ORIGINAL ARTICLE

Impact of Sodium Bicarbonate-Buffered Lidocaine on Patient Pain During Image-Guided Breast Biopsy

SA-CME

Alison Vasan, MD, JD[a], *Jay A. Baker, MD*[b], *Rebecca A. Shelby, PhD*[c], *Mary Scott C. Soo, MD*[b]

Abstract

Purpose: This randomized, double-blind controlled study evaluated the effectiveness of sodium bicarbonate-buffered lidocaine on reducing pain during imaging-guided breast biopsies.

Materials and Methods: This prospective, HIPAA-compliant study randomly assigned 85 women undergoing ultrasound- or stereotactic-guided core-needle breast biopsies to receive intradermally and intraparenchymally either 1% lidocaine buffered with sodium bicarbonate (9:1 ratio) (bicarbonate study group) or 1% lidocaine alone (control group). Pain was evaluated using a 0-to-10 Likert pain scale during both intradermal and intraparenchymal anesthesia injections and during tissue sampling. Prebiopsy breast pain, anxiety, medical history, demographics, biopsy type, radiologist level of training, breast density, and lesion histology were recorded. Data were analyzed using analysis of variance and analysis of covariance.

Results: Unadjusted mean pain scores were 1.47 and 2.07 (study and control groups, respectively; $P = .15$) during intradermal injections, and 1.84 and 2.98 (study and control groups, respectively; $P = .03$) during intraparenchymal injections. Tissue sampling mean pain scores were .81 and 1.71 (study and control groups, respectively; $P = .07$). Moderator analyses found (1) among patients with preprocedural pain, those in the bicarbonate group experienced less intradermal injection pain (0.85 ± 1.23) than patients in the control group (2.50 ± 2.09); (2) among patients with fatty or scattered fibroglandular tissue, those in the bicarbonate group (1.35 ± 1.95) experienced less intraparenchymal injection pain than the control group (3.52 ± 3.13); and (3) during ultrasound-guided biopsies, patients in the bicarbonate group experienced less tissue-sampling pain (0.23 ± 0.63) than the control group (1.79 ± 3.05).

Conclusions: Overall, buffering lidocaine with sodium bicarbonate significantly reduced pain during intraparenchymal injections, and additional pain reduction was found in certain patient subgroups during intradermal injections, intraparenchymal injections, and tissue sampling.

Key Words: Imaging-guided breast biopsy, anesthesia, sodium bicarbonate, lidocaine, patient pain, patient experience

J Am Coll Radiol 2017;■:■-■. Copyright © 2017 American College of Radiology

INTRODUCTION

Pain is a common consequence of percutaneous imaging-guided core-needle breast biopsies (CNBBs) [1,2]. The severity of pain experienced during CNBBs varies with factors such as needle gauge, operator skill, anticipated biopsy pain, and patients' tendencies to magnify the seriousness of pain sensations, known as pain catastrophizing [1,3-5]. Identifying techniques to minimize pain during CNBB is important for improving patients' experiences, but effective pain management may also contribute to improved patient adherence to screening mammography recommendations and can potentially influence national screening recommendations and radiology reimbursements [1]. Replacing traditional

[a]Department of Medicine, Duke University Medical Center, Durham, North Carolina.

[b]Department of Radiology, Duke University Medical Center, Durham, North Carolina.

[c]Department of Psychiatry and Behavioral Sciences, Duke University School of Medicine, Durham, North Carolina.

Corresponding author and reprints: Mary Scott Soo, MD, Duke University Medical Center, Department of Radiology, Box 3808, Room 24244B, 2nd Floor Red Zone, Duke South Clinic, Trent Drive, Durham, NC 27710; e-mail: soo00002@mc.duke.edu.

This manuscript was funded by the Charles E. Putman, MD Seed Fund, 441-0816, from the Department of Radiology at Duke University Medical Center. The authors have no conflicts of interest related to the material discussed in this article.

1546-1440/17/$36.00 ■ http://dx.doi.org/10.1016/j.jacr.2017.03.026

fee-for-service payments, the CMS now links a portion of reimbursements to performance outcomes [6-10]. Using measures such as the Hospital Consumer Assessment of Healthcare Providers and Systems survey to evaluate performance, 30% of metrics assess overall patient satisfaction, including patients' assessments of pain management [6,7,10]. Therefore, efforts to manage patient pain during interventional radiology procedures such as breast biopsies are important issues to be addressed in the radiology community.

Lidocaine hydrochloride is an injectable local anesthetic used during CNBBs to manage procedure-related pain. However, injection of the anesthetic itself can paradoxically cause temporary pain intensification [11-13]. The source of pain may be the acidic pH of lidocaine, which can be as low as 3.5, compared with the physiologic pH of 7.4 [12,13]. Neutralizing acidity of lidocaine with sodium bicarbonate is one method of minimizing lidocaine injection pain as demonstrated in studies of intravenous line placements and minor surgical procedures [12,14-16]. However, prior studies primarily evaluated pain experienced during intradermal injections for superficial procedures [11,17], and a systematic review of buffering lidocaine reported pain reduction in many but not all prior studies [12]. Little has been published about anesthetizing deeper parenchymal organs as required during CNBB. Adding sodium bicarbonate to lidocaine during CNBB also adds time and expense to procedures, yet the benefits are unknown.

Given the lack of data regarding the effectiveness of sodium bicarbonate-buffered lidocaine in CNBB settings, the purpose of this prospective, double-blind, randomized controlled study was to evaluate the effects of buffering lidocaine with sodium bicarbonate on pain levels during intradermal and intraparenchymal anesthetic injections and during the tissue sampling phase of CNBB. A secondary aim was to evaluate whether procedure- or patient-related factors (eg, radiologist experience, lesion histology, tissue density, preprocedural breast pain, anxiety, anticipated pain) moderated the effects of sodium bicarbonate-buffered lidocaine during CNBB.

MATERIALS AND METHODS

Patients

Informed consent was obtained in this HIPAA-compliant, Institutional Review Board-approved study. Between December 2014 and March 2015, women presenting to our single site breast imaging center in a major academic medical center for a clinically indicated percutaneous ultrasound- or stereotactic-guided core-needle breast biopsies were invited by study personnel on the day of their biopsy to participate. Inclusion criteria were English-speaking women at least 21 years of age who were capable of providing informed consent. Patients were excluded if anesthesia other than lidocaine was indicated (eg, lidocaine allergy).

Sample size estimates were determined based on power calculation assumptions, including a difference of 2.0 on a 10-point pain scale for patients in each arm of the trial; standard deviation of each group was estimated at 3.0. Given these estimates, an 80% power required 37 participants in each group to demonstrate a difference using an unpaired t test at a .05 significance level.

All eligible patients were invited by a single study coordinator to participate in the study prior to the start of the biopsy, as time allowed. Of the 102 women invited, 88 (86.3%) women agreed to participate; breast biopsy was subsequently canceled in two women. Eighty-six women underwent biopsy and received intended anesthesia, then completed study measures; one woman was excluded from analysis due to invalid data (ie, she did not use surveys appropriately, giving responses outside of survey options). Overall, 85 women were included in this sample (Fig. 1), meeting intended recruitment goals.

Procedures

After providing written informed consent, patients were randomized by study personnel into either lidocaine-plus-sodium bicarbonate (bicarbonate) or lidocaine-alone (control) groups. Randomization was nonsequential, generated by a random allocation computer software program. Both patient and radiologist performing the biopsy were blinded to the assigned group. After randomization and before CNBB, patients completed questionnaires assessing preprocedural breast pain, anticipated biopsy pain, and prebiopsy anxiety. Patients were then positioned on the biopsy table, and the area of interest was prepped and draped in the usual fashion by biopsy team members. Syringes with the lidocaine formulations were sterilely prepared by medically trained study personnel out of view of the patient and radiologist, then provided at the appropriate time during CNBB, without indication of the presence or absence of sodium bicarbonate within the syringe. All injections were administered by one of seven dedicated breast radiologists, three breast imaging fellows, or eight radiology residents.

Women in the control group initially received intradermal and subcutaneous injections of approximately 3