

Palpable discrete breast masses in young women: Two of the components of the modified triple test may be adequate

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Background. Palpable breast masses in young women, though usually benign, are a common source of anxiety. Current practice is assessment using the modified triple test (MTT). This entails clinical breast examination (CBE), ultrasound scans and cytological examination of a fine-needle aspiration biopsy specimen (FNAC). It is unclear whether it is necessary to utilise all three components in most patients.

Objectives. We aimed to determine the diagnostic value of the MTT for the evaluation of palpable discrete breast masses in women under 35 years of age, and to assess the performance of its components when used individually or in combinations of two.

Design and setting. This was a cross-sectional study carried out between August 2010 and October 2010 in the breast and general surgical outpatient clinics at Kenyatta National Hospital, Nairobi, Kenya.

Patients and methods. Fifty-eight patients presenting during the study period with palpable discrete breast masses satisfying the inclusion criteria were recruited. All patients had a CBE, ultrasound scans and FNAC. A core biopsy was performed as a reference standard.

Main outcome measures. The test results of the MTT and its elements (CBE, ultrasonography and FNAC) were compared with the histological findings (the reference standard).

Results. The age range of the 58 patients was 18 - 34 years (mean 25.5 years, standard deviation 5.1 years). Forty-five patients (77.6%) had concordant MTT results (agreement in all the three components). Concordant MTTs had a sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of 100%. Sensitivity, specificity, PPV and NPV were 100%, 92.3%, 60% and 100%, respectively, for CBE; 100%, 94.2%, 66.7% and 100%, respectively, for ultrasonography; and 100%, 98.1%, 83.3% and 100%, respectively, for FNAC. The combinations CBE plus ultrasound and CBE plus FNAC had sensitivities, specificities, PPVs and NPVs of 100%.

Conclusion. Use of the MTT for diagnosis of palpable breast masses in young women (<35 years of age) yields high diagnostic accuracy. The combinations of CBE plus ultrasound and CBE plus FNAC have high PPVs and NPVs with almost similar concordance in this population, suggesting that they can be used for diagnosis and therefore could be modelled for use in patients choosing between conservative care and excision.

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Breast masses in young women are common, and cause much anxiety. The majority of these lesions are benign. A quick, reliable, non-invasive or minimally invasive means of diagnosis helps to lessen the anxiety and aids in instituting early definitive care. Triple assessment has been considered the best combination of tests.^[1-4]

The triple assessment is evaluation of palpable breast masses by clinical breast examination (CBE), imaging and tissue sampling. Because of their mammographically dense breasts and the fear of exposing them to repeated radiation, ultrasonography is the first-choice imaging method in young women (<35 years) with palpable breast masses.^[5] The modified triple test (MTT) involves clinical breast examination (CBE), ultrasound scans and cytological examination of a fine-needle aspiration biopsy specimen (FNAC).^[1] When the MTT is concordant (agreement in all the three components), the sensitivity and specificity approaches 100%. Patients with non-concordant results are

evaluated further with examination of a biopsy specimen.^[1,2] The absence of standardised CBE, mass descriptors and a reporting system for ultrasonography limit the reproducibility of the results among different clinicians.

The aim of this study was to establish the diagnostic value of the MTT for the evaluation of palpable discrete breast masses in women under the age of 35 years at Kenyatta National Hospital (KNH), Nairobi, Kenya, and the performance of its components when used individually or in combinations of two.

Methods

Subjects were recruited in four clinics at KNH. Patients with breast lesions attend either the breast clinic or one of three general surgical outpatient clinics, where they are usually screened and attended to by breast surgeons or general surgeons with interest in breast disease. Women eligible for and consenting to the study

were recruited by the principal investigator. The surgeons who examined the patients and directed their treatment were made aware of the study.

A palpable mass was defined as discrete/dominant if it was three-dimensional, distinct from surrounding tissues, and asymmetrical relative to the other breast. The characteristics of the mass in terms of location, size, surface/edge, consistency and mobility were assessed. The size was measured at the longest diameter. After examination, the mass was determined to be benign, suspicious or malignant.

The patients were then referred for ultrasound scans by consultant radiologists using a high-frequency (7.5 - 12 MHz) linear probe (Philips HD11 Ultrasound system). The examination involved scans of both breasts and axillary regions with focus on the lesion. Findings were scored using the criterion set in the American College of Radiology (ACR) BI-RADS ultrasound atlas.^[6] Each lesion was described using these features and classified into categories 1 - 5 according to the ACR BI-RADS atlas.

FNAC involved a minimum of three passes into the mass. A minimum of four biopsy specimens were taken using a 16- or 18-gauge biopsy needle and used as the reference standard.

Data were collected and analysed using STATA version 10. Sensitivity, specificity and predictive values were calculated for the MTT and for its elements, especially the combinations of CBE plus ultrasonography and CBE plus FNAC.

Results

Of 63 patients eligible to participate, 5 declined. The median age was 25 years (range 18 - 34 years). The majority of the masses were in the upper outer quadrant (60.3%) and in the right breast. All were solid. The sizes of the masses were categorised into three groups: <2 cm, 2 - 5 cm and >5 cm. Two-thirds of the masses (65.5%) measured between 2 and 5 cm and only 15.5% >5 cm. Histological examination showed most masses (89.6%) to be benign.

Performance of the MTT and its elements compared with histology

CBE had 100% sensitivity, 92.3% specificity, a 60% positive predictive value (PPV) and a 100% negative predictive value (NPV). Ultrasonography had similar sensitivity but higher specificity (94.2%), a PPV of 66.7% and an NPV of 100%. FNAC had a sensitivity of 100%, the highest specificity (98.1%), the

highest PPV (83.3%) and an NPV of 100%. Concordant results of MTT, CBE plus ultrasonography, and CBE plus FNAC had sensitivity, specificity, PPV and NPV of 100% (Table 1).

Non-concordant MTT results

There were 13 patients (22.5%) with non-concordant MTT results, of whom 4 were subsequently confirmed to have a malignant lesion on examination of a biopsy specimen (PPV 30.7%). If the results of all three elements were either suspicious or malignant, the test was 100% predictive. In 1 patient in whom FNAC was falsely negative, the results of CBE and ultrasound were interpreted as malignant and suspicious, respectively.

Discussion

The objective of the study was to establish the diagnostic value of the MTT and its elements in young women (<35 years of age). Of the breast masses 89.6% were benign, which is similar to findings elsewhere in this age group.^[7] CBE had a sensitivity and NPV of 100% but a relatively low PPV of 60%. Vetto *et al.*^[11] reported a sensitivity and NPV of 100%, which is comparable to our findings. However, they did not subject all their patients to biopsy, opting for clinical follow-up for benign concordant results. Their reported PPV was 67%. In their study, they considered findings to be positive when CBE was either suspicious or malignant, and lack of standardised criteria can mean that examiners differ in their interpretation of a malignant or suspicious mass. Ghafouri *et al.*^[4] reported a lower sensitivity of 18.4%, but the NPV and PPV were comparable to ours at 96.7% and 66.7%, respectively. Ghafouri *et al.*^[4] considered only malignant lesions in calculating sensitivity. The high sensitivity and NPV may have been due to the lower incidence of malignancy in these patients, with a bias towards benign masses.

Ultrasonography had a sensitivity and NPV comparable to those of CBE, but a higher PPV of 66.7% for malignancy. Vetto *et al.*^[11] reported a PPV of 33% and an NPV of 100%. Although they did not describe the ultrasound criteria used to classify the breast lesions, the difference in the PPV could have been due to the higher proportion of malignancies in our study. The majority of the lesions identified as benign were scored as category 3 using the ACR BI-RADS atlas. All these masses were confirmed to be benign on histological examination. In a study by Oswald *et al.*,^[8] category 3 classifications had a high NPV of 99.8%.

Table 1. Diagnostic results of MTT elements CBE plus ultrasound, CBE plus FNAC, and MTT

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
CBE	100	92.3	60.0	100	93.1
Ultrasonography	100	94.2	66.7	100	94.8
FNAC	100	98.1	83.3	100	96.5
Concordant MTT	100	100	100	100	100
Concordant CBE plus sonography	100	100	100	100	100
Concordant CBE plus FNAC	100	100	100	100	100

MTT = modified triple test; CBE = clinical breast examination; FNAC = cytological examination of a fine-needle aspiration biopsy specimen; PPV = positive predictive value; NPV = negative predictive value.

Looking at the three elements of the MTT, FNAC had the highest PPV (83.3%). The NPV was 100%. Vetto *et al.*^[1] reported a PPV of 67% and an NPV of 100%, and Bulinda^[9] a PPV of 100% and an NPV of 98.2%. The difference between our results and those of Bulinda^[9] could be attributable to the populations studied, ours being younger women with fewer malignancies. In their meta-analysis, Giard and Hermans^[10] reported the accuracy of FNAC to vary widely, sensitivity ranging from 65% to 98% and specificity from 82% to 100%.

Concordant MTTs had a high diagnostic accuracy. The sensitivity, specificity, NPV and PPV of 100% compared well with other published results.^[1-4] We had concordance of 77.6%, which meant that over three-quarters of our patients could proceed to definitive management without the need for biopsy. Despite our lack of a multidisciplinary specialised clinic, MTT accurately classified patients with palpable breast masses with minimal invasiveness.

When combinations of CBE plus FNAC and CBE plus ultrasound were analysed, both combinations had sensitivity, specificity, PPV and NPV of 100% with almost similar concordance, suggesting that in this population either of the combinations may be used. Our high proportion of clinically benign breast masses and few malignancies could account for the observed findings. It may then be possible to select a combination depending on the final intention to treat. We suggest that CBE and US be used for patients who would prefer their benign mass to be excised, as histological examination will be possible after excision. For those who choose the conservative approach, we would recommend CBE and FNAC (cytological examination for reassurance), and then follow-up.

Conclusion

This study shows that the concordant MTT for the diagnosis of palpable discrete breast masses in women below the age of 35 years is reproducible and yields high diagnostic accuracy. Of the elements of the MTT, FNAC was the most predictive. Concordant combinations of CBE plus FNAC and CBE plus ultrasound have high diagnostic accuracy, comparable to MTT, in the evaluation of young women.

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