Breast Cancer Research and Treatment **36**: 1–9, 1995.

Opinion

When can stereotactic core biopsy replace excisional biopsy? — A clinical perspective

Monica Morrow
Department of Surgery, Northwestern University Medical School, Chicago IL, USA

Key words: breast biopsy, mammographic abnormality, nonpalpable breast lesions, stereotactic core biopsy

Summary

Stereotactic core biopsy is becoming increasingly popular as a technique which provides a histologic diagnosis for mammographic abnormalities while avoiding the trauma, deformity, and much of the cost associated with surgical biopsy. This review evaluates the published literature on the diagnostic accuracy of core biopsy for ductal carcinoma in situ and invasive breast cancer and the ability of core biopsy to characterize malignant lesions sufficiently to allow treatment planning. Issues of cost effectiveness are examined in the context of the degree of suspicion of the mammographic abnormality being sampled by core technique as well as subsequent breast cancer therapy.

Introduction

Studies of breast cancer screening have demonstrated that the regular use of mammography can reduce breast cancer mortality by 20% to 30% in women older than 50 years [1-4]. The increased utilization of screening mammography has resulted in a concomitant increase in the number of breast biopsies which are recommended for clinically occult lesions. It is estimated that if 45% of the 48 million women aged 40 years and older had yearly mammography, more than 4 million of the studies would initially be interpreted as abnormal [5]. Between 60% and 90% of the abnormalities identified by screening mammography are benign [6], and the costs for surgical consultations and biopsies for benign disease represent the major induced cost of screening mammography [7,8].

Stereotactic breast biopsy has been advocated as an alternative to open surgical biopsy for the diagnosis of mammographic abnormalities. Potential advantages of the stereotactic technique include lower cost, less trauma to the patient, and the absence of cosmetic deformity of the breast and scarring on follow-up mammograms. This has led some enthusiasts to conclude that core biopsy "should supplant surgical biopsy as the standard in the vast majority of cases" [9].

However, before core biopsy is considered a standard diagnostic technique, several questions must be answered. First and foremost, what is the diagnostic accuracy of the procedure? Does core biopsy characterize malignant lesions suffi-

Presented in part at the 17th Annual San Antonio Breast Cancer Symposium.
Address for correspondence and offprints: Monica Morrow, M.D., Northwestern University, Department of Surgery, 250 East Superior Street, Wesley 201, Chicago IL 60611, USA; *Tel:* 312-908-9039; *Fax:* 312-908-5447.

ciently to allow treatment planning? Finally, is core biopsy cost effective when considered in relation to the complete surgical management of breast cancer rather than just diagnostic biopsy? This article will address these questions from the perspective of a clinician involved in the therapy of breast cancer.

Accuracy of core biopsy

A stereotactic instrument allowing percutaneous sampling of mammographic abnormalities was described by Bolmgren et al [10] in 1977. The early stereotactic devices used fine needle aspiration cytology as a sampling technique, and although the sensitivity of stereotactically directed fine needle aspiration was reported to be between 79% and 100% [11-21], several problems kept the technique from being widely adopted in the United States. These included the need for a trained cytopathologist, high rates of insufficient samples, the lack of a specific diagnosis for the majority of benign abnormalities, the inability to reliably distinguish in situ from invasive carcinoma, and the necessity of biopsying all lesions with atypical cytology. The development of a biopsy gun which allows the removal of a core of tissue rather than a cytologic sample has resolved many of the problems associated with stereotactic aspiration cytology [22], and has resulted in a marked increase in the number of centers performing stereotactic biopsies [23].

Seven series comparing stereotactic core biopsy to surgical excision have demonstrated sensitivities ranging from 71% to 100% for the core technique [22,24-29] (Table 1). It is important to recognize that the patients in these studies were highly selected and may not represent the majority of women with mammographic abnormalities. Most of the lesions sampled were masses or asymmetric densities. Elvecrog [29] restricted the procedure to women with lesions larger than 5 mm in diameter, and the mean diameter of the lesions sampled by Gisvold et al [28] was 11 mm. The number of cancers presenting as microcalcifications without an associated mass is not stated in the majority of reports. However, based on the numbers of cases of ductal carcinoma in situ (DCIS) which were diagnosed (Table 2), it can be inferred to be fairly small. Of the 196 cancers with surgical confirmation only 35 (18%) were ductal carcinoma in situ, and only 23 (66%) of these were successfully diagnosed. These results are considerably worse than those for mass lesions, and are a cause for concern since DCIS may account for as many as 50% of mammographically detected carcinomas [30-32]. The diagnostic sensitivity of 71% reported by Dowlatshahi et al [24] has been attributed to flaws in their study design and technical errors such as the use of a 20 gauge needle and inadequate sampling [33,34]. However, it is noteworthy that in this study 43% of the mammographic lesions sampled were microcalcifications [24], a factor that might have contributed to the low sensitivity which was noted. Liberman et al [35] have demonstrated that the removal of 3

Table 1. Sensitivity of stereotactic core biopsy

Author	n	% Sensitivity	% Insufficient samples	Needle size (gauge)
Dowlatshahi [24]	250	71	17	20
Dronkers [25]	53	95	6	18
Parker [22]	103	94	1	14-20
Parker [26]	103	96	0	14
Mikhail [27]	60	100	2	14
Gisvold [28]	160	85	1	14
Elvecrog [29]	100	97	0	14

Table 2. Stereotactic biopsy for the diagnosis of ductal carcinoma in situ

Author	Total # cancers	# DCIS	# DCIS diagnosed
Dowlatshahi [24]	76	22	15
Dronkers [25]	45	5	3
Parker [22]	16	2	1
Parker [26]	23	2	1
Elvecrog [29]	36	4	3
Total	196	35(18%)	23(66%)

core specimens resulted in diagnostic material in 98% of mass lesions compared to only 74% of microcalcifications. Increasing the number of cores to 6 or more resulted in diagnostic material in 99% of masses and 92% of calcifications.

Another source of diagnostic inaccuracy in core biopsy is the histologic finding of atypical hyperplasia. Jackman et al [36] reported 19 diagnoses (4%) of atypical ductal hyperplasia in a series of 450 core biopsies. Excisional biopsy and histologic correlation were available in 16 cases, and concordance between the excisional biopsy and the core was present in only 5 cases. Nine of the 11 discrepancies were due to the finding of DCIS (n=6) or infiltrating carcinoma (n=3) at excisional biopsy. Other studies [9,28] have demonstrated a high incidence of malignancy when atypical hyperplasia is identified on core biopsy. Although atypical hyperplasia is present in only 4% of palpable breast lesions when strict diagnostic criteria are used [37], it is present in approximately 15% of mammographically detected abnormalities [30,38], making this a clinically significant problem.

It is apparent from this information that the diagnostic accuracy of core biopsy varies with the type of lesion being targeted and the histologic diagnosis obtained. The high rates of diagnostic accuracy reported in selected patient populations being studied by physicians with special expertise in core technique may not be representative of the results obtained by the practicing general radiologist. In an effort to address the issue of the reliability and reproducibility of core biopsy, Parker et al [9] reported data from a consortium of 20 institutions performing core biopsy in a standardized fashion. A total of 6,152 lesions were sampled and 15 cancers (0.2%) were missed, leading the authors to conclude that core technique should replace surgical biopsy. However, a closer examination of these data reveals that biopsy confirmation of the core diagnosis was obtained in only 1,363 cases. If only patients with biopsy confirmation are considered, the missed cancer rate was 1.1%. Of the 4,702 patients who did not have a confirmatory surgical biopsy, 2,237 had no follow-up, so the missed cancer rate for this group is unknown. The remaining 2,456 patients had a minimal follow-up of six months, and five additional cancers were identified in this group. Overall, 280 women with benign cores had a surgical biopsy and 5.4% were found to have carcinoma. Of the 6,152 lesions studied, 1,637 were microcalcifications. The miss rate for microcalcifications was significantly higher than for mass lesions (p=0.05). The fact that 5% of lesions identified as benign by core biopsy were actually carcinoma raises considerable concern about the widespread use of this technique. In addition, the data in this article were slanted in favor of core biopsy by the grouping of atypical hyperplasia and low grade DCIS together in a category called "mammary intraepithelial neoplasia," thus avoiding the missed cancers associated with a diagnosis of atypical hyperplasia. While such a classification may prove to be appropriate as the natural history of DCIS is better defined, it is not standard at the present time [39]. The multi-institutional study did confirm the safety of core biopsy, with only

0.2% of patients experiencing complications from the procedure.

Proponents of core biopsy point out that surgical excisional biopsy is not a perfect technique and lesions are sometimes missed. Reported miss rates for excisional biopsy of nonpalpable abnormalities range from 0.2-20% [22,28,29,40-42], with the majority of authors reporting miss rates of 1-5% [22,28,29,41]. In my experience with 355 consecutive needle localizations a single lesion was missed (0.3%), a figure closely approximating Kopans [40] report of 2 missed lesions (0.2%) in 1003 cases. These results suggest that the best reported rates of localization and excision are superior to those achieved by the leaders in core technology. More importantly, the failure to remove a lesion at open biopsy is usually readily apparent when the specimen mammogram is reviewed, allowing for prompt development of a treatment plan. The detection of cancers missed by core biopsy is dependent on a change in their mammographic appearance during follow-up. Helvie [43] has demonstrated that patient compliance with follow-up mammography recommendations for low suspicion abnormalities which were not biopsied was 88% at 4 months and fell to 71% at one year. The impact of a reassuring benign histologic diagnosis from a core biopsy on compliance is unknown. The slow growth rates of DCIS and some low grade malignancies mandate several years of follow-up before concluding that carcinoma has not been missed.

Lesion characterization by core biopsy

In order to be clinically useful and allow treatment planning, core biopsy must provide an accurate characterization of the entire malignant lesion. Jackman et al [36] examined the concordance between the core biopsy diagnosis and the results of surgical excision in 116 cancers. Core sampling was performed with a 14 gauge needle and a mean of 7.3 cores per lesion were obtained. Of 43 cases diagnosed as DCIS by core biopsy, 8 (19%) were found to contain invasive carcinoma. Conversely, 2 of 15 patients diagnosed as invasive carcinoma with an extensive intraductal component had only DCIS in the surgical specimen. However, one of these patients had an axillary metastasis, suggesting that invasion was present. In addition, core biopsy failed to identify an extensive intraductal component in 6 of 50 lesions diagnosed as infiltrating ductal carcinoma. Parker et al [9] reported incomplete characterization of high grade DCIS lesions in 11% of cases, and one third of the lesions characterized as low grade DCIS or atypical hyperplasia were incompletely diagnosed. Liberman et al [44] observed discordant results in 4 of 59 cancers undergoing stereotactic biopsy followed by surgery. These included 2 cases of invasion not diagnosed by core, one case of invasion seen only in the core specimen, and one case in which DCIS along the core needle track was misinterpreted as invasive carcinoma. The impact of these diagnostic discrepancies on therapy has not been analyzed, but has obvious implications. Decisions regarding the need for axillary dissection or the extent of lumpectomy and the risk of local failure after breast conserving surgery can only be made with complete knowledge of the character of the lesion. Frozen section at the time of definitive surgery will not resolve this problem. Sacchini et al [45] reported a 12% discordance rate between frozen section readings and the final histopathologic diagnosis in 403 patients with mammographic abnormalities. Difficulty in identifying small areas of invasion and in distinguishing atypical hyperplasia from DCIS, the same problems seen with core biopsy, accounted for the majority of the discrepancies.

In addition to problems of incomplete sampling of malignant lesions, there is also a risk that core sampling may completely remove the mammographic abnormality, making definitive surgical therapy with breast conservation difficult. Mikhail et al [27] reported 34 cancers diagnosed by core biopsy. In 3 cases of infiltrating carcinoma (8.8%), no residual abnormality was apparent on the mammogram and after mastectomy no further tumor was found in the pathology

specimen. Hernandez et al [46] noted two cases of DCIS (6.9%) which were completely removed in a series of 29 cancers identified by core biopsy. After a re-excision of the presumed biopsy site did not reveal any further tumor, these patients were observed. In both series, the number of core specimens was six or less. Whether these cases represent false positive diagnoses or extremely small tumors which were completely removed is not clear. However, complete removal of the mammographic target is a significant problem if breast conserving therapy is undertaken. The correlation between the size of the mammographic abnormality and the size of the tumor has been shown to be poor, particularly for pure ductal carcinoma in situ or invasive lesions with an extensive intraductal component [46-48]. Thus, complete removal of the mammographic abnormality does not eliminate the need for a definitive excision (lumpectomy) with margin evaluation. If surgery is undertaken promptly after core biopsy, residual hematoma on the mammogram can be used as a localization target. However, as many women seek multiple opinions and consider their therapeutic options prior to definitive therapy the hematoma may resolve, leaving no mammographic abnormality to target. A "blind" lumpectomy in the region of the mammographic abnormality is an unsatisfactory approach, as is a mastectomy for a potentially microscopic cancer. As our ability to identify and target extremely small mammographic abnormalities increases, and as the number of core specimens obtained increases in an effort to maximize diagnostic accuracy, this problem is likely to become more frequent.

Cost of core biopsy

One of the major advantages of core biopsy is said to be cost savings [9,22], and this is certainly true if only the costs of the diagnostic biopsy are considered. Schmidt et al [19] reported that the cost of a stereotactic fine needle aspiration cytology, including a 6 month unilateral follow-up mammogram, was 28% of the cost of a surgical needle localization using 1990 charges. However, the true costs of stereotactic biopsy must be considered in terms of the degree of suspicion of the lesion being sampled and the subsequent cancer therapy undertaken if malignancy is diagnosed. Clearly, the use of stereotactic biopsy to sample very low suspicion abnormalities which could be safely followed will result in cost increases rather than cost savings. Sickles [49] and others [43,50,51] have demonstrated that low suspicion mammographic abnormalities (less than 2% risk of cancer) can be reliably identified and safely followed with missed cancer rates of 2% or less. In our experience [30], only half of 267 women referred for surgical consultation because of an abnormal mammogram were found to need a biopsy after a complete radiologic work-up. If a thorough evaluation is not being performed prior to a recommendation for surgery, there is no reason to suspect that such an evaluation will be done before recommending a less invasive core biopsy. Mikhail et al [27], reporting their experience with stereotactic biopsy in 416 patients in a 6 month time period, noted that 24% of the mammographic abnormalities were classified as benign and 49% as likely benign prior to biopsy. The incidence of malignancy in these groups was 1% and 3% respectively, raising the question of why any type of biopsy was performed.

The situation when biopsying highly suspicious mammographic lesions is somewhat different. In this circumstance, if the core biopsy is benign, surgical excision is undertaken to exclude a false negative result. Evans [52] reported that of 117 core biopsies done for high suspicion abnormalities, 30% were benign and required surgical excision, resulting in extra costs. In addition, if breast preservation is undertaken as cancer therapy, needle localization and excision will be required, again making core biopsy an extra step in the diagnostic and therapeutic process. It has been suggested that a preoperative diagnosis of cancer improves the surgeon's ability to perform a lumpectomy. We have reported a 95% negative margin rate after a conservative

diagnostic lumpectomy [53]. The excision of large amounts of breast tissue as part of breast conserving surgery is not warranted in the majority of patients and worsens the cosmetic result. In general, wide excisions are reserved for women with positive margins after a more conservative excision, or those with an extensive intraductal component [54], a condition not readily identified by core biopsy [36]. Thus, for high suspicion mammographic abnormalities a benign core biopsy does not eliminate the need for surgical excision. Women with small mammographically detected cancers are usually excellent candidates for breast conserving surgery and will require localization and excision of their carcinoma as part of local therapy. In this circumstance, surgical excision as the initial step in the diagnostic process provides complete histologic information and often serves as the definitive lumpectomy.

It is in the management of mammographic abnormalities of low to intermediate suspicion that core biopsy will result in the greatest cost savings. Schmidt et al [19] calculated the relative cost of stereotactic fine needle aspiration cytology based on the degree of suspicion of the mammographic abnormality. This calculation included the cost of surgical biopsy for lesions diagnosed as atypical or those with insufficient specimens. For lesions of low malignant potential (10% to 20% risk of cancer), the relative cost of stereotactic aspiration was approximately one half the cost of surgical biopsy. As the level of suspicion of the mammographic abnormality increases to 50%, the cost of stereotactic biopsy increased to 84% of the cost of surgical biopsy. Based on these findings, Schmidt [23] has used stereotactic aspiration and/or core biopsy to diagnose 276 mammographic abnormalities of low to intermediate suspicion with a predicted cancer risk of 2% to 10%. Only 39 (14%) of these cases went on to surgical biopsy, and 70% of the biopsied cases proved to be carcinoma. Since approximately 70% of the mammographic abnormalities referred for biopsy are of relatively low suspicion [23], the use of stereotactic biopsy in this setting has the potential to decrease health care costs while still allowing the early diagnosis of cancer.

Table 3. Indications for stereotactic biopsy

- Low suspicion, but not clearly benign lesions
- Sample other abnormalities in the ipsilateral breast of women with cancer who desire breast preservation
- Diagnose mammographic abnormalities seen on only one view
- Diagnose suspicious lesions in patients who are only candidates for mastectomy
- Alternative to surgical biopsy in patients with severe comorbidities

Conclusions

Based on this review, a number of conclusions may be drawn regarding core biopsy. The procedure is safe and well tolerated. In the hands of experienced operators, false negative rates are low and insufficient samples are uncommon. However, the accuracy of the procedure varies with the type of lesion (microcalcification or mass) being targeted. Potential indications for stereotactic biopsy are listed in Table 3. Benign cores from mammographically suspicious lesions are an indication for surgical biopsy, as is the finding of atypical hyperplasia on a core biopsy. When a program of core diagnosis for nonpalpable abnormalities is initiated, a careful audit of results must be carried out to ensure that surgical biopsy is performed when the findings of core biopsy do not adequately explain the mammographic abnormality, and that missed cancer rates are similar to those reported in the literature.

There are a number of unanswered questions about core biopsy which must be addressed before a final decision regarding the utility of the technique can be made. The reproducibility of the technique remains uncertain, and this is a major issue. A careful study of the ability to plan definitive local therapy on the basis of core characterization of malignant lesions is needed. Further work must be done to evaluate the cost

effectiveness of core biopsy of high suspicion mammographic abnormalities. Such a model will have to consider variations in the amount of breast conserving surgery performed across the country, the frequency of re-excision lumpectomy for mammographic abnormalities, and the use of frozen sections to improve lesion characterization. Further information on patient compliance with follow-up recommendations after a benign core diagnosis is also needed.

Finally, quality assurance in this field remains ill defined. The credentialing of physicians to perform stereotactic biopsy should be more than the ability to purchase a machine. Audits of missed cancers, biopsy yields, and complication rates must be carried out. The performance of an invasive procedure includes the responsibility for a meaningful discussion of the results of the procedure. The ability of the radiologist to inform a woman that she has cancer and initiate treatment counseling varies widely. Similarly, women with benign diagnoses require information on cancer risk and follow-up procedures.

Stereotactic core biopsy is an exciting development in the diagnosis of mammographic abnormalities. Clarification of appropriate indications for its use will require close collaboration between radiologists and clinicians.

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