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Editorial Comment

Needle core biopsy for screen detected breast lesions: Time to raise the bar?

*Helena M. Verkooijen**

Department of Community, Occupational and Family Medicine, National University of Singapore, 16 Medical Drive, 117597 Singapore, Singapore
Geneva Cancer Registry, Geneva University, Switzerland

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Over the past decades, we have seen a spectacular evolution in the early detection and diagnostic work-up of breast cancer. Since the 1980s, breast cancer screening programmes have been increasingly introduced in both Europe and the United States, and the detection rate of nonpalpable lesions has been rising ever since. In the early years, most screen detected lesions, needing pathologic confirmation, were diagnosed by wire-localised open (surgical) breast biopsy. This was indeed a very reliable procedure, but rather unsatisfactory for several reasons. In case of cancer, a second operation was generally necessary to achieve safe tumour margins and to perform axillary clearance, while in the case of benign disease, the patient was 'unnecessarily' left with a disfiguring scar and distorted breast tissue.

After stereotactic guided needle biopsy of the breast was first described in the 1970s and automated core needle breast biopsy in the 1980s, it took until 1990 before the image guided core needle biopsy started to gain popularity in the field of screen detected breast lesions. In this year, Parker et al. reported a first series of digital stereotactic large-core needle biopsies[1]; subsequently, a multitude of series followed and they all came to the same conclusion: image guided large core needle biopsy appeared to be equally accurate in diagnosing nonpalpable breast cancer as wire guided open breast biopsy, but was associated with lower costs, less complications and better cosmetic results.[2]

Advantages of core needle biopsy over fine needle aspiration were obvious as well: even though fine needle aspiration biopsy is faster, cheaper, less prone to complications and provides an almost immediate diagnosis, core needle biopsy allows a more complete characterisation of the lesion, including differentiation between invasive and *in situ* disease and grade and hormone receptor status, and there is also no need for a specialised cytopathologist to interpret the slides.

Large, multi-institutional studies were undertaken to address the feasibility of image guided core needle biopsy in routine settings. Additional advantages of image guided core needle biopsy were identified, including a reduced time to diagnosis, a reduction in the number of surgical procedures for complete treatment of nonpalpable breast cancer and lower levels of physical discomfort and pain. Cost effectiveness studies also favoured core needle biopsy over surgical breast biopsy.[3]

However, shortcomings and pitfalls were also recognised. In rare cases, there was complete removal of small lesions by core needle biopsy, which hampered future surgical excision in case of carcinoma. Insertion of dedicated clips or haematoma localisation provided an answer to this problem.

* Address: Department of Community, Occupational and Family Medicine, National University of Singapore, 16 Medical Drive, 117597 Singapore, Singapore. Tel.: +65 6516 8414; fax: +65 6779 1489.
E-mail addresses: cofhmv@nus.edu.sg, Lenny.Verkooijen@imsp.unige.ch.
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More problematic was the tendency of core needle biopsy to underestimate the severity of disease. Around 20–30% of lesions, diagnosed as ductal carcinoma *in situ* (DCIS) on core needle biopsy, were upgraded to invasive cancer after surgical excision. These patients needed to undergo a third intervention (second surgical procedure) to complete the cancer treatment with axillary clearance. Similarly, some core needle biopsy diagnoses, such as atypical hyperplasia, lobular carcinoma *in situ*, radial scar, etc., carried a high risk of being upgraded to DCIS or invasive cancer after open biopsy. It was therefore advocated that this category of core biopsies diagnoses, now classified as B3 (lesion of uncertain malignant potential) or B4 (suspicion of malignancy), should always be followed by surgical biopsy.

Since these shortcomings affected only a small proportion of women undergoing core needle biopsy, they did not prevent large-scale introduction of core needle biopsy for screen detected lesions.

Eighteen years after Parker's landmark study, stereotactic or ultrasound guided core needle biopsy is the preferred technique for diagnosis of screen detected lesions. In this issue of the *European Journal of Cancer*, El-Sayed et al. report an audit of performance of 10 years of needle core biopsy of screen detected lesions in the NHS Breast Cancer Screening programme (1997–2007).[4] Their series, including 20,001 women assessed by core needle biopsy, is by far the largest to report on the performance of needle core biopsy of screen detected lesions to date.

The audit has shown that the annual number of core needle biopsy procedures more than doubled over the course of 10 years. This increase was accompanied by a steady improvement in diagnostic accuracy. Complete sensitivity increased from 91% to almost 100%, implying that practically all breast cancers were identified as abnormal by core needle biopsy. The audit also showed a moderate improvement in DCIS underestimate rate: towards the end of the study, 22% of core needle biopsies diagnosed as DCIS were upgraded to invasive cancer, versus 28% during the first years of the study. Both phenomenon, i.e. the increased complete sensitivity and decreased DCIS underestimate rate, may partly be attributed to the improvement in sampling techniques, such as vacuum assisted needle biopsy, whereby larger tissue samples are obtained, allowing a more complete diagnosis. In addition, increasing experience in triple assessment of core needle biopsies and multidisciplinary evaluation have probably also contributed to better performance characteristics.

The results, however, have to be interpreted with some caution. With the increase in number of biopsies performed and the experience gained, the number of surgical biopsies following benign core needle biopsies declined from around 10% in 1997–1998 to <1% in 2006–2007. As the chances of missed cancers being recognised decreased 10-fold, it is not unthinkable that more false negative core needle biopsies have been missed towards the end of the study.

Despite the increased experience and improvement in sampling techniques, the old problem of management of high risk core needle biopsies (B3 lesions, including atypical hyperplasia, lobular carcinoma *in situ*, radial scar) is increasing. Even though the proportion of B3 lesions upgraded to DCIS or invasive cancer after surgical biopsy has come down slightly (from 25–30% in the early years to around 15–20% in recent years), the magnitude of the problem has increased substantially due to the steady increase in number of core needle biopsies diagnosed as B3. In 1997–1998, only around 20 (1.7%) core needle biopsies were categorised as B3, while in 2006–2007, this number had increased to around 160 (6.1% of all biopsies). Several studies have, rather unsuccessfully, tried to identify B3 subgroups with particularly high or low risk of malignancy, facilitating further management. Dynamic contrast-enhanced magnetic resonance imaging (MRI) of women with B3 lesions could be useful as well. In a small series including 79 B3 lesions, only one out of 55 diagnosed as non-suspicious on MRI was malignant on excision histology, suggesting a high negative predictive value of MRI in B3 lesions.[5] Large prospective series are warranted to confirm these preliminary results. Additional research, looking at molecular markers or predictive models, may also be useful in differentiating between benign and malignant outcomes in women with B3 lesions.

The introduction of core needle biopsy has unmistakably changed the landscape of management of screen detected breast lesions. El Sayed et al. have highlighted that extremely high levels of diagnostic accuracy are feasible and that practically 100% of nonpalpable breast cancers can be detected as abnormal in a routine setting. It is therefore appropriate to challenge the current minimum performance measure of complete sensitivity of 80% (preferred >90%). Since the effectiveness of screening programmes is largely dependent on the diagnostic trajectory following screening, it may no longer be justified to allow 20% (or even 10%) of screen detected cancers to be missed. With their study, El Sayed et al. have convincingly shown that it is time to raise the bar.

Conflict of interest statement

None declared.

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