Audit on breast biopsies of non-palpable and difficult-to-access lesions

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Abstract
Fine-needle aspiration biopsy (FNAB) is done regularly at our mammography unit on lesions that are non-palpable and difficult to access. Studies done at other hospitals on palpable and non-palpable lesions show a wide variety of results. Therefore we wanted to develop a database of information regarding FNAB results at our own unit.

A retrospective descriptive study was done from the reports of all patients who had FNABs at our unit over a 1-year period (15 December 2004 – 1 December 2005). A convenient sampling of 48 women of all ages was used. Four patients did not fit the study criteria and were excluded. Cytological data were retrieved from the original reports and no standardised criteria were used to determine adequacy.

Of the available cytology results 23.9% (11 of 46) were positive for malignancy, 17.4% (8 of 46) were negative for malignancy, 4.4% (2 of 46) showed atypical cells and 54.3% (25 of 46) of reported results were inconclusive. In the group of fine-needle aspirations that showed atypical cells (2 patients), neither had a follow-up ultrasound after 3 or 6 months, but both patients were followed up with a mammogram after 6 months.

In patients with fine-needle aspiration results that were inconclusive, 20% were followed up with ultrasound after 3 months. After 6 months 8% had a follow-up ultrasound and 36% had a follow-up mammogram. Four per cent of the patients had a routine mammogram at 1 year and 56% were referred to the surgery department. (Some patients had more than one follow-up examination.)

The aim of our audit was to develop baseline statistics regarding FNAB results for our unit. The high number of inconclusive results in our study (56.82%) could be due to the fact that FNABs of non-palpable lesions are more difficult to perform. The level of experience of each radiologist performing the aspiration as well as the skill of the cytologist should also be considered. FNABs will be continued at our unit and a follow-up study for comparison of statistics is planned. Such a comparison between studies will assist us in setting a standard for future FNAB results at our unit.

Introduction
Fine-needle aspiration biopsy (FNAB) is done regularly at our mammography unit.

Aspiration is only done on lesions that are non-palpable and difficult to access. FNAB of palpable lesions is done at the surgery clinic as preferred by the dedicated breast surgeons.

The reason for the execution of our study was to develop a database of information regarding the results of FNABs done on breast lesions that were not palpable and difficult to access. The patients were all seen at our mammography unit. Based on our own audited results, continuation of only FNAB (sometimes complemented by core biopsy) on these breast lesions will be considered.

Methods
A retrospective descriptive study was done from the reports of all patients who had FNABs performed between 15 December 2004 and 15 December 2005 at our mammography unit, Universitas Hospital, Bloemfontein. This was a convenient sampling of 48 women of all ages.

The information was taken from computerised files. Approval for the study was obtained from the Ethics Committee, Faculty of Health, University of the Free State. Cytological data were retrieved from the original reports and no original slides were re-evaluated. No standardised criteria were used to determine adequacy. According to internal protocol ultrasound-guided FNABs were only done on lesions that were non-palpable or difficult to biopsy without ultrasound guidance (hereafter referred to as difficult-to-access lesions).

The physical examination was not recorded in the patient files. Radiological studies (mammogram or ultrasound) were considered non-suspicious if no abnormality was detected or where a benign finding such as a well-circumscribed mass was visible. Only lesions that appeared suspicious on ultrasound were sampled. Lesions with the typical appearance of a fibro-adenoma, cyst or intraparenchymal lymph node were therefore excluded.

Fine-needle aspirations were done by a radiologist with a 20 ml syringe and a 22 gauge needle. Each patient's skin was surgically cleaned and anaesthetised with lidocaine. The lesion was then aspirated while negative pressure was applied to the syringe. Suspicious cystic lesions were aspirated and fluid was sent for cytological examination. Solid lesions were aspirated with the needle being repeatedly advanced and withdrawn in various directions within the lesion.

The aspirated content was smeared on glass slides and was immediately evaluated by the cytologist for an adequate amount of cells.

Results
During the period 15 December 2004 to 15 December 2005, 48 patients underwent invasive biopsy procedures at our mammography unit. These procedures were performed in response to suspicious lesions having been found during imaging of the breasts. From the original group of 48 patients, 4 patients did not meet the study criteria and were excluded. Fine-needle aspirations were done on the remaining 44 patients.

Of the 44 patients included in this study, 22 patients underwent more than one FNAB. Despite this, more than one cytology result was available for only 2 of the patients, resulting in a total of 46 available cytology results.
The results of the screening assessment were then compared with the logical features and the findings of FNAB and core biopsy, if performed. Assessments in 182 lesions. Data were recorded on patient demographics, radiological age of patients who would benefit most from the more expensive core biopsy. Between January 1996 and June 2000, the dominant radiological realization proved to be a highly accurate, rapid and cost-effective means of triaging patients, the use of fine-needle aspiration cytology in the palpable breast lesions, FNAB proved to have limited value because of the high insufficient sample rate and greater diagnostic accuracy of other interventions, e.g. core-needle biopsy and needle-localised open surgical biopsy. At 18 institutions, 442 women who underwent 22-25 gauge imaging/guided FNAB were enrolled. Definitive surgical, core-needle biopsy and/or follow-up information was available for 423 (95.7%) of these women. When insufficient samples were included in the analysis and classified as positive, the sensitivity and specificity of FNAB were 85-88% and 55.6-90.5% respectively. The diagnostic accuracy of FNAB was significantly better for detection of masses than for detection of calcifications and with ultrasound guidance than with stereotactic guidance.

According to another study done in December 2003 on breast-screening patients, the use of fine-needle aspiration cytology in the assessment of highly suspicious mammographic microcalcifications proved to be a highly accurate, rapid and cost-effective means of triaging patients who would benefit most from the more expensive core biopsy. Between January 1996 and June 2000, the dominant radiological abnormality was classified prospectively as high-grade microcalcifications in 182 lesions. Data were recorded on patient demographics, radiological features and the findings of FNAB and core biopsy, if performed. The results of the screening assessment were then compared with the final histological findings. FNAB had a sensitivity of 77.22% and a positive predictive value of 100%.

FNAB is used as a diagnostic tool and done regularly at our mammography unit on lesions that are non-palpable and difficult to access. This procedure is relatively easy, simple to perform and has a low cost which makes it suitable for developing countries where other complicated diagnostic instruments may not be readily available.

The aim of this audit was to develop baseline statistics regarding FNAB results for our mammography unit. Positive cytological results confirm the diagnosis of breast carcinoma and ensure prompt referral to the surgery department.

In our audit 23.9% of FNAB results showed malignant results, 17.4% no malignancy, 4.4% atypical cells and 54.3% were inconclusive.

In a retrospective study done in Massachusetts General Hospital, 1 062 breast FNABs were performed on palpable as well as non-palpable breast lesions: 10% were reported unsatisfactory, 42% negative, 20% atypical, 3% suspicious and 25% positive for malignancy.

The fact that palpable as well as non-palpable breast lesions were sampled in the abovementioned study, made comparison with our audit very difficult.

FNABs of non-palpable lesions are more difficult to perform. The high number of inconclusive results in our study (54.3%), could be attributed to this fact. The level of experience of each radiologist performing the examination as well as the skill of the cytologist, should also be considered.

FNABs will be continued at our unit. A follow-up study for comparison of statistics, that will include information regarding clinical examination, radiological reports and FNAB results, is planned and this will assist us in setting a standard for future FNAB results at our unit.

Discussion

In a study done in June 2001 at the Department of Radiology, University of North Carolina, 1 to determine the diagnostic accuracy of ultrasonographically and stereotactically guided FNAB in the diagnosis of non-palpable breast lesions, FNAB proved to have limited value because of the high insufficient sample rate and greater diagnostic accuracy of other interventions, e.g. core-needle biopsy and needle-localised open surgical biopsy. At 18 institutions, 442 women who underwent 22-25 gauge imaging/guided FNAB were enrolled. Definitive surgical, core-needle biopsy and/or follow-up information was available for 423 (95.7%) of these women. When insufficient samples were included in the analysis and classified as positive, the sensitivity and specificity of FNAB were 85-88% and 55.6-90.5% respectively. The diagnostic accuracy of FNAB was significantly better for detection of masses than for detection of calcifications and with ultrasound guidance than with stereotactic guidance.

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