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## RSNA Press Release

### Over-the-Counter Anesthetic Gel Puts the Squeeze on Mammogram Pain

Released: July 22, 2008

Note: On January 16, 2009, the Food & Drug Administration posted an advisory on the Potential Hazards of Skin Products Containing Numbing Ingredients for Relieving Pain from Mammography and Other Medical Tests and Conditions

#### At A Glance

- An over-the-counter topical anesthetic gel containing 4 percent lidocaine significantly reduces breast discomfort during mammography.
- Many women don't follow established mammogram guidelines. Some cite fear of pain or discomfort as their reason for avoiding mammograms.
- Ninety-eight percent of study participants said they would probably or definitely get a mammogram the following year.

([http://www.fda.gov/cder/drug/advisory/topical\\_anesthetics2009.htm](http://www.fda.gov/cder/drug/advisory/topical_anesthetics2009.htm)). It is important to note that no adverse effects were reported in the 2008 study by Lambertz, et al., published in *Radiology*, which was conducted using an over-the-counter 4% lidocaine gel product, as opposed to the prescription-strength product containing both lidocaine and tetracaine prompting an earlier FDA Advisory in 2007. However, patients should always consult a healthcare professional before using a topical anesthetic prior to mammography or any medical procedure.

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OAK BROOK, Ill. — The simple application of a pain-relieving gel may reduce the breast discomfort some women experience during mammography exams, according to the results of a clinical trial published in the online edition of *Radiology*.

"We now have something that we know reduces discomfort with screening mammography in women who expect higher discomfort—lidocaine gel," said the trial's principal

investigator, Colleen Lambertz, F.N.P., a nurse practitioner at St. Luke's Mountain States Tumor Institute in Boise, Idaho. "With a more positive experience, we hope women will undergo more regular mammography screening."

Breast cancer affects more women than any other non-skin cancer and, according to the American Cancer Society, accounts for more than 40,000 deaths annually in the U.S. Most experts agree that the best way to decrease breast cancer mortality is through early detection using mammography and clinical breast exam.

"Mammography is the only screening tool proven to reduce mortality from breast cancer in women over 40," said study co-author James R. Maxwell, M.D., medical director of St. Luke's Breast Care Services. "Annual screening is the most important option available to a woman to best ensure early detection and decrease the chance of being diagnosed with an advanced stage breast cancer."

For a mammography exam, a radiologic technologist positions the patient's breast on a platform in a mammography unit. The breast is then gradually compressed with a paddle. The patient may feel pressure and occasionally some discomfort or pain. Fear of this discomfort leads many women to avoid mammograms altogether. Studies have shown that as many as two-thirds of women don't follow established guidelines for mammography.

"Breast tenderness, anxiety and expectation of pain are all directly correlated with the amount of discomfort women experience with mammography," Lambertz said.

For the clinical trial, the researchers recruited 418 women, ages 32 to 89, who expected significant discomfort with screening mammography. Fifty-four of the women reported that they had probably or definitely delayed their mammograms due to concern over possible discomfort.

The women were randomized to receive placebos or pre-medication with acetaminophen, ibuprofen and/or a local anesthetic gel followed by mammography screening. The gel was applied to the skin of the breasts and chest wall and then removed 30 to 65 minutes before mammography. The gel had no effect on subsequent image quality.

The results showed that oral medication produced no significant differences in breast discomfort, nor did other factors such as breast density. However, women who received a topical application of 4 percent lidocaine gel reported significantly less breast discomfort during mammography.

"We designed this study around safe and available over-the-counter products in order to put women more in control, so they may have a more comfortable and satisfactory experience," Lambertz said.

Eighty-eight percent of study participants indicated they would definitely get a mammogram the following year, and 10 percent said they would probably get a mammogram the following year.

Lidocaine gel is a readily available, over-the-counter anesthetic that is easy to apply and remove. For the study, the gel was applied by the attending nurse; however, women could apply the gel at home one hour prior to appointment time and remove it right before undergoing the exam.

"Women can now take charge of the situation," Lambertz said. "They can schedule a mammography appointment for a time in their cycle when their breasts are least tender, apply the gel at home and drive to the appointment knowing they have taken steps toward a positive experience with this potentially life-saving procedure."

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"Premedication to Reduce Discomfort during Screening Mammography." Collaborating with Lambertz and Dr. Maxwell were Christopher J. Johnson, M.P.H., and Paul G. Montgomery, M.D. The study will appear in the September print edition of *Radiology*. Journal attribution requested.

This study was supported by the St. Luke's Mountain States Tumor Institute and the Mountain States Tumor Medical Research Institute. A brand-name (Topicaine) lidocaine gel was provided at no charge to the researchers for use in the study. The authors had full control of the data and information submitted for publication.

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