For Debate

Fibroadenosis of the breast does not require excision biopsy

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Introduction

This debate addresses the question of whether fibroadenosis of the breast should ever be managed by excision biopsy. The immediate problem is one of nomenclature and definition. 'Fibroadenosis' is a term used to cover a spectrum of histological changes which are seen both in association with clinically palpable lumps in the breast and in breasts which are normal on examination. These histopathological changes include fibrosis, adenosis, microcysts, and epithelial hyperplasia. These changes have been ascribed disease status, although recently there has been agreement that, with the possible exception of atypical epithelial hyperplasia, they constitute aberrations of normal development and involution (ANDI).¹ The dilemma faced by the surgeon is whether or not to excise an apparently benign lump, or whether on the basis of examination and investigation, a patient with such a lump can be managed non-operatively.

The case for the motion

The case for non-operative management of fibroadenosis of the breast rests on the following arguments. It is now accepted that fibroadenosis is not a disease. The overriding reason for excision of a lump in the breast is to exclude a carcinoma, but modern diagnostic techniques allied to clinical examination can now reliably exclude such a possibility. Finally there may be an increased risk of cancer in some patients who have had a biopsy for fibroadenosis, but this risk is not confined to the clinically abnormal area, and so excision of that area is unnecessary.

It has long been known^{2–4} that the 'pathological' changes seen on microscopy in excision biopsy

specimens are widely present in normal breast. Love *et al.*⁵ questioned whether fibroadenosis can be regarded as a disease. Such changes are seen in a large proportion of breasts at post mortem^{2,3,6} and one study has shown that more than 50% of premenopausal women have breast abnormalities on clinical palpation.⁷ This perhaps suggests that we need to redefine what constitutes the normal breast, as it appears to be present in only a minority of women!

If benign lumps are so common in the female breast, what is it that brings women to the clinic complaining of a lump? There may have been a localized change, with the appearance or increase in size of a lump, or there may be pain and tenderness. The clinical outcome in such cases managed without excision biopsy indicates that many of these masses will resolve completely and most become smaller during the subsequent 12 months.⁸ The accuracy of diagnosis is crucial to the management of these women. In the last 10 years mammography (both X-ray and ultrasound) and fine needle aspiration cytology have been developed as extremely reliable investigations for the management of solid lumps in the breast. Whilst individually these modalities are variably accurate in the diagnosis of cancer, if all three are positive then the predictive value for carcinoma is 100%.⁹ Dixon *et al.*¹⁰ have shown that it is also possible to exclude cancer with a combination of clinical examination, mammography and cytology. If all three features indicate benign disease it is clearly reasonable to observe the lesion, although careful follow-up is required. Many of these masses will resolve, but if any suspicious feature develops the lesion should be excised. This approach will not impair prognosis, even if a carcinoma is present, as we know that earlier detection of symptomatic cancer does not improve survival.¹¹

It is conceded that the non-operative management of a lump in the breast will always leave some doubt in the mind of the doctor or patient that a

carcinoma may have been missed. It has been known for some time that women who have had a breast biopsy for benign disease are at an increased risk of developing breast cancer.^{12,13} However, the excess risk is small and is not related to the site of initial biopsy. Page *et al.* have shown that the women at risk are within a group of 30% who have features of epithelial hyperplasia in the biopsy.¹⁴ Even within this group only 5% show the changes of atypia in which the cancer risk rises to 4.5 times that of the general population. The risk of developing breast cancer from such atypical hyperplasia is equal in either breast, independent of the site of the biopsy. These areas of atypical hyperplasia are generally impalpable clinically and so they were discovered by chance at excision biopsy. The excised lesion itself was not malignant and it would be unrealistic to advocate biopsy of all clinical fibroadenosis as a means of detecting those women at increased risk of subsequent malignancy. The yield from such an approach would be far too small to justify what is, in effect, the most invasive form of breast cancer screening.

What of the malignant lesion that presents with clinical features suggesting benign disease? The possibility of this presentation has been the justification for excision biopsy of all breast lumps which present to the surgeon. We have seen that with modern methods of imaging and cytology to supplement clinical examination, the diagnosis of benign disease can be made with great accuracy. When there is agreement between clinical, radiographic and cytological evidence, excision biopsy is superfluous. The accepted teaching that any clinically palpable lump in the breast must be removed can no longer be accepted.

The case against the motion

The proposition that an apparently benign lesion in the breast does not require excision biopsy cannot be supported for the following reasons. Firstly, the diagnosis of a benign lesion is notoriously difficult, and a carcinoma may be overlooked. Such a delay in diagnosis is a devastating psychological blow to the patient, and the delay may allow progression of the disease. Secondly, when a benign lesion is excised, there may be histological features which indicate an increased cancer risk for that individual. This information will allow appropriate follow-up of selected patients. It is therefore better to err on the side of caution and excise the clinically obvious lesion, malignant or benign.

It is now accepted that the histological appearances of the excision biopsy can predict increased cancer risk. 'Moderate hyperplasia' (epitheliosis) is associated with a doubled risk of future development of breast cancer. 'Atypical

hyperplasia' increases this cancer risk to five times the control population. These risks are doubled again if there is a family history of breast cancer.^{15,16} Excision biopsy with subsequent histological diagnosis of atypical hyperplasia will identify women at greatly increased risk of breast cancer. These women can then be offered appropriate screening. Other patients with no increased risk of breast cancer can be reassured of the benignity of the presenting lesion, and also that they have no increased risk of developing cancer in the future.

Although modern methods of diagnosis have greatly increased the accuracy of preoperative diagnosis, with small lesions the sensitivity of clinical examination is only 73%, and this is even lower (53%) in the fourth decade of life.¹⁷ At this age fibroadenosis is common and so diagnostic confusion and difficulty is likely.

Although aspiration cytology is virtually 100% specific for the diagnosis of cancer, sensitivity is much lower (80%),¹⁸ and so failure to obtain malignant cells does not exclude carcinoma. Furthermore, the aspirate is most frequently unsatisfactory in the presence of fibroadenosis.¹⁸ After an unsatisfactory aspirate for cytology, 'Tru-cut' biopsy may provide additional useful information. The value of this combination of techniques for the exclusion of malignancy has not been studied.

Mammography is 80% to 90% sensitive in the detection of cancer in most series^{18,19} but this sensitivity is lower in young women due to increased breast density. Ultrasound mammography may improve the sensitivity for the detection of breast cancer.¹⁹

The use of a scoring system based on clinical examination, aspiration cytology, and mammography by X-ray and ultrasound can give very accurate preoperative diagnosis of breast cancer,¹⁹ with only one of 169 cases of breast cancer classified as benign. Nevertheless, if excision biopsy had not been used to verify the diagnosis, that case of cancer would have been missed and results could not have been considered satisfactory. A further question is raised when considering lesions detected by breast screening programmes. Here the investigator is faced by the same question as the surgeon faced with a clinically palpable lump. Are the observed changes entirely benign, or do they represent malignancy? If screening is to be effective in the reduction of breast cancer mortality, and if patients are to have confidence in the system, all screening detected lesions which could possibly represent a cancer must be excised. This means that a considerable number of benign lesions must be removed. The ratio of benign to malignant lesions removed after screening varies from 1–6 to one.²⁰

Despite modern methods it is not always possible to diagnose breast lesions with complete accuracy and this is especially so in the context of screening

programmes. Missed diagnosis of breast cancer even for a short period results in psychological trauma to the patient and loss of confidence in her medical advisors. The disease may also progress during the interval between first presentation and correct diagnosis. Therefore excision biopsy even of apparently benign lesions is necessary to ensure that breast carcinomas are not missed.

Chairman's comments

The problem of how to manage a lesion in the breast is the same whether that lesion is clinically obvious or detected by screening. If a lesion is suspicious of malignancy by any criterion, it must be removed. This debate addresses the question of how to manage the lesion which appears on all available evidence to be benign. Although Dixon *et al.*¹⁰ are confident that they can exclude cancer reliably, using a combination of clinical assessment, mammography and cytology, this clearly depends on the availability of expertise in all three areas. Others with similar expertise¹⁹ found one cancer in 43 cases classified as benign on all three criteria. Is it reasonable to excise all benign breast lumps in order to avoid delay in diagnosis of carcinoma in a small number of patients?

Although breast biopsy may give useful information relating to increased risk of cancer in a small proportion of patients, biopsy and the subsequent scar makes the breast more difficult to assess, both clinically and mammographically. The scar itself may also be a cause of symptoms such as disfigurement, pain and fibrosis.

The question of anxiety suffered by patients is extremely difficult to quantify. The anxiety resulting from a missed carcinoma must be set against the

psychological stress of many unnecessary biopsies.

The arguments above are based on the assumption that initial assessment is by experienced clinicians. If biopsy is not undertaken, careful follow-up by the same clinician is essential. One particular area not addressed by the above arguments is how to manage a patient who has previously had an excision biopsy which showed fibroadenosis. Probably the best approach is to treat this second lesion entirely on its merits, after full clinical, radiographic and cytological examination. If the lesion appears perfectly benign it can be safely observed, but if there are any worrying features it should be treated, as should a primary lesion, by excision biopsy. One further feature of a second lump in the breast is that if the histology of the first lesion shows epitheliosis, this can taken into account when assessing the risk of cancer in the second presentation.

Finally the question of how to manage fibroadenosis, or benign-appearing lumps in the breast, rests on the definition of normality. If more than 50% of premenopausal women have palpable 'abnormalities' in the breast⁷ and if the histological features of 'fibroadenosis' are seen in up to 89% of women³ then it becomes necessary to redefine what is normal and abnormal. A working party has recently examined the nomenclature of benign breast disease, and the definition of normality.²¹ It is hoped that this will clarify our thinking, and rationalize the management of patients with a benign lump in the breast. After such redefinition, an individual patient with clinical, radiographic, and cytological appearances of a benign process might well be managed without an excision biopsy.

Author's note: The order of authorship does not indicate support for a particular point of view.

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