Abstract The aim of this study was to evaluate accuracy of 11 G vacuum-assisted percutaneous biopsy (VAPB) carried out on digital stereotaxic table, on breast non-palpable lesions (NPLs), non-visible by US. Prospective study on 132 consecutive NPLs (126 patients) not reliably found by US; 82% showed microcalcifications. Surgical confirmation was obtained in all malignant cases and when VAPB reported atypical lesion (ductal or lobular), radial scar or atypical papillary lesion. All patients with benign results were included in a mammographic follow-up programme. Two cases could not be dealt with due to technical difficulties. One to 26 cylinders were obtained from the remaining 130 NPLs. Sixty-four lesions were surgically confirmed. Forty-six of the 47 malignancies were correctly diagnosed. In one case of a malignant tumour, an atypical lesion was classified with VAPB. All cases of histologically verified lobular carcinoma in situ, atypical ductal or lobular hyperplasia, radial scar or atypical papillary lesion were correctly diagnosed preoperatively. The remaining lesions were benign in VAPB, and after 1 year of follow-up, no false negative has been found. Based on this short-term follow-up, absolute sensitivity was 97.9%, absolute specificity 84.3% and accuracy was 99.2%. For predicting invasion, accuracy was 89.1%. Vacuum-assisted percutaneous biopsy is a very accurate technique for NPLs which are not detectable by US. It can replace approximately 90% of DSB with no important complications, avoiding scars and providing a higher level of comfort.

Keywords Breast · Biopsy · Breast neoplasm · Diagnosis · Stereotaxis

Introduction

In the past 20–25 years surgical hook-wire-guided excision has been considered as the best technique for a proper diagnosis of the breast non-palpable lesions (NPLs) [1, 2] thus leading to the concept of diagnostic surgical biopsy (DSB). It is still the reference technique, even though some authors have reported failure rates between 2 and 8% [2]. Diagnostic surgical biopsy presents some problems, such as a cutaneous and parenchymatous scarring, a variable grade of psychic trauma, the risks implied in the operation (frequently under total anaesthesia) and high costs, including hospitalisation. Moreover, 60–80% of DSBs produce benign results [1, 2]; therefore, they could be considered unnecessary. The rest, those with malignant results, require a therapeutic-aimed new operation, since the NPL group is seldom suitable for an intraoperative frozen-section analysis, because of the small size and/or the absence of tumour mass visible for the pathologist [3].

Consequently, many surgical procedures are required for an accurate diagnosis and treatment of NPLs. This fact has encouraged the development of various guided-puncture techniques, whose goal is to make a complete
diagnosis by percutaneous way. The most common techniques are fine-needle aspiration (FNA), which provides samples for a cytological analysis, and needle core percutaneous biopsy (NCPB), which provides specimens suitable for a histological study. Both techniques can be directed by US or stereotactic guidance.

Fine-needle aspiration cytology is an inexpensive and easy technique, but with a limited reliability, as it presents false negatives and an excessive rate of inadequate specimens [4, 5]. It is especially ineffective on NPLs with calcifications, where inadequate samples can reach 50% [5]. Finally, FNA cytology does not provide information on the in situ or invasive character of the malignant NPLs, which means that in a great number of cases it does not reduce the number of surgical procedures. Ultrasound-guided FNA can be very useful in diagnosis of clearly nodular NPLs, which are usually detectable by US [6, 7]. When these types of lesions are malignant, they are due in almost every case to invasive carcinomas. Anyway, it is widely accepted that, in order to achieve a high level of accuracy, FNA cytology samples need to be evaluated by very experienced cytologists [5, 6, 7, 8].

Needle core percutaneous biopsy is a very reliable technique for percutaneous diagnosis, slightly more expensive than FNA cytology but much cheaper than DSB. It can provide a specific diagnosis of both benign and malignant NPLs, including their in situ or invasive condition [9, 10, 11, 12, 13, 14, 15]. This technique is much more accurate on nodules than on distortions, asymmetric densities and calcifications [16, 17], lesions that normally are not recognisable by US, so that their reliable diagnosis must be made by stereotaxy. At least five to ten passes are necessary, each one requiring a new insertion of the needle [9, 12, 16]. The sensitivity in this type of NPL does not exceed 90%; that is why DSB may frequently be necessary [18, 19].

There have been recent technological improvements on percutaneous diagnosis of NPLs. Perhaps the most promising is vacuum-assisted percutaneous biopsy (VAPB), which can also be carried out by US or stereotaxy [20, 21, 22, 23, 24, 25, 26].

Vacuum-assisted percutaneous biopsy is usually carried out on especially dedicated digital stereotactic tables, with the patient in a prone position and using 14- or 11-G needles [27]. It has all the advantages of NCPB and furthermore it is capable of obtaining a higher volume of suspicious tissue after only one puncture. Eleven-gauge needles allow the insertion of small metallic marks, very useful on small-sized NPLs, cases in which VAPB may extirpate the whole radiological image [28, 29].

In April 1999 our breast imaging unit installed a digital stereotactic table, to which a vacuum-assisted system was also added. We carried out all VAPB procedures reported below using this equipment. The goal of this study was to evaluate the accuracy of VAPB carried out on digital stereotactic table, on suspicious breast NPLs, non-visible or non-accessible by US.

Materials and methods

We designed a prospective study on all the cases detected in our department from April to December 1999 and remitted to us by other centres in the same period. The inclusion criteria were suspicious breast NPL, which could not be reliably found by US. No case was excluded because of age, breast size, NPL location or any other criteria. Ultrasound-detectable NPLs were punctured by means of NCPB or FNA under US control and therefore were excluded from this study.

One hundred thirty-two NPLs, present in 126 consecutive patients fulfilled the required criteria. Six patients presented bifocal lesions, in one or both breasts. Patients were aged from 29 to 81 years (mean 50.5±10.2 years). Fifty-nine NPLs (44.7%) had been detected thanks to the Navarre Early Detection Programme and the other 73 (55.3%) had different origins.

The radiologist personally provided all the patients with written and oral explanations on this technique, according to the published literature, after which their informed consent was requested.

Radiological features of the NPLs were 82 cases (62.1%) of calcifications only; 24 cases (18.2%) of nodule/density/distortion; 26 cases (19.7%) of mixed lesions (calcifications and increased density). All NPLs were classified before the procedure, according to BI-RADS system [30, 31].

All stereotactic procedures were carried out with the patient in a prone position on a Lorad Stereoguide table (Danbury, Conn.). Collection of samples was achieved by means of the Mammotome device (Biopsys/Ethicon Endosurgery, Cincinnati, Ohio).

A disposable 11-G needle was used in all cases. Initially we planned to obtain a minimum of 7 and a maximum of 13 cylinders from each NPL (one to two sweeps around the clock).

In all cases superficial anaesthesia was used (Mepivacaine HCL 5 ml at 2%). We firstly placed the tip of the cannula in the middle of the NPL and then did an automatic shot of the Mammo-tome. After placing the acquisition window in the correct position and before extracting samples, a dissolution of 2 ml of mepiva- caine HCL at 2% mixed with epinephrine 1:100,000 was injected through the cannula, in order to achieve vasoconstriction and to improve deep anaesthesia.

Two stereotactic views were taken after the extraction of the sample, in order to verify the grade of removal of mammographic image. A metallic mark was left on the biopsy bed in the cases of very small lesions which could have been completely removed.

In the NPLs with calcifications, a radiological view of the collected cylinders was done straight away on the Lorad Stereoguide table. For NPLs that presented no calcifications, a two-view conventional mammogram of the punctured breast was done in order to confirm derived signs from the puncture in the desired area (haematoma, cavity or air bubble).

All explorations were carried out by the same radiologist and nurse. Post-operative care included supine position on an adjacent stretcher, 10 min sustained compression, adhesive suture stitches application, sterile apposite placement and checking of the incision 20–30 min later.

All NPLs diagnosed as malignant by VAPB were prescribed conservative or radical surgical treatment. Axillary lymphadenectomy was recommended when an invasive carcinoma was reported on the VAPB.

All the patients whose VAPB results were lobular carcinoma in situ, atypical hyperplasia (ductal or lobular), radial scar and atypical papillary lesion, underwent surgical biopsy. The DSB was also carried out in the NPLs BI-RADS-5 whose VAPB result was benign. All other patients were not operated on, and were included in