Tumour profiling tests to guide adjuvant

chemotherapy in early breast cancer

The Association of Breast Surgery (ABS) is extremely disappointed with the conclusion that NICE has drawn from reviewing the evidence for use of these novel technologies in the NHS. NICE suggest that there is not enough evidence to recommend the routine use of these tests. However, one such test, Oncotype DX, has been available in the NHS since it was recommended for clinical use by NICE itself (DG10, 2013).

There is clear evidence that the use of these tests can reduce the burden of chemotherapy in women with oestrogen positive lymph node negative breast cancers, with the outcome of the tests having real world impact on decision making in the clinic (1-5) including clear examples from the NHS (1).

The evidence favours use of tumour profiling in those groups of patients where the benefits of chemotherapy were previously uncertain and where targeted use of chemotherapy in appropriate patients (as identified by these tests) can result in individualised treatment (6, 7). This results in financial savings for the health service (1) but more importantly, it also allows women to be spared the consequences of unnecessary chemotherapy (1 – 7).

ABS feels that the calculations utilised by NICE in their cost effectiveness analysis are flawed for the following reasons;

a) NICE do not accept that any of the tests predict chemotherapy effect, but apply a model where there is equal benefit of chemotherapy to all patients – we know that is not true eg, histological grade 1 vs grade 3;

b) NICE calculate an artificially high rate of recurrence even in the lower risk patients, creating an erroneous impression that withholding chemotherapy even to these women is detrimental to patient outcome (in absolute and relative senses). We know that this is not true. The TaylorX, a multicentre prospective study of over 10 000 women, showed that low risk patients, as identified by a low Oncotype DX score, could be safely treated with hormonal therapy alone. These patients avoided the need for chemotherapy yet had a less than 1% risk of distant recurrence at 5 years (8).

c) NICE assume that, in an economic sense, giving chemotherapy is inherently a "good" thing across the board if a patient’s risk of recurrence is high enough. This does not apply universally. Multidisciplinary teams will have in depth knowledge of individual patients and be able to assess, with the addition of tumour profiling test outcomes, the value of chemotherapy in individual patients (9).

ABS is of the opinion that the withdrawal of the availability of these tests in the NHS will have a significant impact on our ability to tailor treatments to the individual patient and be a retrograde step in the management of breast cancer. Patients will be denied the opportunity to avoid unnecessary chemotherapy and the toxicity accompanying this. In addition, those women identified as high risk by genomic testing will be denied this extra valuable information to help them make their choices (10).

The analysis performed by NICE is flawed as described above. We hope that this decision will be reconsidered.

**The Association of Breast Surgery represents almost 1600 surgeons and nurses involved in the diagnosis, treatment and management of women with breast cancer throughout the United Kingdom. The above statement distils the widespread concerns relayed to us by our members.**

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