Is Specimen Mammography Beneficial?

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Hypothesis: Specimen mammography is not beneficial in the management or outcome of patients undergoing image-guided needle-localized breast biopsies.


Setting: National Cancer Institute (Bethesda, Md)–designated comprehensive cancer center.

Patients: One hundred sixty-four patients underwent 165 needle/dye-localized breast biopsies for suspicious mammographic abnormalities.

Results: In only 3 (1.8%) of 165 patients did the patient clearly benefit from specimen mammography. In no patient was a malignant neoplasm missed. The mean time for the specimen mammogram was 20 minutes, adding an additional 55 hours of operating room time. Specimen mammography cost an additional $60,522 and was incorrect in 41 (24.8%) of 165 patients.

Conclusion: Specimen mammography added little to patient care, as only 3 (1.8%) of 165 patients benefited from the information.

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Specimen mammography (SM) is commonly practiced as an adjunct to image-guided needle-localized (IG-NL) breast biopsy. Proponents of SM report that this radiologic procedure allows surgeons to assess the adequacy of their excision, and reduces the number of metachronous reexcisions that are required to achieve margin-negative resections. Proponents, such as the American College of Radiology (Reston, Va), state that SM is the “standard of care” for localization breast biopsy.¹ They use the explanation that SM reduces the frequency of missed lesions by providing the surgeon with immediate hard-copy confirmation that the appropriate abnormality was removed. Thus, the patient is protected from the risks of a missed malignant neoplasm and the surgeon or radiologist from the risks of litigation. Specimen mammography, however, is not without its drawbacks.

Specimen mammography prolongs surgical procedures and adds surgical, radiological, and pathological expenses to the cost of IG-NL breast biopsy. Specimen mammography is not a perfect test and has been shown to be incorrect (false-positive and false-negative results) in as many as 44% of cases.² Incorrect results can lead to the excision of unnecessary tissue, delay in recognition of a malignant lesion, and a false sense of security that the abnormality has been appropriately excised.³

See Invited Critique at end of article

This article discusses the current use of SM. The continued use of SM should be contingent on its benefits in the management and outcomes of patients. If the time, incorrect results, and added expense (discordance of the SM with the pathological or postoperative mammographic findings) outweigh these benefits, then the usefulness of SM must be reconsidered. Specimen mammography can play a role in 2 scenarios of IG-NL breast tissue excisions. In diagnostic biopsies, the SM might confirm that the suspicious lesion is contained in the biopsy specimen. In therapeutic excisions, it might show that the entire lesion has been removed with a surrounding margin of normal tissue. We do not debate that SM is a radiologically sound test that can adequately identify lesions that have been ex-
PATIENTS AND METHODS

One hundred sixty-five consecutive diagnostic needle- or needle/dye-localized breast biopsies were performed in 164 patients between January 1, 1993, and December 31, 1995, by 4 surgical oncologists at our National Cancer Institute (Bethesda, Md)—designated comprehensive cancer center. Patient records were retrospectively analyzed for demographic information, preoperative mammographic findings including American College of Radiology Breast Imaging Reporting and Data System (BIRADS) classification, time used for operating room and SM, and SM results. Initial biopsy, synchronous and/or metachronous excision pathological results, definitive surgical procedure, and postoperative mammography results were also evaluated.

Needle- and needle/dye-localization procedures were performed preoperatively in the radiology suite. Biopsies were performed under monitored anesthesia with intravenous sedation and supplemental local anesthesia. The intact biopsy specimen with localization needle was weighed in the pathology division and placed in a Transpec Dubin Specimen Radiography Device (E-Z-EM Inc, Westbury, NY) with a solid compression plate. A single-view specimen mammogram was then obtained, interpreted by the radiologist, and reported to the operating surgeon. Possible results included (1) entire mammographic lesion present in the biopsy specimen; (2) partial lesion present in the biopsy specimen; and (3) no lesion seen in the biopsy specimen. The decision to terminate the procedure or to perform a synchronous reexcision of the biopsy cavity was made at the discretion of the operating surgeon.

cised from the breast. We do, however, question the overall benefit of SM’s diagnostic function and its sensitivity during therapeutic excisions.

RESULTS

One hundred sixty-four women with a mean age of 58.9 years (age range, 33.9-80.5 years) underwent 165 localized breast biopsies for mammographically suspicious lesions. The mean maximum lesion diameter was 1.0 cm (range, 0.3-3.0 cm). Benign pathology was present in 96 patients (59%). Of the malignant diagnoses, 24 were ductal carcinomas in situ (DCIS) and 45 were invasive carcinomas. Preoperative mammograms demonstrated microcalcifications in 86 patients (52.1%), masses in 58 patients (35.2%), architectural distortions in 4 patients (2.4%), or a combination in 17 patients (10.3%). Malignant findings were seen in 30 (35%) of 86 biopsy specimens where the preoperative mammogram demonstrated suspicious calcifications and 27 (47%) of 58 biopsies where the preoperative mammogram demonstrated a suspicious mass. If both findings were present on preoperative mammogram, the rate of malignancy increased to 7 (70%) of 10. Lesions (n=68) had a BIRADS classification of 2 (benign finding) in 1 patient (1.5%), 3 (probably a benign finding) in 1 patient (1.5%), 4 (suspicious abnormality) in 59 patients (86.8%), and 5 (highly suggestive of a malignant abnormality) in 7 patients (10.3%). The BIRADS-classified 4 lesions were found to be malignant in 22 (37.2%) of 59 patients and BIRADS-classified 5 lesions (n=7) were malignant in 100% of cases.

All patients had SM performed. Of the 165 SM procedures, 138 (83.6%) revealed the entire lesion, 17 (10.3%) identified a partial lesion or a close margin, and 10 (6.1%) revealed no lesion (Figure 1, top). Fourteen of the 17 patients with partial or close margins identified on SM had no further synchronous excisions (Figure 1, bottom). The other 3 patients had synchronous reexcisions of tissue based on the SM results. Six of the 10 patients in whom SM revealed no lesion also had synchronous reexcisions of tissue based on the SM results (Figure 1, bottom). Two of the 10 patients had no additional tissue excised. The remaining 2 patients went on to reexcision based on intraoperative findings. Thus a total of 9 patients underwent synchronous reexcision of tissue based on the results of SM (Figure 1, bottom).

Of the 16 patients who did not undergo removal of additional tissue, 9 had benign lesions and 7 had malignant lesions (Figure 2). No further excision was performed for the patients with benign diagnoses. Two of the patients with malignant diagnoses had margin-positive DCIS requiring a metachronous reexcision for negative margins. These 2 patients might have benefited from the SM results by having synchronous excisions of additional tissue. None of the 5 remaining patients benefited from SM. Three had margin-negative DCIS and required no further surgical therapy. The other 2 patients demonstrated invasive ductal carcinoma requiring additional surgery for definitive treatment of the primary and axillary node sampling (modified radical mastectomies in both cases).

Of the 9 patients who underwent reexcision based on SM results, 5 had benign lesions and 4 had malignant le-
sions (Figure 3). One of the patients with a malignant diagnosis had a first SM that showed no lesion, and additional tissue was excised. The second SM results revealed that the lesion had been removed. Pathological investigation revealed DCIS in both biopsy specimens and the patient went on to have a total mastectomy 2 months later. This SM was beneficial despite being incorrect, as it prompted a reexcision of additional multifocal DCIS. The other 3 patients with malignant diagnoses did not benefit from SM. The second patient had a first SM that revealed an incomplete lesion, and additional tissue was excised. The results of the second SM showed that the lesion had been entirely removed. Pathological tests revealed a benign nonproliferative lesion in the first biopsy and margin-positive DCIS in the reexcised specimen. The patient was definitively treated with a modified radical mastectomy. Had the SM not been performed, the DCIS would not have been excised. However, the preoperative mammographic interpretation (BI-RADS classification of 4) would have been discordant with the pathological findings (benign) and an early postoperative mammogram would have been performed. This study would have identified the unexcised lesion and the DCIS would have been removed at a second surgical procedure. The remaining 2 patients demonstrated invasive ductal carcinoma in their first biopsy, requiring additional surgery for definitive treatment of the primary and axillary node sampling (modified radical mastectomy in both cases).

A total of 3 (1.8%) of the 165 patients benefited from SM. In 2 patients, SM might have prevented a second surgical procedure, and in 1 patient, lack of SM might have resulted in a delayed diagnosis. In no patient was a malignant lesion missed.

Of the 138 patients with the entire lesion identified on SM, 31 had specimens with pathologically positive margins. Of the 27 patients with no lesion, a partial lesion, or close margins by SM, 10 patients had pathological findings that did not correlate with the SM reading. Thus, of the 165 patients, 41 (24.8%) had incorrect SMs (discordance of the SM with the pathological or postoperative mammographic findings).

The patient and surgical team waited in the operating room while the specimen was being delivered and the SM processed. If the SM showed no lesion, a partial lesion, or close margin, additional tissue was removed at the discretion of the operating surgeon. The mean SM time was 20 minutes (range, 3-59 minutes), increasing the mean operating room time to 45 minutes (range, 20-115 minutes). For the 165 biopsies, an additional 55 hours of operating time was accrued.

Specimen mammography incurred additional radiologic, pathological, and surgical costs. All costs were calculated based on the cost to our institution during the year 2000. To perform and read all of the primary and secondary SMs would cost the Department of Radiology $16,358. The additional cost to the Department of Pathology to process all localized breast biopsies and reexcised specimens is $11,604. Fifty-five hours of additional operating time at our institution costs $30,690 in operating room, ancillary staff, and nursing time, and $1,870 in Anesthesia Department time. The addition of SM to 165 localized breast biopsies would cost an additional $60,522.

The 164 patients in our study are demographically similar to those in comparable studies in the literature except that 41% of our patients had malignant lesions. Most studies report a malignancy rate of approximately 20% to 30% for diagnostic IG-NL breast biopsies.2,4-7 This significantly increased rate of malignancy can be explained in that ours is a tertiary cancer care center that sees a select patient population. Many of these studies also question the accuracy and usefulness of SM.

Our findings suggest that the diagnostic usefulness of SM is limited. Of our entire study population, 99.4% had either the entire lesion removed or the diagnosis confirmed by 1 localized biopsy. In only 1 patient, 0.6% of patients, was the diagnosis changed by the results of SM-initiated reexcisional biopsy. Similar studies have also demonstrated a 90% to 100% success rate for excision of localized mammographic abnormalities on the first attempt.2,8,9 If only a small percentage of lesions will be missed during the initial localized biopsy and if these lesions can be defined with early postoperative single-breast mammograms, what is the usefulness of the SM?

We also found that SM has a limited ability to predict margin status. Of the 138 patients who had the entire lesion identified with SM, 31 patients with malignant diagnoses had positive pathological margins. Patients with benign diagnoses may have also had partial lesions removed, but these margins were not evaluated. Discordance between the SM result and the pathological or postoperative mammographic findings was also noted in 10 of 27 patients with no lesion, partial lesion, or close margin on SM. Thus, in a minimum of 24.8% of the patients, SM provided the surgeon with an incorrect result. Two studies from the radiology literature arrived at similar findings. Lee and Carter,10...
using specimen compression and a single-view technique, found that SM had a false-negative (SM demonstrating complete excision and pathologically positive margins) rate of 44%. They concluded that a “specimen radiograph that suggests complete excision of the mammographic lesion should not be relied on to exclude the presence of residual tumor in the breast.”

Graham et al. using similar techniques, determined the negative predictive value of SM in predicting tumor-free margins to be only 32%. Such poor predictive value of margin positivity also brings into question the value of SM during therapeutic excisions.

Our results indicate that only a small percentage of patients (1.8%) benefit from SM. To obtain these benefits, a cost of 55 additional operating room and staff hours, $60,522, and 24.8% incorrect SM studies was incurred. We believe that alternative methods may be more appropriate. To continue the current standard is expensive, time-inefficient, and plagued with an unacceptable number of incorrect studies.

One possibility is to perform SM in a fashion similar to the postoperative pathological examination of tissue. This would save 55 hours in operating room time, and $32,560 in operating room and anesthesia fees. The patients with partially excised and discordant lesions could return for metachronous reexcisions. Reid et al. reviewed their experience with a similar protocol in which patients’ incisions were closed without waiting for the SM results. After comparing the specimen radiographs with postoperative mammograms, they reported a 3% rate of missed lesions, all of which were identified on the postoperative mammograms, they reported a 3% rate of missed lesions, all of which were identified on the postoperative mammograms. This would save 55 hours in operating room time, $32,560, and $60,522 in operating room and anesthesia fees. Since this is not a prospective study, the authors argue back against SM altogether. This would save 55 hours in operating room time, $60,522, and 24.8% incorrect SM studies. Instead, early postoperative single-breast, 2-view mammograms could be performed on the patients with discordance between their preoperative mammographic findings and pathological results.

Specimen mammography is an expensive procedure that uses considerable operating room time. Since most localization breast biopsies completely excise suspicious mammographic abnormalities on the first attempt, SM does little to decrease metachronous reexcisions. The high rate of incorrect diagnoses with SM makes it a poor determinant of margin status, and calls into question the usefulness on SM even in therapeutic excisions.

DISCUSSION

Ronald Latimer, MD, Santa Barbara, Calif. This topic is timely, and the question asked does prove provocative. Rather than being laudatory and heaping praise, for discussion purposes I am going to play the “devil’s advocate” and be critical. To begin with, I suggest the term “specimen mammography,” although acceptable parlance, is incorrect, and truly the subject is “specimen radiography.”

In the “Patients and Methods” section of the paper, the reader is not told (1) whether the surgeon has the original mammograms and a copy of the localizing film in the operating room; (2) whether the surgeon reviews the specimen radiograph himself before wound closure; (3) whether the single-wire or the bracketed multiple-wire localization technique is used; and finally (4) whether the biopsy site marking clips are placed to facilitate reexcision or boost radiotherapy if indicated.

Since this is not a prospective study, the authors argue backward from the data to justify conclusions. In addition, they seize on today’s “argument of frugality” to suggest the abandonment of this procedure. The primary purpose of specimen radiography is to confirm that a nonpalpable mass, an asymptomatic density, or a group of calcifications is removed for histological examination. The authors were very successful, achieving complete excision in 138, or 84% of their patients.

Benefit, like beauty, must be in the eye of the beholder. The authors fail to concede that in their 138 patients the procedure was beneficial; they rather focused their attention on 27 patients in whom either partial removal was performed or no lesion was found when specimen radiograms were reviewed.

On the other hand, I really feel quite secure when I view a successful specimen radiograph, and it certainly instills a large mea-
sion because, as mentioned earlier, the primary purpose of this technique is to provide tissue for histological examination and not for making the diagnosis per se. Therefore, the conclusion that 27% of the patients had “incorrect specimen mammograms” cannot be validly used as an argument to abandon the procedure.

An additional bias enters the conclusions. By the exclusion of 2 patients because of unexplained “intraoperative findings” despite the fact that the specimen radiographs were performed and were found wanting a lesion implies that the procedure failed, when in truth it confirmed the absence of the suspect lesion and demanded further beneficial operative intervention.

Including these 2 patients, a total of 11 patients benefited by synchronous reexcisions. Our authors report that after histological review, 2 additional patients with DCIS would have benefited from synchronous reexcision based on specimen radiography.

So depending upon the denominator selected, 13 (48%) of 27 patients with partial excision or no lesion demonstrated benefited by the procedure. Again, depending on a positive perspective, the 138 patients with complete excision plus these 13 patients adds up to 151 of the 164 patients—91% of patients who benefited from the technique.

Time is certainly money. With analysis of the system errors inherent within this procedure, cost-cutting suggestions can be made. Why were the specimens sent to the pathology department first? Many surgeons place the specimen directly to the x-ray department. Since no mention of frozen section analysis was made, the specimen and the films can be returned immediately to the operating surgeon and both sent to the pathologist at a later time.

Purchase of a small-specimen radiographic device with placement near the operating room would allow the surgeon, according to the authors, to visualize successful removal 84% of the time and only in 16% of the cases would it entail a radiologist-surgeon dialogue.

The authors have documented the procedural costs for the specimen radiography at their tertiary care facility. What they have not documented for us is that with the elimination of this technique, what would the cost be for a radiological-surgical encore for the 27 patients with partial removal or no lesion identified?

Furthermore, the chagrin surgeons could feel when they explain that utilization of the technique of specimen radiography might have prevented this revisitation to the operating room plus the ensuing emotional costs to the patient are both very difficult to price.

In conclusion, the authors’ subject certainly provoked my interest. Change is difficult. Their paper has failed to convince me to abandon specimen radiographs.
ferent places have different techniques and styles of performing needle-localized breast biopsies. At our institution, the pathology department must register the specimen before it can be moved around the institution. The additional time is about 3 minutes; probably a little less than that because the personnel are ready to run the specimens down to the x-ray department for us.

We have all of the films available to us in the operating room to review. The surgeon reviews them before, during, and after the excision. They are then sent along, and the radiologist has all of the films when looking at the specimen mammogram. It is imperative if you use a full-bore approach to specimen mammography, or specimen radiography if you choose that term, that the radiologist review it because some of the clarification and guarantee that you have removed what was said to be there by the radiologist is through having that same radiologist review it. In fact, that can turn out to be a problem in places where we are doing some freestanding work where the radiologist might not be available at the end of the procedure to review that film for you. It is going to become problematic as surgeons become more skilled in using ultrasound where the documentation of what has been removed cannot be done the way it can be done with specimen radiography. We generally use a single wire, sometimes a wire and a hook. There are a number of techniques. I don’t think that that changes things very much. Now one point that came up again and again and may be also part of this controversy is the crossover between diagnostic and therapeutic. Remember that the time of this study was about 3 or 4 years ago, and we have seen some evolution in the use of core biopsies performed preoperatively so that we do know the diagnosis when we enter the operating room and we’re performing therapeutic intervention, not diagnostic intervention. These were all done as diagnostic tests, and that is why we felt comfortable in saying that the number of nonbeneficial specimen mammograms is 138; none of those patients had a change in their management based on the radiological study. If the radiologist and the surgeon who have looked at the film both say that the specimen mammography shows the complete excision of the lesion, but in 31 of 138 times the complete lesion isn’t in the specimen, then I don’t think you can call that correct, and certainly I don’t think that the patient benefited. That can be carried over quite powerfully into the therapeutic scenario because in the therapeutic scenario, mistakes are made to take up a significant amount of time in just looking at a radiograph and not having the pathologic margin confirmation.

We tend to use a narrow margin of excision. We have been participants in NSABP [National Surgical Adjuvant Breast and Bowel Project] for quite a while and a negative margin is a close margin. We tend to reduce the amount of tissue we take the first time around to improve cosmetic results. Specimen mammography did not impact our specimen size.

Now the 2 patients who had intraoperative findings, I should speak to specifically. That is where the surgeon felt that there was something else palpable, in that 20-minute or so period while waiting for the report on the specimen mammogram. Those were surgical decisions and I don’t think the surgeon can be taken out of the equation because palpation of the bed of what was perceived to be the site of the lesion location is also critical.

Dr Goodson’s point is exactly correct, and I hope everybody heard Dr Bimston say it also: to really choose 1 of these 3 ways of performing specimen mammograms or specimen radiographs, we must do the study prospectively. A way to do that might be to perform no specimen mammogram vs performing a 2-view mammogram where we might perceive to have a higher rate of identifying positive or negative margins.

Dr Goodnight asked about the difficulty in postoperative mammograms. I think that is a good point. We do many postoperative mammograms in preparation for the radiation therapy that is given as a part of lumpectomy’s breast conservation. I think radiologists are experienced; certainly our breast radiologists are experienced in reviewing those particular films to make an accurate assessment.

Dr Vetto: I think I spoke to your points about therapeutic vs diagnostic, and I think those are very important issues. With the preoperative malignant diagnosis on a core biopsy or needle aspiration where you are planning a therapeutic biopsy, you are going to have a different strategy entering the operating room. I will caution you, as I was somewhat awakened, that the group of 138 patients had a significant error rate (22%) in analysis of complete excision by specimen mammography.
One hundred sixty-four patients underwent 165 needle/dye-localization biopsies in the reported series from the City of Hope Cancer Center (Duarte, Calif). The authors estimate that specimen mammography (SM) was only beneficial in 1.8% of the patients and no cancer was missed. On the other hand, SM was incorrect in 24.8% of patients and added $60,522 in costs to the institution with an additional 55 hours of operating time.

The main reason given in support of SM is that it allows the surgeon to judge the adequacy of the excision and perhaps avoid reexcisions for negative margins and for medical-legal purposes. Specimen mammography is incorrect in up to 44% of cases, resulting in the unnecessary excision of tissue, missed tumors, and a false sense of security for the surgeon. Specimen mammography is considered wrong when there is a discordance between its outcome and the pathological and postoperative mammographic finding. The American College of Radiology (Reston, Va) judge it to be the standard of care for needle-localization biopsy.

My question for the authors is, why are the specimens initially taken to the pathology suite to be weighed? Specimens should be placed directly on the specimen grid from the operating room table and taken directly to the radiology department. Additionally, for only 6 of 10 patients in whom the SM did not contain the lesions was a reexcision done. Why wasn’t a reexcision at least attempted in the other 4?

It is too much to expect SM to have a role in margin determination. Margin determination is a histologic finding, not something determined by studying x-ray films. Most surgeons will do a diagnostic procedure first (ie, a needle-directed breast biopsy). In this setting, the specimen mammogram serves to assure the surgeon that the mammographic abnormality has been removed. Only very suspicious lesions (some Breast Imaging Reporting and Data System [American College of Radiology] classifications of 4, and all lesions with classifications of 5) can be approached with the intent of establishing the diagnosis, as well as trying to obtain clear margins. In this instance, the SM can serve, as the authors imply, as an aid in determining whether adequate margins have been obtained. This is certainly a minority of lesions and it would be too cost-ineffective to try to evaluate margins on all needle-localization biopsies, since the majority are not cancerous. Nor is SM able to determine whether all calcifications have been removed with a needle-localization breast biopsy, yet some surgeons try to use the test in this way. Follow-up mammograms during the postoperative period are best in evaluating whether all suspicious calcifications have been removed. Because of these 2 scenarios, it is unfair to say that the SM has an inaccuracy rate of 24.8%. Two other studies quoted in the discussion confirm that SM cannot be used to definitively evaluate margins, so surgeons and radiologists should not try.

In the “Results” section, the authors state that 3 patients with malignant diagnoses did not benefit from SM and yet in 1, a focus of ductal carcinomas in situ would have been missed. It is presumptive to think that this would have been sorted out in the postoperative period. The other 2 patients had infiltrating ductal carcinoma on their biopsy specimen, the SM showed that the lesions had been removed, and the patient returned to the operating room on a different date for definitive cancer surgery. One could argue that the SM was helpful in both of these cases, demonstrating that the mammographic abnormality had been removed.

If, as the authors argue in the “Comment” section, that 90% to 100% of the needle-localization biopsies will remove the mammographic abnormality, and the small percentage of lesions missed will be identified on early postoperative single-breast mammogram, why perform SM? The authors fail to mention that in the up to 10% of lesions that are missed, another anesthesia and operation is necessary. What are the medical-legal implications of taking the patient to the operating room, administering intravenous sedation, making an incision in the breast, and not removing the abnormality? In addition, what are the costs of postoperative single-breast mammography? This involves 2 films, instead of 1 SM, and is uncomfortable for the patient with a fresh biopsy and will increase the cost of care. In addition, one could argue that this postoperative study would not be necessary, and instead in many clinics is not performed, if a SM shows that the mammographic abnormality has been removed.

The saying, “If you have a hammer, everything looks like a nail” may be appropriate here. Just because a test is available, it should not be used in ways in which it was not intended and in which it has been shown to be ineffective. The authors’ cost argument is a more compelling one, but I question the practice pattern of performing both SM and a single-breast mammogram in the immediate postoperative period. In addition, one needs to be reminded that missed breast cancer is the number 1 reason why doctors get sued and the average award for these cases is in the order of $250,000 to $1 million. A surgeon would have to perform a lot of breast biopsies to make up for one missed breast cancer!

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