size and the possibility that the VAS may not have been the best instrument to measure pain. However, previously documented inabilities of subjects to conceptualize the pain phenomena and define it on a horizontal line, or individual subject's perceptual motor issues were not a problem in this study. Patients who wore glasses

were instructed to keep them on during both the procedure and pain assessment so that they would be able to mark the VAS without visual impairment.

Another limitation of the study is that some women may not be able to isolate their pain/discomfort associated with only the needle stick because the entire procedure is done with mammography enhancement. In a recent study, it was noted that women reported discomfort that ranged from moderate to extreme during mammography alone.³⁶

³⁶Dullum, J. R., Lewis, E. C., & Mayer, J. A. (2000). Rates and correlates of discomfort associated with mammography. *Radiology*, 214(2), 547-552.

It has been noted that women undergoing breast biopsy have a higher anxiety level when compared to patients scheduled for other types of surgeries,³⁷ and that regardless of the diagnostic outcome, women experience significant levels of distress before the biopsy. The anxiety associated with the outcome following biopsy may be related to the surgical procedure itself, the threat of breast cancer, or the risk of developing breast cancer. Anxiety levels may also be affected by the fact that women are aware that they will not receive anesthesia during NWL.

³⁷Deane, 1997

The implications from this study are many. First, the use of EMLA cream has been shown to be effective in reducing pain associated with minor

surgical procedures and can reduce the discomfort/pain associated with needle stick prior to NWL. This information has the potential to impact the standard of care in breast centers for women who undergo this procedure. Second, with the use of EMLA, patients will be informed prior to the procedure that an anesthetic will be used and thus diminish some of the anxiety the patient may experience. Staff will need to be able to provide emotional support to women scheduled for NWL, factual and sensory information about the procedure. Sensory information, in this situation would include descriptions of the various sensations the patient could expect to experience during the procedure. For example, the sensation of compression that accompanies mammography, as well as the numbness and tingling that may occur after several minutes of compression.

Further studies are needed to assess women's knowledge of breast health and breast cancer, and their understanding of diagnostic procedures used for breast abnormalities. This information, and the level of understanding by the patient, may also affect the level of anxiety the woman experiences prior to biopsy.

Table 1. Between-group Comparison of Pain Scores as Measured by the VAS, with and without EMLA Pretreatment

	Experimental (n=20)	Control (n=20)
Mean pain score	1.405	3.090
S.D.	0.270	0.551
d.f.	38	
Test Statistic	-2.744	
Critical <i>t</i> -value	-1.686	
<i>p</i> value	0.009	

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