Is clinical breast examination a necessary component in the assessment of women with breast symptoms?

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Aims and objectives

There has been an increased emphasis on breast screening programmes in recent years in order to detect breast cancer at a preclinical stage and, therefore, improve survival(1). The majority of women with breast cancer, however, present with symptoms(2). The current gold standard for the management of symptomatic breast disease is triple assessment, otherwise known as the one-stop clinic (OSC)(3). This involves clinical assessment by a breast surgeon/clinician, mammography and/or ultrasound and fine needle aspiration or core biopsy if a suspicious lesion is identified. The sensitivity of triple assessment has been reported as high as 99%(4). The primary aim of symptomatic breast clinics is to separate the patients who do not have breast cancer (~93% of referrals) from those who do have cancer(5).

There is a widely-held view that direct access to breast imaging for General Practitioners (GPs) is inappropriate since one element of triple assessment, the clinical breast examination, is excluded(6). The examining clinician determines the clinical examination score (P), described by Willett et al, scoring the level of suspicion for malignancy on a 5-point scale (P1-5)(7). The radiologist then records the suspicion for malignancy on imaging, again, on a 5-point scale(8). Any discordance between the two scores should prompt further investigation ensuring that there are no missed cases of malignancy. In breast screening, radiologists perform clinical breast examinations at the time of assessment of women recalled for imaging and therefore a large number of breast radiologists are already experienced in clinical breast examination. Nevertheless, in symptomatic practice, it has been generally accepted that a breast surgeon/clinician should perform a clinical breast examination despite the GP having already examined the patient. However, one of the most consistent findings in healthcare research is the gap that exists between evidence and clinical practice(9).

This study sought to challenge this current model of practice. We considered whether direct GP access to radiology, without initial surgical examination, would offer a similar diagnostic yield and result in a more streamlined, cost-effective service. Given the volume of resources dedicated to OSCs, we sought to identify a more efficient clinical pathway to effectively assess patients. It is of crucial importance that any alternative pathway has equivalent or better cancer detection rates. There is a duplication in resources as the patient is clinically examined by both the GP and the surgeon before undergoing mammography and/or ultrasound and biopsy. In addition, breast radiologists examine the area of concern in the breast, often for a third time, before performing focused ultrasound. The purpose of this study was to evaluate the role of the surgical examination and determine whether direct GP referral to radiology would be a more efficient pathway for this cohort of patients(10).
Methods and materials

Analysis of a prospectively updated database of patients seen in 2015 was performed. Data collected included GP and surgeon clinical examination scores, number of cancers diagnosed, histology and radiological investigations performed and radiological score. Patients not referred from a GP to the OSC were excluded.

Concordance of surgical clinical examination with final pathology was defined as a clinical examination score (P) of 3-5 on the side of disease. Discordance was defined as a P score of 1-2 on the side of disease. Concordance of GP examination with final pathology was defined as the GP referring the patient with a lump, skin distorsion, ulceration, recent nipple retraction or nipple eczema on the side of concern. Discordance was defined as a referral with breast pain or other symptoms with a normal clinical examination.
Results

A total of 5,602 patients were seen in the OSC in 2015 in whom 231 breast cancers were diagnosed, including 6 cases of bilateral disease. Of these, 216/237 (91.1%) correlated with GP examination findings and 92% with surgical examination (score 3-5). The average age at diagnosis was 58.7 years. The clinical examination (P) scores were as follows; P1-2: 16, P3: 54, P4: 62, P5: 105.

Of 21 cancers that were discordant with GP findings, surgical examination detected 17 of these. All cancers discordant with GP clinical findings were in women >40 years and mammographically visible, apart from a unilateral M2 reading in one of the patients with bilateral disease. There were three imaging occult carcinomas (M1-2/U1-2) during the period, which included one case of Paget's disease. One of these was clinically and mammographically occult but detected on MRI when staging contralateral disease, one was mammographically occult but biopsied later when it increased in size and became apparent on mammography and the case of Paget's presented with nipple eczema and underwent biospsy despite being mammographically occult.
<table>
<thead>
<tr>
<th>P Score of Breast Cancers</th>
<th>Number</th>
</tr>
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<tbody>
<tr>
<td>P1/2</td>
<td>16</td>
</tr>
<tr>
<td>P3</td>
<td>54</td>
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<tr>
<td>P4</td>
<td>62</td>
</tr>
<tr>
<td>P5</td>
<td>105</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>237</strong></td>
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**Table 1:** P scores assigned by breast surgeons/clinicians to breast cancers in clinic

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Fig. 1: Flow chart of activity in symptomatic breast clinic in 2015

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Conclusion

Triple assessment clinics are well established for the assessment of patients with breast symptoms(3). They are seen as an effective "one-stop shop" where patients are referred by their GP and have another clinical assessment by a breast surgeon and radiological and/or histological assessment as indicated. Approximately 93% of patients referred to a triple assessment clinic, however, do not have breast cancer(5). The concept of direct access for GPs to radiology would mean that surgical teams would no longer have to review a large majority of this 93% of disease-free patients. If this were feasible, it could potentially expedite the clinical pathway and allow breast surgeons to dedicate their time to patients with proven breast cancer.

Radiological management of women with breast symptoms is protocolised(7). In Ireland, all women with breast symptoms, regardless of symptom type undergo mammography if over 35 years. Those with a P3-5 examination score undergo ultrasound regardless of age.

Our results support the hypothesis that initial surgical examination of patients with breast symptoms is not always necessary. The role of the triple assessment clinic is to isolate the 7% of symptomatic patients who have breast cancer and deliver their treatment without delay. In our study, GP clinical assessment was accurate in 93.5% of cancer cases and, in the remaining 6.5% of cases, the carcinoma would still have been identified by mammography as all patients were over 35 years with a mammographically visible lesion. The surgical clinical examination had a similar sensitivity to the GP findings, correctly identifying cancer in 92.4% of cases. This suggests that direct GP referral to radiology would be equally as effective as triple assessment in identifying cancer cases and that surgical teams would then be able to better focus their time and resources on treating known cases of malignancy.

There were only three (1%) radiologically occult carcinomas in this study, the negative predictive value has been reported as 99% and this would therefore be consistent with international standards(11). Patients with nipple changes and unilateral discharge despite normal radiological imaging will still always require assessment by a breast surgeon/clinician. A pathway that removes the surgeon from the initial assessment would have to allow the radiologist to seek a surgical opinion if required.

The second role of the OSC is to reassure patients with benign disease. All women who undergo breast biopsy (10% of all OSC patients in our cohort) need to be followed up, as some will require surgical excision of indeterminate and benign lesions. Women with breast pain require reassurance and counselling on management. All patients under 35
years with breast pain would still need to be reviewed in the breast clinic as they may not require imaging. Those over 35 years, despite benign mammographic examinations, may also need to be reviewed by a breast surgeon/clinician or a breast nurse.

This proposal is aimed at streamlining the pathway for breast cancer patients and improving cost-effectiveness of symptomatic breast services. It is critical that this does not lead to undiagnosed cases of malignancy, as this would be unacceptable. A mechanism where patients can have urgent surgical assessment, in the absence of radiological findings, if suspicious clinical symptoms were present, would lead to more responsibility for the breast radiologist. The radiologist, in addition to deciding on the appropriate imaging modalities to use and whether or not a biopsy is warranted, would need to decide if a patient needs urgent surgical follow-up, surveillance imaging or discharge. This is not necessarily a responsibility that radiologists would want to assume.
Fig. 2: Mammogram of left breast - R2

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**Fig. 3:** Breast MRI of same patient showing left sided 6cm multi-centric breast cancer following detection of suspicious lesion on ultrasound

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