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Premedication to Reduce Discomfort during Screening Mammography¹

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ABSTRACT

Purpose: To test the hypothesis that premedication with acetaminophen, ibuprofen, and/or 4% lidocaine gel would decrease discomfort and improve satisfaction with screening mammography in women who expect a higher level of discomfort.

Materials and Methods: In this HIPAA-compliant, institutional review board–approved, prospective, double-blinded, placebo-controlled clinical trial, 418 women aged 32–89 years who expected substantial discomfort with screening mammography were randomly divided to receive premedication with acetaminophen, ibuprofen, and/or 4% lidocaine gel. Subjects provided informed written consent. The primary outcome was discomfort. Secondary outcomes were satisfaction and plans for future mammography on the basis of discomfort. Subjects completed structured questionnaires with visual analog scales to measure discomfort and satisfaction. A generalized linear mixed-models framework was used to assess the effect of medications on discomfort during mammography, and satisfaction with technologist and machine combinations was included as a random effect. The "plans for mammography next year" outcome was modeled by using a binary distribution and logit link function.

Results: Discomfort was significantly lower in the lidocaine gel group ($P = .01$). Satisfaction was significantly negatively correlated with discomfort ($P < .001$). Satisfaction and whether or not the subject had delayed her mammography because of fear of discomfort had significant effects on plans to undergo mammography next year ($P < .001$ for both). There were significant differences in discomfort between different combinations of technologists and machines.

Conclusion: Premedication with 4% lidocaine gel significantly reduced discomfort during screening mammography, and reduced discomfort may improve the likelihood of future mammographic screening and early detection of breast cancer.

INTRODUCTION

Breast cancer affects more women than any other nonskin cancer and accounts for one-fifth of all deaths in women aged 40–50 years (1,2). Only recently have mortality rates declined, with decreases of 2.3% per year between 1990 and 2002. These decreases are believed to be primarily the result of earlier detection and improved treatment (1).

A number of randomized clinical trials have shown that early detection of breast cancer with mammography reduces breast cancer mortality in women aged 40–74 years by about one-third to one-half (3–8). Still, recent reports suggest that approximately one-half to two-thirds of women do not follow established guidelines for mammography (1,9).

One factor affecting the utilization of mammography is fear of pain (10–17). It is well documented that many women experience discomfort in their breasts during mammography (15,18–21) and that expectation of pain and anxiety are important predictors of pain with the procedure (19–25). Physician recommendation is one of the strongest predictors of participation in mammography, yet physicians avoid ordering mammograms because of concerns about the discomfort associated with the procedure (12,26–31).

To our knowledge, little research has been performed to discover methods of reducing the discomfort associated with mammography (32). Kornguth et al (13) found that patients who were allowed control over the compression portion of the mammography procedure perceived significantly less discomfort and improved overall satisfaction. A serendipitous finding was that almost one-fourth of the patients studied took pain medication or a tranquilizer before the procedure, but the sample size was not sufficient to determine the effects of these medications on perceived discomfort.

In a 1998 prospective, randomized, double-blinded, placebo-controlled trial (32), 265 subjects were premedicated with 1000 mg of acetaminophen before undergoing screening mammography. No significant difference in discomfort was noted between the intervention, placebo, and usual care groups. Expectation of higher discomfort was not a criterion for inclusion.

We conducted this study to test the hypothesis that premedication with acetaminophen, ibuprofen, and/or 4% lidocaine gel would decrease discomfort and improve satisfaction with screening mammography in women who expect a higher level of discomfort. A more comfortable experience may increase the number of women who participate in regular mammographic screening and increase early detection of breast cancer.

MATERIALS AND METHODS

This prospective, randomized, double-blinded, placebo-controlled clinical trial complied with the Health Insurance Portability and Accountability Act and received institutional review board approval. All subjects provided informed written consent. The 4% lidocaine (**Topicaine**) was provided at no charge by the manufacturer (ESBA Laboratories, Jupiter, Fla). The authors had full control of the data and information submitted for publication.

Recruitment

Eligible subjects were women scheduled to undergo screening mammography between March 30 and June 9, 2006, who expected discomfort of 40 or higher on a verbal report scale (VRS) (0, no discomfort; 100, worst pain imaginable) (33). Excluded from the study were women who (a) expected discomfort levels of less than 40; (b) were unable to adhere to the study protocol; (c) had a sensitivity or allergy to acetaminophen, ibuprofen, or lidocaine; or (d) had known liver or kidney dysfunction.

Screening telephone calls were placed to 2140 potential subjects. Of the 1565 potential subjects who met the study criteria, 521 agreed to participate. They were instructed to avoid taking any pain medication 24 hours before appointment time and arrive at the mammography center at least 60 minutes early. Reminder calls were made the day before the appointment.

Of the 521 subjects who initially agreed to participate, 103 later became ineligible owing to inability to arrive 60 minutes early, rescheduling of appointments outside the enrollment period, use of pain medication before arrival, or voluntary withdrawal before signing the consent. Four hundred eighteen subjects completed the study.

At enrollment, subjects rated their premammography level of anxiety, breast tenderness, and expectation of discomfort with visual analog scales (VAS) (0, none; 100, worst imaginable anxiety, tenderness, or pain, respectively) (33,34). A registered nurse randomly divided subjects into 12 study groups: (a) 1000 mg of acetaminophen, (b) 800 mg of ibuprofen, (c) oral placebo, (d) 1 oz or less of 4% lidocaine gel, (e) gel placebo, (f) 1000 mg of acetaminophen and 1 oz or less of 4% lidocaine gel, (g) 1000 mg of acetaminophen and gel placebo, (h) 800 mg of ibuprofen and 1 oz or less of 4% lidocaine gel, (i) 800 mg of ibuprofen and gel placebo, (j) oral placebo and 1 oz or less of 4% lidocaine gel, (k) oral placebo and gel placebo, or (l) routine mammographic screening (usual care) in order of arrival at the clinic. This design ensured evaluation of all combinations of the study medications.

Oral medications and placebos were identical in appearance. The 4% lidocaine was transferred from manufacturer's packaging to single-dose syringes indistinguishable from the placebo gel syringes. The medications and placebos were packaged in sequentially numbered envelopes according to a random number list generated by the random number generator function under data analysis in Excel software (version 5.0; Microsoft, Redmond, Wash). Empty envelopes indicated the "usual care" group. The randomization schedule was concealed until enrollment ended.

Trained by the principal investigator, the registered nurse administered the oral medications or placebos, applied the gels to the skin of the chest from the clavicles to the inferior costal margins and laterally to the midaxillary lines, and covered the gels with plastic wrap to ensure consistency of application. The registered nurse also assisted with gel removal at appointment time.

Absorption time (time between drug administration and the first mammographic film) for the oral medications ranged from 36 to 129 minutes (mean, 81.3 minutes; median, 80 minutes). Gel absorption time (amount of time the gel was on the skin) ranged from 30 to 75 minutes (mean, 47.8 minutes; median, 48 minutes). The time between gel removal and the first mammographic film ranged from 30 to 65 minutes.

Before mammography, subjects underwent breast examination by a registered nurse examiner (standard procedure in this facility), who recorded palpable abnormalities if present. The registered nurse breast examiners and mammographic technologists were blinded to study subjects. After mammography, subjects completed a structured questionnaire that measured several variables to determine their influence on discomfort

and satisfaction, including age, race, marital status, education, history of prior mammography, personal history of breast cancer, whether or not the subject had delayed the study mammography because of concern over possible discomfort, and perceptions about the technologist and nurse examiner ([Table 1](#)). The questionnaire was similar to one used in the 1998 acetaminophen study ([32](#)).

A VAS was used to rate discomfort (0, none; 100, worst pain imaginable) and satisfaction (0, not at all satisfied; 100, highest possible satisfaction). Plans for future mammography on the basis of discomfort and other variables were measured by using self-report questions with fixed-alternative responses. Adverse events were documented as they were reported by subjects or observed by enrolling registered nurses. After completion of the questionnaires, the subjects were discharged from the center with no further follow-up.

Radiologists certified in mammographic interpretation were blinded to study subjects and read the mammograms at a separate site the day after mammography was performed. Film quality was judged according to American College of Radiology quality parameters and quality assurance data required by the Mammography Quality Standards Act of 1992, for example, the standard technologist retake rate (total number of retakes at the time of mammography divided by total number of patients). Mean unadjusted scores by intervention for the 12 groups are shown in [Table 2](#).

Statistical Analysis

Based on effect sizes observed in the 1998 acetaminophen study ([32](#)), the estimated sample size was 60 subjects per group, for a total of 720 subjects. Sample size estimates were based on the following: standard deviation within group, 20; analysis of variance design, 4 x 3; α level, .05; and power, 80%; adjustments were made for nonindependence among patient observations. Owing to logistical changes at the study site that required an extended delay in further enrollment, interim analysis was conducted after enrollment of 418 subjects. Significant effects were observed in the interim analysis, and enrollment was ended.

SAS software (version 9.1; SAS Institute, Cary, NC) was used to calculate descriptive statistics and Spearman rank-order correlation coefficients between continuous study variables and to perform analysis of variance of categorical variables on continuous variables. SAS PROC GLIMMIX software (version 9.1, SAS Institute; <http://support.sas.com/rnd/app/da/glimmix.html>) was used to assess the effect of oral drug and gel drug administration on perceived discomfort during mammography in a generalized linear mixed-models framework. Oral medication, gel medication, and their interaction were modeled as fixed effects, and the combination of technician and mammography machine was included as a random effect. Because multiple subjects in different intervention groups underwent mammography with the same combination of technician and mammography machine, this effect was included as a second (hierarchical) level in the model. Estimates from a generalized linear model fit (a model without random effects) were used as the starting values for the generalized linear mixed model, which was optimized by using a Newton-Raphson algorithm with ridging.

The satisfaction outcome was modeled in a similar fashion, assuming a normal distribution with identity link function. The "plans for mammography next year" outcome was modeled by using a binary distribution and logit link function, with nurse examiner as the second (hierarchical) level in the model.

Models were adjusted for pertinent covariates. In the perceived mammography discomfort model, adjustments were made for expected discomfort, age, breast density (as judged by the radiologist), and history of previous screening mammography. In the satisfaction model, adjustments were made for discomfort, personal history of breast cancer, and the rating of how well the nurse listened and made adjustments when told to do so. In the "plans for mammography next year" model, adjustments were made for perceived discomfort, satisfaction, and delay of the study mammography owing to concern about discomfort. In that model, discomfort and satisfaction

were parameterized to yield the effect of a 10-point change in these variables on the odds of undergoing mammography next year (definitely yes vs otherwise). The value of 10 was chosen to reflect a reasonable or potentially clinically relevant difference in pain scores.

Safety

The medications were chosen for their accessibility and safety profiles. Acetaminophen and ibuprofen are well-tolerated, over-the-counter analgesics with few side effects with a single dose. **Topicaine** is an over-the-counter product that is water soluble and is easily removed before mammography. According to the manufacturer, potential side effects include hypersensitivity and local skin reaction manifested by mild, transient erythema or edema. According to the package insert, systemic adverse reactions after appropriate one-time use are unlikely because of the small dose absorbed. Recommended safety precautions on dosing and application were followed for all medications.

RESULTS

Discomfort and Anxiety

Expected discomfort during the screening interview for the upcoming mammography ranged from 40 to 100 on a VRS (mean, 64.0; median, 60.0). At enrollment, expected discomfort scores for that day's mammography ranged from 0 to 100 on a VAS (mean, 57.6; median, 60), with 76.3% (315 of 413) of subjects rating their discomfort higher than 40.

Premammography breast tenderness ratings ranged from 0 to 95 (mean, 26.6; median, 20.0), with 27.1% (112 of 413) of subjects reporting no tenderness and 28.6% (118 of 413) reporting tenderness scores of more than 40. Scores for anxiety about the upcoming mammography ranged from 0 to 100 (mean, 21.0; median, 10), with 20.2% (84 of 415) of subjects reporting anxiety scores of more than 40.

Scores for discomfort during mammography ranged from 0 to 100 (mean, 39.8; median, 38.5). Only 2.6% (11 of 418) of subjects reported no discomfort, 42.3% (177 of 418) reported discomfort scores of more than 40, and 2.9% (12 of 418) reported discomfort scores of 90 or higher. The most frequently reported causes of discomfort were tightness of squeezing (70.4% [293 of 416] of subjects), pulling on the skin (31.0% [129 of 416]), edges poking into the body (37.5% [156 of 416]), and the cold feeling of the machine (11.8% [49 of 416]).

Women who expected greater discomfort both at screening and at enrollment experienced more discomfort during their mammographic examination ($P < .001$ for both). Those with more tender breasts and higher anxiety also experienced more discomfort ($P < .001$ for both). Similarly, higher expectations of discomfort at screening and enrollment, anxiety, and breast tenderness negatively affected satisfaction with the mammography experience ($P = .03$, $P < .001$, $P = .003$, and $P = .02$, respectively).

Satisfaction

Satisfaction ratings ranged from 7 to 100 (mean, 83.5; median, 90.0) and were higher than 80 for 63.7% (265 of 416) of subjects. The majority of subjects reported that interactions with the technologists and nurse examiners were positive. [Table 3](#) illustrates the perceived interactions between subjects and the technologists and nurse examiners. Women who experienced more discomfort during the study mammography were significantly less satisfied with the experience ($P < .001$), and those who were less satisfied were also more likely to have delayed the study mammography ($P = .004$).

Mammography Delay

Fifty-four of 416 (13.0%) subjects reported that they probably or definitely had delayed their mammographic examination because of concern over possible discomfort. Another 51 (12.3%) subjects said that they probably had not delayed their mammographic examination because of discomfort, and 286 (68.8%) said that they definitely had not delayed their mammographic examination for that reason.

Eight of 416 (1.9%) subjects said that they probably or definitely would not undergo mammography next year given the level of discomfort experienced during the study mammography. Another 42 (10.1%) subjects reported that they probably would undergo mammography next year, leaving some measure of doubt. The majority of subjects (366 [88.0%] of 416) indicated that they definitely would undergo mammography next year. Women who had delayed the study mammography owing to concerns over discomfort were significantly less likely to undergo mammography next year ($P < .001$), and those who were more satisfied were significantly more likely to do so ($P < .001$).

Safety

Six of 418 subjects reported side effects from the interventions, including three of 144 (2.1%) who received placebo gel and three of 140 (2.1%) who received lidocaine gel. This resulted in an overall side effect rate of 1.4% (six of 418 subjects). All six subjects with side effects reported only local symptoms from gel administration. Five (three who received lidocaine gel and two who received placebo gel) reported a mildly itchy, pink discoloration of the skin on the breasts in the area of gel application on removal of the plastic wrap, consistent with potential side effects described in the lidocaine gel package insert. In these subjects, all symptoms subsided within approximately 1 hour. The sixth subject (who received placebo gel) called to report that several hours after gel removal she experienced itching and hives only on the breasts. These symptoms resolved in a few days with over-the-counter steroid cream. There were no differences in adverse effects between the gel intervention groups. No systemic side effects were reported.

Image Quality Assessment

No films were judged by the radiologist to be inadequate because of study-related issues. The standard technologist retake rate did not vary owing to study-related issues, and the overall quality of the study films was judged as 100% acceptable.

Primary Outcome: Discomfort (Model Results)

After adjustment for expected discomfort, age, breast density, and history of previous screening mammography (fixed effects) and for the combination of technologist and mammography machine (random effect), there were significant differences in discomfort during mammography by type of gel ($P = .01$) ([Table 4](#)). No significant differences in discomfort were observed between types of oral medication ($P = .35$), and there was no interaction between gel and oral medication type ($P = .84$). Discomfort scores did not vary significantly by breast density in a univariate model ($P = .35$) or the mixed model ($P = .149$); all other covariates were significant in the mixed model. Topical application of 4% lidocaine gel resulted in significantly lower discomfort during mammography than placebo or no gel.

Secondary Outcomes

Satisfaction.—After adjustment for discomfort, personal history of breast cancer, and subjects' ratings of how well the nurse listened and made adjustments when told to (fixed effects) and for the combination of technician and mammography machine (random effect), there were no significant differences in satisfaction by gel type ($P = .55$), oral medication ($P = .25$), or their interaction ($P = .84$) ([Table 5](#)). Discomfort significantly decreased satisfaction ($P < .001$). Having a personal history of breast cancer was associated with higher satisfaction ($P = .05$), as were higher ratings of how well the nurse listened and made adjustments when the subject told her to (P

< .001). Subjects who felt the technologist listened and made adjustments when told to, explained the procedure in terms they could understand, and cared about them as persons reported higher satisfaction ($P < .001$, $P < .001$, and $P < .001$, respectively).

Plans for future mammography.—After adjustment for perceived discomfort, satisfaction, and delaying the study mammography because of concern about discomfort (fixed effects) and for nurse examiner (random effect), there were no significant differences in plans to undergo mammography next year by gel type ($P = .49$), oral medication ($P = .32$), or their interaction ($P = .25$). Plans to undergo mammography next year (definitely yes vs otherwise) were significantly related to satisfaction ($P < .001$) and delaying of the study mammography because of concern over discomfort ($P < .001$) but not to actual discomfort during this study mammography ($P = .40$) ([Table 6](#)).

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► DISCUSSION

Nearly three-fourths of the potential subjects screened for participation (1565 [73.1%] of 2140 subjects) expected discomfort scores of at least 40 with the study mammography, as did all subjects who participated when asked during the screening interview. Most subjects (315 [76.3%] of 413) also expected this level of discomfort at enrollment. There are several possible explanations for the slight change in expectation of discomfort between screening and enrollment: (a) VRS scores tend to be slightly higher than VAS scores ([33](#)); (b) there may be changes in breast tenderness or anxiety between the screening interview and the day of the mammography; (c) subjects may have felt intimidated when rating expected discomfort in the presence of the enrolling registered nurse; and (d) subjects may have understood the VRS (explained over the telephone) differently from the VAS (explained on the day of the examination).

The expected discomfort scores indicate that the general belief in this motivated population of women was that undergoing mammography hurts. Despite this belief, however, these women scheduled mammography. We do not know, however, how many women do not schedule mammography at all because of this same concern.

The results of this study indicate that expectation of discomfort, anxiety, and perceived discomfort negatively influence women's satisfaction with screening mammography and their likelihood to undergo regular screening, a cycle that could lead to delays in the detection of breast cancer. Premedication with 4% lidocaine gel significantly reduced discomfort during screening mammography in this study population, with few side effects and no substantial adverse reactions. This gel is a readily available, over-the-counter, topical anesthetic that is easy to apply and remove. Although the gels were applied by a registered nurse to ensure consistent application during the study, in the future, women could apply the gel at home 1 hour before appointment time and remove

it on arrival at the screening facility, minimizing or eliminating additional cost to the facility. Lidocaine gel would be especially useful to women who expect discomfort and may be tempted to delay or avoid screening mammography.

We found that interactions with the technologists and nurse examiners have a significant effect on discomfort and satisfaction with screening mammography. Identification and mentoring of the attributes and techniques of these professionals that contribute to comfort might help reduce mammography-related discomfort even more. Further study in this area is warranted.

Our study had limitations. Although premedication with 4% lidocaine gel applied to the breasts and chest wall significantly reduced discomfort during mammography compared with placebo or no gel, the magnitude of the reduction may need to be balanced against the cost of the gel and the time required for self-application. We did not attempt to quantify these costs, but we believe them to be low. The study population included only women who expected greater discomfort. It is unknown whether the findings apply to women who do not expect much discomfort.

Lidocaine gel significantly reduced discomfort during mammography even though the gel was removed at least 30 minutes, and sometimes more than 60 minutes, before mammography. The reduction in discomfort may be even greater if mammography were performed immediately after gel removal.

As is standard in this facility, a minimum of two films were obtained for each breast, but the total number of films obtained for each subject was not recorded. It would be interesting to know whether discomfort scores varied significantly by the number of films obtained, and further study may be warranted. This study was limited to a single site with a homogeneous population. Expansion to multiple sites with a more heterogeneous population may change the outcome, and further exploration is encouraged.

In conclusion, premedication with 4% lidocaine gel applied to the skin of the breasts and chest wall significantly reduces discomfort during screening mammography in women who expect greater discomfort. This simple intervention could be offered to these women to improve the mammography experience and break the cycle of anxiety and fear that leads to delays and avoidance of this potentially lifesaving procedure.

▶ ADVANCES IN KNOWLEDGE

- Premedication with 4% lidocaine gel applied to the breasts and chest wall provided a significant reduction in discomfort during mammography ($P = .01$).
- Discomfort significantly decreased satisfaction with the mammography experience ($P < .001$).
- Satisfaction had a significant effect on plans for undergoing future mammography ($P < .001$).
- Delaying the study mammography because of fear of discomfort had a significant effect on plans for undergoing future mammography ($P < .001$).
- Discomfort and satisfaction were significantly affected by the mammographic technologist ($P < .001$ for discomfort, $P = .004$ for satisfaction) and interactions with the technologist ($P < .001$ for both) and nurse examiner ($P < .001$ for both).

► IMPLICATION FOR PATIENT CARE

- Premedication with 4% lidocaine gel provided a significant reduction in discomfort during screening mammography, which could improve the likelihood of regular mammographic screening and early detection of breast cancer.

► FOOTNOTES

Abbreviations: VAS = visual analog scale • VRS = verbal report scale

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See Materials and Methods for pertinent disclosures.

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