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Original article

The impact of stereotactic large-core needle biopsy in the treatment of patients with nonpalpable breast lesions: a study of diagnostic accuracy in 510 consecutive cases

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Abstract. The objective of this study was to assess the usefulness of stereotactic large-core needle biopsy (LCNB) in the management of nonpalpable breast lesions (NBL) and compare it with stereotactic fine-needle aspiration biopsy (SFNA) performed simultaneously in a significant number of cases. From November 1993 through June 1997, 510 consecutive patients with NBL underwent 14-gauge LCNB with 354 women undergoing simultaneous 21-gauge SFNA in the same lesion. Mammographic findings, lesion size, number of core biopsy specimens, complications and diagnoses of both techniques were analysed. Surgical biopsy, tumorectomy or mastectomy was indicated for malignancy or poor correlation between SFNA or LCNB results and clinical or radiological findings. Values of diagnostic accuracy of both LCNB and SFNA were determined. The ratio benign surgical biopsies/malignant surgical biopsies (BB/CB) of the series was calculated. A total of 171 patients underwent surgical treatment; in 31 (18.1 %) a benign process or atypical ductal hyperplasia was the final diagnosis. The ratio BB/CB was 0.22. Sensitivity and specificity were 93.2 and 100 %, respectively, for LCNB, and 77.2 and 92.3 %, respectively, for SFNA with cytological analysis. Large-core needle biopsy provides more accurate diagnosis than SFNA in the management of nonpalpable breast lesions and obviates a surgical diagnostic procedure in a significant number of cases.

Key words: Biopsy technology – Breast biopsy – Breast neoplasm, diagnosis – Stereotactic biopsy

Introduction

Mammographic screening is useful in the detection of nonpalpable breast lesions. It enables early treatment and has brought about a significant drop in the mortality related with these lesions. Nevertheless, despite the advances made in mammographic study and the use of other radiological techniques to complement it, accurate characterization of these lesions for malignancy continues to be problematic [1–3]. The positive predictive value of mammography in this context is considered to be below 40 %, assuming that higher values are due to a high rate of missed cancers [4]. In 1986 stereotactic fine-needle aspiration (SFNA) was introduced as a cytological diagnostic method for nonpalpable breast lesions. Despite recent series with excellent results, most studies have shown a high rate (up to 38 %) of explorations yielding inadequate (unrepresentative or insufficient) material for diagnosis, with a 5–14 % rate of false negatives and a 1 % false-positive rate [5]. In many cases it is impossible to reach a conclusive diagnosis. Moreover, it is impossible to determine whether a neoplasm is invasive. The cytopathological study is complex to carry out and requires experience with the technique. For these reasons, the use of SFNA as a diagnostic method in these patients is declining, and therapeutic decisions continue to be based on surgical biopsy [6].

With the aim of reducing the frequency of surgical biopsies of benign lesions, Parker et al. [7] incorporated stereotactic large-core needle biopsy (LCNB) as a diagnostic tool in the study of suspicious lesions detected by mammography in the late 1980s. In November 1993 our Mammary Pathology Unit initiated a prospective study of the diagnostic usefulness of LCNB in nonpalpable breast lesions.

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Materials and methods

The study period comprised the 55 months from November 1993 to June 1997. Five hundred ten lesions consecutively detected by mammography were studied by LCNB. All nonpalpable lesions detected on mammography considered suspicious or indeterminate were included [categories 4 and 5 of Breast Image Reporting and Data System (BI-RADS) and category-3 cases with associated risk factors, which all call for histological study). Breast Image Reporting and Data System categories used for assessment of mammographic findings included: category 0 (assessment is incomplete, needs additional imaging work-up); category 1 (negative, routine screening); category 2 (benign finding negative, routine screening); category 3 (probably benign finding, short-term follow-up); category 4 (suspicious abnormality, biopsy should be considered); and category 5 (highly suggestive of malignancy, appropriate action should be taken). No exclusion criteria were established regarding minimum size of lesion or specific radiological pattern. All lesions detected were confirmed using additional mammographic views prior to being scheduled for stereotactic biopsy.

Two planar radiographic views acquired at + 15° and –15° relative to a line perpendicular to the image receptor were obtained using a LoRad Stereoloc Unit (LoRad, Danbury, Conn.) and the three spatial coordinates of the lesion are calculated. After cutaneous anaesthesia, a single SNFA sample was obtained using a 21-gauge needle with attached syringe. Images of the exact location of the needle were obtained at this time in each case. After that, a 14-gauge needle (Sterylab spq, Milan, Italy) with a sample notch of 22 mm mounted in an automatic gun (Sterylab spq, Milan, Italy) was inserted and prefire images were obtained to ensure correct location. The number of samples varied with the progress of the study. Two to five samples were obtained in most cases during the initial period, whereas at least five samples of each lesion were obtained when patient tolerance permitted.

Cytological samples obtained by SFNA were fixed in 96% alcohol for Papanicolaou staining, and air dried for May-Grünwald-Giemsa staining, followed by cellular block from the clot for inclusion in paraffin when enough material was present. The cylinders of tissue obtained through LCNB were fixed in 10% formaldehyde for a mean time of 6 h and included in paraffin. Three-micra-thick seriated sections were obtained (an average of five preparations, with four sections per preparation) and stained with haematoxylin and eosin. Cytological study was performed by an experienced pathologist, previously informed of the clinical context and degree of radiological suspicion. The LCNB samples were all evaluated by a single other pathologist, previously informed of the clinical context and degree of radiological suspicion though blind to the results of cytological study carried out simultaneously on material obtained by SFNA.

Values were recorded for the following variables: age, pattern of lesion microcalcifications (MIC), architectural distortion (AD) and nodule without microcalcifications (NOD), size in millimetres defined in mammography and number of samples of the LCNB. Patients evaluated the degree of discomfort experienced and any complications in the procedure (pain, lipothymia, haematoma) were recorded by the attending radiologist.

The following groups were established for histological diagnosis with LCNB:

1. Inadequate material for diagnosis: mammary parenchyma absent or unrepresentative. When microcalcifications were observed on mammography, the material was considered to be adequate when dystrophic microcalcifications were visible with haematoxylin and eosin staining or with polarized light. If microcalcifications could not be confirmed in this material, it was only considered to be adequate after joint clinical, radiological and pathological evaluation. Radiological confirmation of microcalcifications in the samples was considered sufficient evidence of accurate representation of the lesion. However, in the first stage of the study this confirmation was not performed in all cases. When radiological patterns were indicative of nodular lesions or architectural distortion, or when nonspecific parenchymatous changes were found in the LCNB, samples were considered representative only after joint clinical, radiological and pathological evaluation.
2. Diagnosis of benign processes (fibroadenoma, proliferative/nonproliferative fibrocystic disease, moderate ductal hyperplasia, lobular hyperplasia, atypical ductal/lobular hyperplasia, etc.).
3. Diagnosis of malignancy (carcinoma in situ and infiltrating ductal/lobular carcinoma, specifying type and histological grade).

The following groups were established for diagnosis with SFNA:

1. Inadequate material
2. Nonspecific benign (negative for malignant cells) and specific benign (fibroadenoma, etc.)
3. Atypical
4. Suspicious for malignancy
5. Positive for malignant cells

For statistical purposes, groups 2 and 3 were considered benign and groups 4 and 5 malignant.

When a lesion was diagnosed as benign with LCNB, a conservative therapeutic approach was adopted. In cases with a radiological pattern of AD or NOD, deferred biopsy was performed only when radiological and pathological findings were in clear disagreement, or when the LCNB findings disagreed with the SFNA findings. All patients without surgical intervention were scheduled for follow-up mammography at 6 months or 1 year depending on the type of benign process (fibrocystic changes, mild/moderate/severe ductal hyperplasia, fibroadenoma, etc.). Patients with specific benign diagnoses (fibroadenoma, intramammary lymph nodes, etc.) were scheduled for a second mammographic follow-up at 2 years.

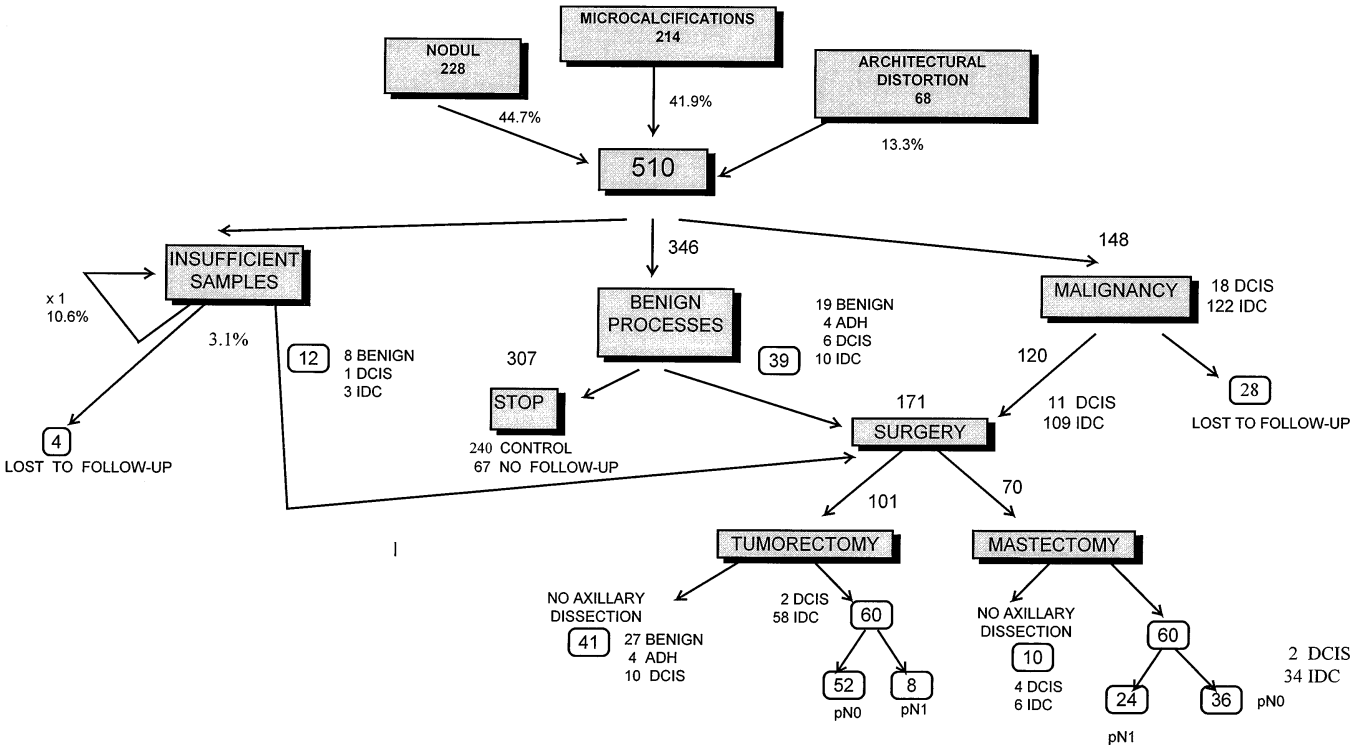

Fig 1. Diagnostic distribution for LNCB

An LCNB diagnosis of atypical ductal hyperplasia called for deferred biopsy of the lesion. An LCNB diagnosis of intraductal carcinoma called for removal of the tumour with intraoperative study (when the lesion was macroscopically defined and greater than 1 cm in diameter) or deferred biopsy. An LCNB diagnosis of invasive carcinoma called for removal of the tumour and axillary lymph nodes and intraoperative macroscopic evaluation of the margins of resection or mastectomy with removal of axillary lymph nodes without intraoperative study.

Descriptive analysis of frequency and rank, absolute-values measurement and 95% confidence intervals for sensitivity, specificity and positive and negative predictive values of LCNB (and of the simultaneous SFNA) were used in the statistical evaluation of the diagnostic accuracy. These values were studied for the cases with adequate material for diagnosis in relation with an established gold standard (i.e., cases with posterior surgery and cases with benign diagnoses by LCNB and clinical follow-up of at least 1 year with no incidence on annual follow-up mammography). Large-core needle biopsy diagnoses of atypical ductal hyperplasia that call for surgical biopsy under the protocol of the study have been excluded in the calculations of diagnostic accuracy. For LCNB diagnoses of specific benign processes (fibroadenoma, adenomyoepithelioma, intramammary lymphatic node, etc.) the same restrictive criteria were followed in establishing the gold standard, posterior surgery and/or clinical and radiological follow-up of at least 1 year.

Results

Large-core needle biopsy was tested on 510 consecutive lesions over a 55-month period (November 1993 to June 1997). Mean age of patients was 57 years (range 50–70 years) making up approximately 50% of the total. The distribution of radiological patterns showed 41.9% MIC (214 cases), 44.7% NOD (228 cases) and 13.3% AD (68 cases). The number of LCNB samples varied between two and ten, being between two and five in 62.9% of the cases and greater than five in 37.1%. Of the patients, 10.6% needed a second exploration with LCNB, the absolute rate of inadequate material for diagnosis being 3.1% (16 lesions of 510). No major complications attributable to LCNB were observed. Minor complications were 2 cases of lipothymia resolved with change of posture and 3 cases of haematoma with spontaneous resolution in the weeks following the exploration. Large-core needle biopsy gave a diagnosis of benign process in 346 lesions (67.8%), carcinoma in situ in 21 cases (4.1%) and infiltrating carcinoma in 127 cases (24.9%; Fig. 1). A total of 223 lesions (67.8%) were considered to be fibrocystic changes (nonproliferative fibrocystic breast disease, with fibroadenoma (9.4%), moderate/severe ductal hyperplasia and adenosis (10.3%) and atypical ductal hyperplasia (2.7%) being the most prevalent benign diagnoses. Other less frequent diagnoses were: adenomyoepithelioma (1 case), hamartoma (4 cases) and intramammary lymph node (6 cases).

A gold standard to measure diagnostic accuracy was available for 411 lesions. In 171 cases this was posterior surgical intervention (mastectomy or tumour removal), and in the remaining 240 cases this was at least 1 year of clinical follow-up including mammography. In 99 pa-

Table 1. Values of diagnostic accuracy of large-core needle biopsy (LCNB) and fine-needle aspiration biopsy (FNAB). PPV positive predictive value; NPV negative predictive value; FPR false-positive rate; FNR false-negative rate

	Sensitivity (%)[a]	Specificity (%)	PPV (%)	NPV (%)	FRP (%)	FNR (%)
LCNB	93.2 ± 2.5	100	100	96.5 ± 1.8	0	2.1
SFNA	77.2 ± 5.2	92.3 ± 3.3.	92.4 ± 3.3	76.9 ± 5.2	1.5	5.6

[a] ± 95% confidence interval

tients a gold standard was not available. This group included 24 patients with malignancy diagnosed by LCNB who chose to be treated in other centres, 71 with less than 1 year of follow-up and 4 patients lost to follow-up. Of the 171 cases studied surgically, 140 lesions (81.8%) were malignant and 31 were benign (18.1%). The 140 cancers included 18 cases of carcinoma in situ (12%), whereas the other 122 cases were invasive carcinoma. Of the tumours, 84% measured less than 2.5 cm in maximum diameter and 65% of the invasive carcinomas were classified as stage pT1. The diagnostic distribution of carcinoma in situ and invasive carcinoma with respect to the radiological pattern was 49 cases of MIC (22.8% of all MIC), 63 cases of NOD (27.6% of all NOD) and 36 cases of AD (52.9% of all AD). In 9 cases in which LCNB had diagnosed benign processes, posterior surgery demonstrated the presence of neoplasia (false-negative rate of 2.1%). In these cases, the radiological pattern that called for LCNB study was NOD in 6 cases, AD in 1 case, and MIC in 2 cases. Eight of the nine false negatives occurred in the initial period of the study, with two to four samples taken. In the 2 cases of microcalcifications there was no radiological confirmation of microcalcifications in the cylinders.

The final histological diagnosis was invasive carcinoma in all cases and lesions were smaller than 1 cm in 6 cases. Simultaneous SFNA was positive or suspicious for malignant cells in 4 cases (2 cases of MIC and 2 cases of NOD). None of the patients with LCNB diagnoses of benign processes and no posterior surgery showed any signs of cancer or any change in the appearance of the lesion on mammographic follow-up. There were no false positives for LCNB diagnoses of carcinoma in situ or invasive carcinoma (false-positive rate 0%). Of the 14 cases LCNB diagnosed as atypical ductal hyperplasia, posterior surgery was performed in 11 cases (8 tumourectomies and 3 simple mastectomies). The final diagnosis was atypical ductal hyperplasia in 4 cases, intraductal carcinoma in 6 cases and invasive carcinoma in 1 case. The mean number of samples in this group was 5.3 and the mean size of the lesions was 1.6 cm. In the group of patients LCNB diagnosed as having carcinoma in situ (21 cases), 4 cases were lost to follow-up. Of the 17 remaining cases, 9 underwent tumourectomy and the final diagnosis was intraductal carcinoma in 5 cases and invasive carcinoma in 4 cases. In the 8 patients undergoing mastectomy, the final diagnosis was intraductal carcinoma in 4 cases and invasive carcinoma the remaining 4 cases. In this group of patients the mean number of samples was 5.1 and the mean lesion size was 2.5 cm.

The values of diagnostic precision determined for LCNB in absolute values and 95% confidence intervals are: sensitivity 932 ± 2.5%, specificity 100%, positive predictive value 100% and negative predictive value 96.5 ± 1.8%.

Simultaneous SFNA was performed in 354 lesions, with adequate material obtained for diagnosis in 181 cases. The diagnostic frequency was benign lesion in 66 cases (36.5%), atypical in 39 cases (21.5%), suspicious for malignancy in 12 cases (6.6%) and positive for malignant cells in 64 cases (35.3%). The rate of false negatives was 5.6% for SFNA and the rate of false positives was 1.5%. The values found for the diagnostic accuracy of SFNA were sensitivity 77.2 ± 5.2%, specificity 92.3 ± 3.3%, positive predictive value 92.4 ± 3.3% and negative predictive value 76.9 ± 5.2% (Table 1).

Discussion

Mammographic screening of asymptomatic women has proved to be efficacious in detecting nonpalpable breast lesions and has played an important role in the reduction of the mortality rate associated with breast cancer. Nevertheless, given the limitations inherent in mammography and complementary radiological studies, an increase in the number of lesions detected necessarily implies an increase in the number of eventually benign lesions studied to rule out cancer [8]. Experience in screening programs has led to the formulation of different scales to measure the accuracy of mammography. One such scale is the ratio of anatomopathologically negative to positive biopsies. A value of approximately 2.5 (2.5 negative biopsies for every biopsy showing cancer) is considered to be acceptable. A high ratio is due to a lack of specificity, which leads to unnecessary surgical intervention [9–11].

It seems obvious that if we are to increase the efficiency of health care management with respect to the early detection of breast cancer, mammography needs to be complemented by other diagnostic techniques. Surgical biopsy is currently the most widely accepted source of anatomopathological diagnosis [12]. However, surgical removal is expensive, it leaves scars that can interfere with follow-up radiological examinations, and it can also – though rarely – be ineffective. Researchers have sought other techniques to minimize unnecessary surgery.

Until recently, most studies to this end concerned the usefulness of SFNA in characterizing nonpalpable lesions [13, 14]. All of these studies, with some exceptions (including the pioneers in this diagnostic approach [15]), report a high rate of inadequate material for diagnosis (6–47%). A wide range of false negatives (1–31%) have been reported and false-positive rates of up to

1% have been found. Moreover, in many cases it is impossible to reach a specific diagnosis or to differentiate between carcinoma in situ and invasive carcinoma [16]. The rate of inadequate material reported in the present study is exceptionally high (48.8%). This is partly due to the design of the study (a single pass of the needle as opposed to two or three samples common in other series). When comparing these results with other SFNA series, the lack of exclusion criteria (for size or radiological pattern) and the fact that explorations were not repeated in the present study must be taken into consideration. However, the analysis of diagnostic accuracy (which included only those cases with adequate material for diagnosis) also reveals lower values for sensitivity (77.2%) and negative predictive value (76.9%) than LCNB, as well as a 5.6% rate of false negatives and 1.5% of false positives. Although it is noteworthy that SFNA correctly diagnosed malignancy in 4 cases in which LCNB gave false negatives, this does not seem to be a strong enough argument to recommend routine simultaneous exploration with both techniques. In fact, these 4 cases belong to the first stage of the study with an average of 3.4 samples per lesion. These results could be better explained by the bias introduced by the learning period, rather than by a real difference in the diagnostic power of the two techniques. We believe these results corroborate the view that SFNA is not the best diagnostic approach to nonpalpable lesions and does not have a decisive role to play in reducing the number of surgical interventions on benign lesions detected on mammographic screening [17–20].

Large-core needle biopsy, however, does seem to be a viable alternative to open surgery. It combines high diagnostic performance with a low rate of minor complications. In our study the only complications seen were lipothymia and cutaneous ecchymosis with spontaneous resolution, which affected only 1.25% of patients. The sensitivity (93.2%), specificity (100%) and positive and negative predictive values (100 and 96.5%, respectively) are similar, or in many cases superior to, those previously reported by other groups (Table 2) [23–27]. Nine cases of false negatives (2%) were found over the entire study period. In all but 2 cases, the radiological pattern was NOD or AD. Unlike microcalcifications, there is no histological marker to confirm adequate representation of these lesions in LCNB. In these cases a close correlation between radiology and pathology is essential. Mammographic follow-up at 6 months is mandatory when the benign diagnosis is not specific (fibroadenoma, etc.).

The rate of inadequate material for diagnosis in our series (3.1%) is similar to those published by other groups, which range from 0 to 17%. In the most recent groups of patients, the ratio of material inadequate for diagnoses approaches zero, especially for the MIC lesion type. Radiological confirmation of microcalcifications in the LCNB samples, routine repetition of biopsy-gun exploration to confirm the presence of microcalcifications in the case of poor correlation between mammography and pathology, and the fixation of samples in nonaqueous media are methods recommended for improving the efficiency and performance of the technique [28–31]. In the earlier stages of the study between two and five LCNB samples was the norm. The absence of relevant complications led to a progressive increase in the number of samples (seven on average in the latter stages of the study) and a resultant increase in efficiency.

Table 2. Diagnostic accuracy of LNCB. Review of the literature

Reference	No. of cases	Sensitivity (%)	Insufficient samples (%)	Needle size (gauge)
[28]	102	94	1	14–18
[24]	250	71	17	20
[23]	53	95	6	18
[43]	100	97	0	14
[48]	60	100	2	14
[47]	160	85	1	14

When atypical ductal hyperplasia or carcinoma in situ are diagnosed using LCNB, surgical biopsy is required for proper histological analysis [32]. In the case of atypical ductal hyperplasia, this is due to the criteria used by histologists to differentiate between low-grade intraductal carcinoma and atypical ductal hyperplasia. Often the quantity of lesion has an important influence on the histological analysis (lesions under 2 mm or affecting only one or two ducts with histological traits similar to low-grade intaductal carcinoma are classified as atypical ductal hyperplasia). Another factor is the lack of objective or homogeneous criteria for diagnostic decision making. Jackman et al. [33] found nearly 70% discordance in a series that included 19 cases diagnosed as atypical ductal hyperplasia by LCNB (of 16 cases with posterior surgery, only 5 were confirmed as atypical ductal hyperplasia, whereas 9 cases corresponded to cancer and 2 cases were benign).

In our series surgical biopsy was carried out in 11 of the 14 cases diagnosed as atypical ductal hyperplasia with LCNB (2.7% of the total). The LCNB diagnosis was confirmed in only 4 cases; in 6 cases the definitive diagnosis was intraductal carcinoma and in 1 case invasive carcinoma. The need for surgical biopsies in these cases is evident.

In the case of intraductal carcinoma, histological diagnosis with LCNB again fails to reach an acceptable level of efficiency. A total of 21 intraductal carcinomas were diagnosed by LCNB (4.1% of the total). Seventeen of these cases led to tumourectomy or simple mastectomy. An invasive component was confirmed in 8 (40%), although it is noteworthy that all 8 measured < 1 cm in diameter and 5 (60%) were under 0.5 cm or microinvasive (pT1 a). Seven of the eight invasive cancers were pN0. It remains to be seen to what extent an increase in the number of samples could improve diagnostic precision in these cases. In any case, the LCNB diagnosis of atypical ductal hyperplasia or carcinoma in situ represented < 7% of all LCNB. At present, surgical biopsy is necessary to reach an acceptable level of diagnostic efficiency in these cases.

Although surgical biopsy is considered to be the gold standard, surgery is not absolutely infallible. Localiza-

tion with surgical marker is a difficult technique, and the rate of improperly excised lesions with local anaesthesia can reach 20 % (due to serious bleeding that complicates the operating field, migration of surgical marker, etc.) [34, 35]. The surgical margins of resection are affected by a high percentage of carcinoma cases (43–86 % depending on the series), with the consequent therapeutic implications [26]. Last, but not least, there are the high costs and after-effects of surgery, such as cosmetic disfiguration and difficulties in reading posterior mammographies due to scarring [36, 37].

The risk of transferring neoplasic cells by LCNB (occurring in as many as 0.2 % of cases in some reports [38]) is more theoretical than real, because a malignant diagnosis with LCNB is followed by surgical removal that should include the path of the needle. This is accomplished performing the surgical marking using the same path as in the LCNB when possible.

Whereas all studies agree that LCNB plays a major role in the approach to nonpalpable breast lesions, there is no consensus as to the optimal strategy for its use in the different clinical situations found in these patients. Models for LCNB use and incorporation into the diagnostic algorithm vary, differing in the manner and extent of use, as well as in the use of other diagnostic techniques [39–44]. We propose that LCNB be used as an alternative to surgical biopsy in all nonpalpable lesions, with the exception of probably benign lesions. The likelihood of a lesion classified as a highly probable benign lesion by mammography (lesions in category 3 of Breast Image Reporting and Data System, BI-RADS [45]) being malignant has been calculated as between 0.5 and 2 %. Periodic mammographic follow-up seems more appropriate for these patients, resorting to other measures only when follow-up cannot be carried out or in the case of patient preference or anxiety [46]. On the other hand, it has been calculated that more than 80 % of those patients with lesions classified as highly suspicious by mammography (category 5 of BI-RADS: "Highly suggestive of malignancy – appropriate action should be taken") have cancer. Surgical biopsy can only be obviated in these patients when malignancy can be ruled out with a high degree of certainty. The usefulness of LCNB in this group of patients is controversial. Our group favours the use of LCNB in this context. Its specificity of 100 % and positive predictive value of 100 % (common to all series including this one) allow LCNB to reach a definitive diagnosis. The need for intraoperative study is eliminated, contributing to the optimal use of surgery both through its role in reducing unnecessary intervention and in planning surgical treatment. However, sometimes reintervention is necessary, assuming that cases diagnosed as atypical ductal hyperplasia by LCNB (and radial scarring and adenosis for some) and carcinoma in situ (no greater than 7 % of the patients in our series) always call for surgical biopsy to establish the definitive diagnosis and program an appropriate therapeutic approach. These limitations do not, in our opinion, detract from the usefulness of LCNB in this type of lesion.

In any case, the area in which LCNB can be considered a real alternative to surgical biopsy is the group of lesions classified as indeterminate on mammography (also referred to as category 4 of BI-RADS: "Suspicious abnormality – biopsy should be considered") and with a probability of malignancy between 2 and 80 %. The positive predictive value of mammographic screening, calculated at 40 %, leads directly to surgical biopsy, with all of its drawbacks, for a high percentage of asymptomatic women with lesions that will eventually prove to be benign. Our results for diagnostic accuracy suggest that LCNB should be incorporated in the diagnostic algorithm of these patients. Large-core needle biopsy gives specific benign diagnoses on histological analysis and contributes to the characterization of malignant lesions. With a specific benign diagnosis (e.g. fibroadenoma), surgical biopsy can be obviated, and a diagnosis of malignancy that includes characterization for invasive components aids in planning a definitive surgical therapeutic approach, with no need for intraoperative study of the lesions. There will always be a percentage of patients whose therapy will depend on an exhaustive study through surgical biopsy, but that does not detract from the intrinsic value of LCNB as a diagnostic alternative in these patients.

In conclusion, surgery should be confined to its therapeutic role when possible, and its diagnostic role could be played by LCNB incorporated into a multidisciplinary protocol (including surgeon, radiologist and pathologist). Although criteria for use are not as yet agreed upon, LCNB is a powerful, cost-effective diagnostic tool that should be incorporated into the diagnostic algorithm for the study of nonpalpable breast lesions.

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