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Audit of eliminating biopsy for presumed fibroadenomas with benign ultrasound greyscale and shear-wave elastography findings in women aged 25–39 years

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1 **Audit of eliminating biopsy for presumed fibroadenomas with benign ultrasound greyscale and**
2 **shear wave elastography findings in women aged 25-39 years**

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5 **Key words**

6 Breast, Ultrasound, shear wave elastography, fibroadenoma

7

8 **Introduction**

9 Fibroadenomas account for approximately 40% of breast biopsies performed around the world (1-3).

10 The performance of these biopsies, pathological processing, pathological interpretation and

11 discussion of the results is a large part of the workload of breast clinics.

12 The different ultrasound (US) features of breast cancer and fibroadenomas are well known (4,5) and

13 the sensitivity of US for the detection of breast cancer is around 95%. Studies have shown that the

14 sensitivity and specificity of ultrasound is statistically significantly greater than mammography in

15 patients with breast symptoms for the detection of breast cancer and benign lesions particularly in

16 dense breast and in young women (6). However, US of triple-negative (TN) cancers poses a particular

17 problem as they often show benign US features such as distal enhancement and a well-defined

18 margin (7,8). This problem is compounded by the young age distribution of TN breast cancer, which

19 likely means that the pre-test probability of malignancy is relatively low. However, given the very

20 low cancer incidence in women under 25 years old, many centres are now routinely using US

21 features alone to determine when breast masses are benign (9,10). Some centres have also

22 increased this age threshold to 30 years.

23 Shear wave elastography (SWE) is an US technique which measures tissue stiffness quantitatively
24 and reproducibly. It has a similar sensitivity for invasive breast cancer as greyscale US (11). It takes
25 about two minutes to perform and two minutes to extract the quantitative readings per case. The
26 small proportion of cancers with benign SWE values tend to be small, screen-detected and low-grade
27 (12). Such cancers are, however, rarely missed or misclassified by greyscale US. This means that SWE
28 and greyscale US are complementary when used in combination to assess breast masses, with
29 greyscale US missing some high-grade lesions and SWE some low-grade cancers. This is especially
30 true when assessing women with symptoms, where small, low-grade cancers are less common. In a
31 series of almost 700 symptomatic solid lumps, none of the cancers showed both benign greyscale US
32 features and benign SWE features (13). A particular advantage of SWE is that its sensitivity for the
33 detection of lobular cancer is similar to that for ductal (no-special-type) cancers (14). This is in
34 contrast to all other routine breast imaging modalities.

35 Because of the above studies, our centre adopted a policy of not biopsying or following up
36 symptomatic, clinically benign masses with benign greyscale US and SWE findings in women under
37 40 years of age. This policy was adopted in 2017. The aim of this study was to assess the outcomes
38 of this policy in women aged 25-39 years, where a minimum of 12 months' follow-up data is
39 available.

40 **Methods**

41 Patients were included after attending a one-stop clinic for women referred from their family doctor
42 with breast symptoms. All patients complaining of a breast lump routinely have a focussed breast
43 ultrasound scan with SWE examination of any solid mass seen on ultrasound. Four SWE images are
44 obtained in two orthogonal planes and quantitative data obtained using a 2mm region of interest
45 (ROI). Patients aged 25-39 with lesions showing benign US and clinical features and SWE findings
46 below the threshold value (50 kPa average mean stiffness from the four SWE images) were
47 reassured and discharged from the clinic without biopsy or follow-up. Mammography was not

48 performed as the patients were under 40 years and did not have suspicious clinical or US findings.
49 Patients managed in this way had their details recorded on a dedicated audit form for review by a
50 second radiologist. The single reviewing radiologist, an internationally recognised expert with 25
51 years specialist experience in breast imaging, checked that the lesion did have definitively benign US
52 features. If the second radiologist did not agree with the benign US designation, the patient was
53 recalled for repeat US and possible core biopsy.

54 Patients managed in this way before 01/05/2019 were included in this audit. Local electronic records
55 were viewed to establish whether patients re-presented with the same or different benign breast
56 problems, developed breast cancer, or had further diagnostic biopsies. If local records did not show
57 recent attendance, then the national picture archiving and communication system (PACS) was
58 accessed to identify any subsequent breast imaging anywhere in the NHS in the devolved UK nation
59 that was the setting for this study.

60 Rates of recall and re-assessment review of stored US images by the second radiologist were
61 documented. Similarly, rates of re-presentation with the same benign lesion, other benign problems
62 and breast cancer were calculated.

63 **Results**

64 Seventy-six consecutive patients were eligible for the audit. The age range was 25-39 years with a
65 mean age of 33 years. The minimum follow-up was 12 months. Average follow-up was 2 years. One
66 patient was excluded as she died of non-breast causes two weeks after attending the clinic, leaving
67 75 women in the cohort.

68 Three (4%) patients were recalled after review of the US images by the second radiologist. Two were
69 discharged following a second US scan while one underwent a core biopsy with a benign result. Five
70 (7%) patients re-presented with the same lump, two of those had a core biopsy at this second
71 presentation because of enlargement of the lesion, with benign results. Three women had a similar

72 sized lump as at initial presentation and were further reassured and discharged. None of the five
73 patients who re-presented had a surgical excision of the lump. Three (4%) patients presented with a
74 different benign problem during follow-up.

75 Two patients presented with breast cancer, both in the ipsilateral breast. In neither patient was the
76 cancer in the same area as the previously assessed benign lump. In both cases, imaging including
77 MRI scan confirmed the cancers as separate from the previously assessed benign lesions.

78 None of the women in the study cohort presented to other NHS breast units in the country and had
79 breast imaging recorded on PACS during the follow-up period.

80 The number of women aged 25-39 who had symptomatic clinically benign masses with benign core
81 biopsy results who were biopsied because of atypical US appearances or stiffness at SWE was not
82 recorded.

83 **Discussion**

84 We have found that a policy of not biopsying or following up symptomatic, clinically benign solid
85 breast masses with benign US and SWE features appears safe so far, as no cancers were diagnosed
86 at follow-up in the area of the previously assessed benign masses. There was good consensus among
87 the radiologists regarding the benign US findings as only 4% were recalled for reassessment after
88 review of the stored US images by the second radiologist, and all such reassessments had a benign
89 outcome. Only 7% of patients re-presented with the same lump and these episodes resulted in two
90 core biopsies but no surgical excisions. The lack of surgical excisions may imply that the patients on
91 the new pathway were adequately reassured.

92 The number of women aged 25-39 years who had their clinically benign masses biopsied during the
93 study period because of either non-benign US greyscale features or above-threshold stiffness at SWE
94 was not recorded. It is therefore not possible to say what percentage of women with benign
95 symptomatic masses in this age group avoided core biopsy due to adoption of this policy.

96 It is estimated that 10% of all women have a fibroadenoma (15) and that about 40% of breast
97 biopsies are from fibroadenomas (1-3). The burden of work caused by fibroadenomas is therefore
98 difficult to overstate. Given the greater and increasing complexity of radiological workup of cancer
99 cases, any decrease in work from benign problems will enable breast radiologists to give more time
100 to imaging of cancer cases.

101 The follow-up of an average of two years in this study is short and it is possible that missed cancers
102 may yet appear. Therefore, these results can only be interpreted as promising rather than as
103 definitive evidence of the safety of this approach. However, most re-presentations of an
104 undiagnosed but already symptomatic cancer occur within two years (16). Only 7% of cancers
105 occurring as “interval cancers” after assessment at one-stop symptomatic clinics occur in women
106 aged under 40; therefore, reducing diagnostic interventions in this age group would appear not be a
107 high-risk strategy (16).

108 A further limitation of this study is that it is a small sample from a single centre with an academic
109 interest in SWE. However, SWE is a simple, reproducible technique so it would be surprising if these
110 results could not be replicated by other centres. SWE is also a quick, relatively low-cost procedure,
111 so its introduction into the standard workflow of any breast clinic should not present problems.

112 The adoption of this approach by other centres is only recommended after individual centres assess
113 a cohort of patients to confirm that no cancers are missed by both SWE and US, while continuing to
114 biopsy clinically benign masses with benign US and SWE features in the age-group concerned. The
115 majority of cancers missed by SWE are small (11), so some may wish to adopt this approach for
116 lesions over 10mm in size only.

117 As follow-up and biopsy of benign masses constitutes a large part of breast radiologists’ workload, in
118 health care systems where a fee-per-item model exists there may be concerns about resultant
119 decrease in income.

120 Extending the age limit for this policy to 49 years could be contemplated after longer follow-up of a
121 larger numbers of patients. However, it should be noted that women aged 40-49 are those most
122 likely to have a cancer presenting following a one stop clinic negative assessment (15) so such an
123 approach should be considered cautiously.

124 In conclusion, early results of a policy of not biopsying or following up benign solid masses with
125 benign US appearances, which are soft on SWE, in women aged 25-39 suggest this approach may be
126 safe and acceptable. Data on larger cohorts from multiple centres with longer follow-up are required
127 to confirm this early promise.

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