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Usage of Oncotype Dx Testing in Breast Cancer in Practice

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Abstract

Background The Oncotype Dx testing in breast cancer is commercially available multigene expression testing to determine patients with breast cancer with potential benefit from chemotherapy and the risk of recurrence. The aim of this study was to determine the patients' selection for this type of testing.

Methods We have collected retrospective study over period of 3 months in our breast unit in a view to collect all relevant data and determine whether the right patients has been selected for testing. The gold standard was NICE guidelines recommendation.

Results We have collected 51 patients in total. Calculating the NPI we have been able to establish that 22 patients should have been offered Oncotype Dx testing. This was only offered to 10 patients and to 2 more patients who were not eligible according to NICE guidelines.

Conclusion This study has shown that the compliance with NICE guidelines in our unit is quite poor. Only 43% of patients eligible and 55% of patients in total have been offered Oncotype Dx testing. It would be interesting to compare these results to other unit in the country.

Discussion Oncotype Dx is good quality genetic testing and predictive tool for right patients. Unfortunately it does not take into account other patients' factors which may influence the outcome.

Background

The Oncotype Dx testing in breast cancer is commercially available multigene expression testing. There is clinical evidence that validated its availability in prediction of chemotherapy (ACT) benefits and the likelihood of recurrence. This applies to early-stage invasive breast cancer.[1]

The Oncotype Dx test is designed to analyse activity of 21 genes in the tumour tissue. The results are transformed to a number with value between 0 and 100. This is called recurrence score and can provide information about likelihood of breast cancer recurrence within 10 years of diagnosis and also the likelihood of the benefit from chemotherapy.

All these tests are performed on small amount of tissue that has been removed from patient's body previously (during biopsy, wide local excision and mastectomy).

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Oncotype Dx enables stratification of ER+ve, Her-2 & node negative breast cancer patients into different risk groups indicative of their potential benefit from chemotherapy.[2]

Aims

NICE guidelines (DG 10, Sep 2013) indicate that this is to be used for intermediate risk group breast cancer patients. This is defined as having a Nottingham Prognostic Index (NPI) score of ≥3.4.[3]

Nottingham Prognostic Index

This index is a prognostic value following surgery for breast cancer. It is calculated based on pathological criteria, using the formula bellow:

NPI = [0.2 x S] + N + G

Where S is size of the lesion in CM

N is node status (no nodes N = 1, 1-3 nodes N = 2 and more than 3 nodes N = 3)

G is grade of tumour

NPI is interpreted towards survival in 5 years time. [4]

The main aim of this study was to establish whether patients' selection for on co type Dx. testing in the Breast Unit (QAH) meets NICE Guidelines.

The secondary aim was to into reasons why we are not using on co type Dx testing and whether there is any other pathway to determine need for chemotherapy.

Methods

We have collected retrospective audit between November 2017 and January 2018 in Breast Unit at Portsmouth Hospital, UK. We have included all patients diagnosed with estrogen receptor (ER) positive and Her 2/lymph node negative breast cancer diagnosis.[5] These patients have been diagnosed and had tissue diagnosis discussed at MDT.

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INCLUSION CRITERIA	ER positive
	Her 2 negative
	lymph node negative
	having tissue diagnosis from November 2017 to January 2018
EXCLUSION CRITERIA	ER negative
	Her 2 positive
	lymph node positive

Table1.shows inclusion and exclusion criteria of study

For all of the patients, we have calculated NPIs. These results we compared to the oncology data and explored whether the patient has been offered on co type testing, what was the outcome of on co type Dx and the final offer of chemotherapy including patient's decision.

PRIMARY AIM	compliance with NICE guidelines
SECONDARY AIMS	Oncotype Dx testing offered
	Oncotype Dx testing performed
	outcome of Oncotype Dx testing
	final offer of chemotherapy

Table 2.shows primary and secondary aims of study

Results

We have collected in total 51 patients who full fill the inclusion criteria. These patients were all women.

We have calculated NPI for all patients using the formula above and compared it to the NICE guidelines recommendation. There were 22 patients with NPI ≥ 3.4 and therefore eligible for Oncotype Dx testing.

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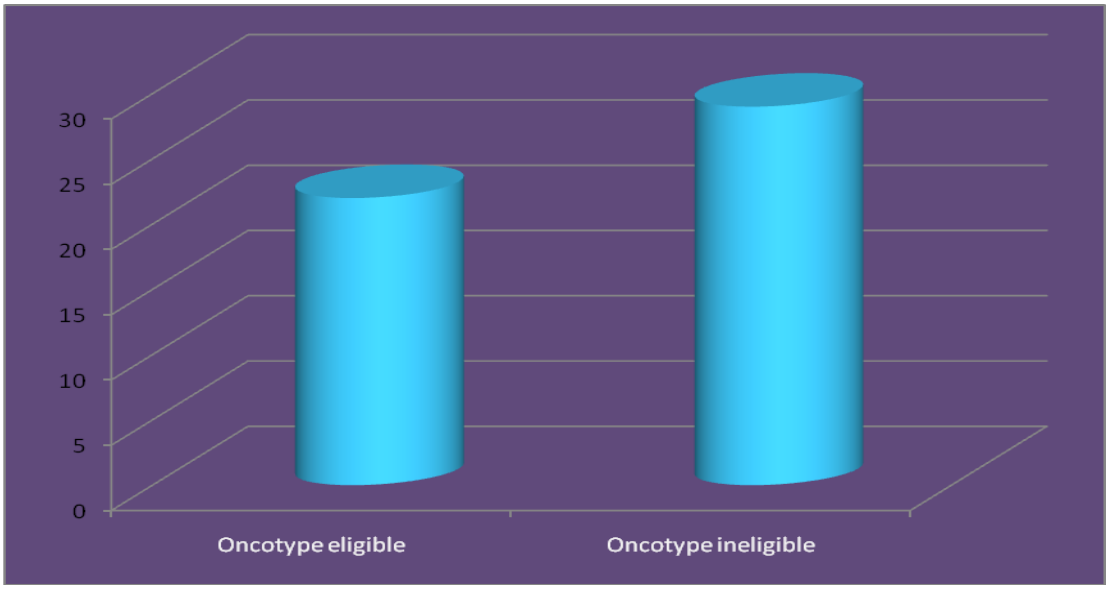
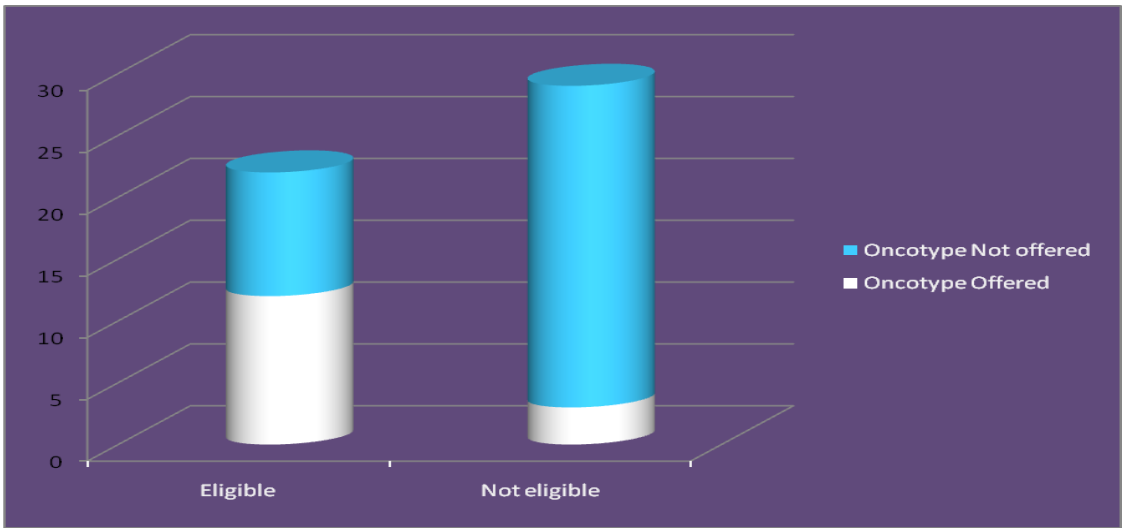


Graph 1.shows total amount of patients with on co type eligibility

Out of the 22 patients (43%) eligible Oncotype Dx testing, this was offered to 10 patients. Surprisingly, out of the group that was not eligible for Oncotype, this testing was offered to 2 patients. There were 12 patients (55%) in total who were offered this testing.



Graph 2.Eligibility vs offer of Oncotype Dx testing

We have divided patient s into subgroups according to their age. The first subgroup consists of patients bellow 60 years of age, the second subgroup had patients between 60 and 70 years of age and the last subgroup had patients of more than 70 years of age.

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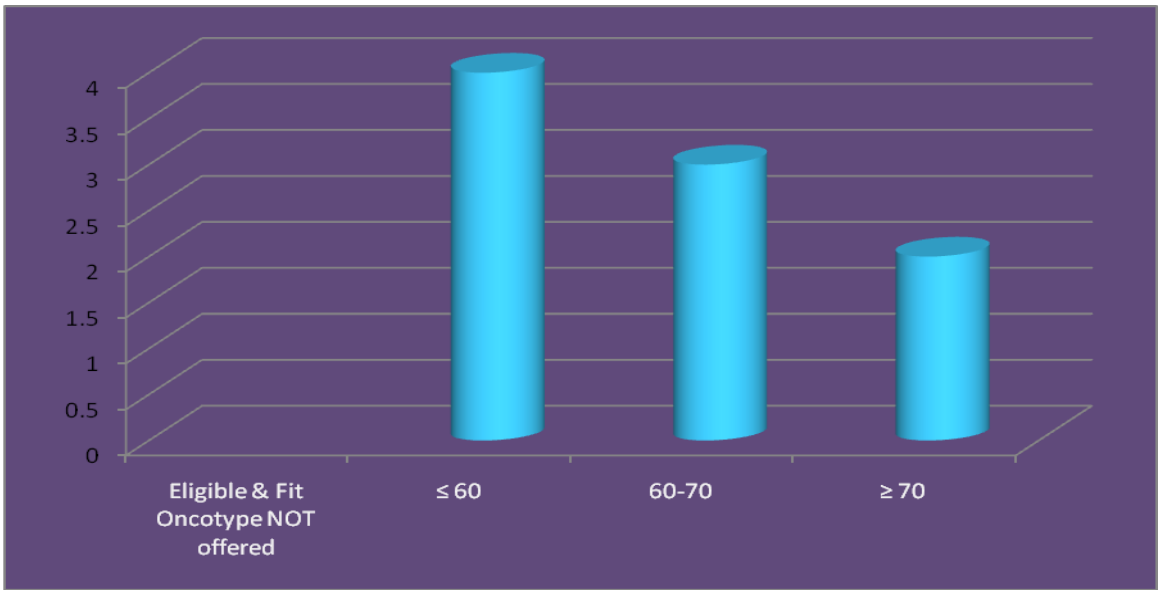
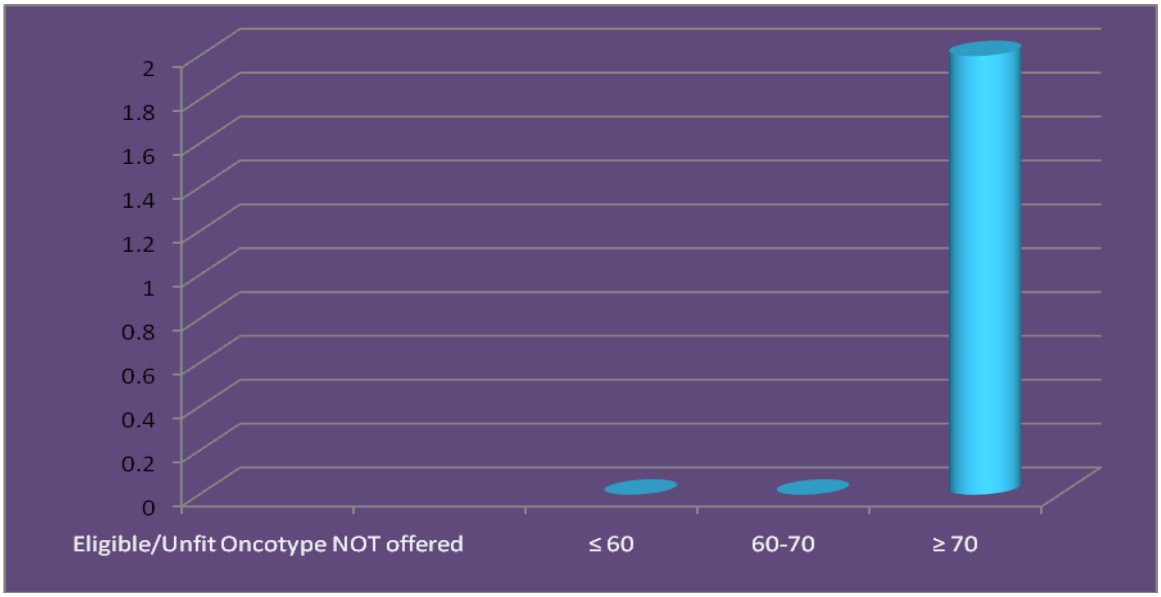
The following graphs show likelihood of patients in the subgroups eligible for this testing but the Oncotype Dx was not offered to them.



Graph 3.shows eligibility of Oncotype Dx testing with relation to age



Graph 4.shows eligibility of Oncotype Dx testing with relation to age

The results showed that patients over the age of 60 who were suitable for Oncotype Dx testing were less likely to be tested or receive chemotherapy.

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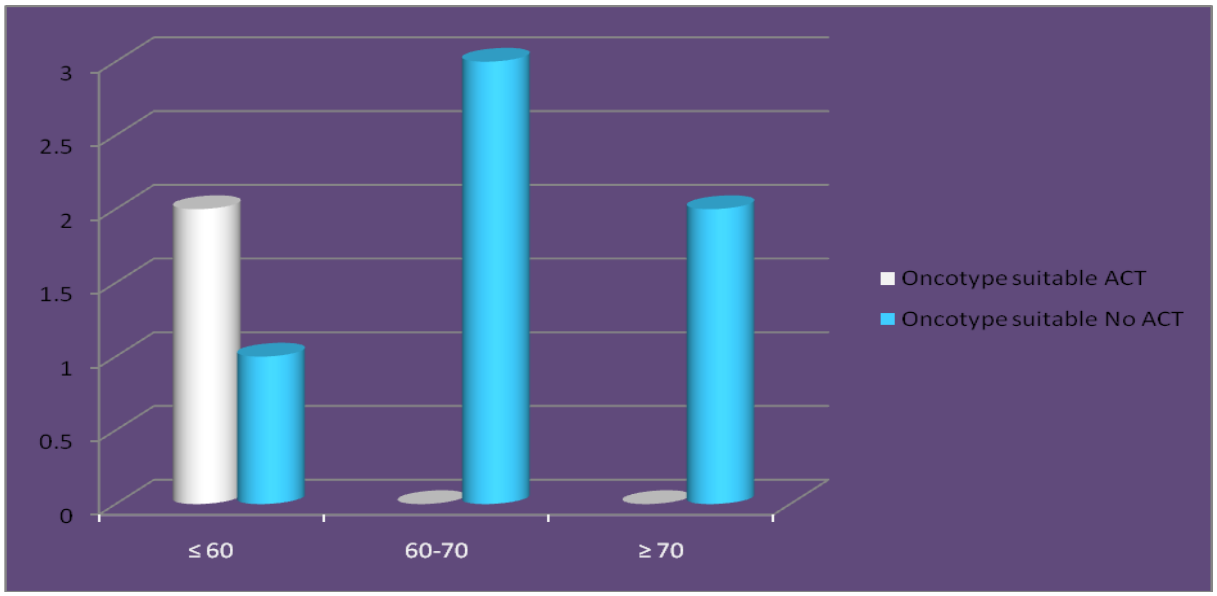
The last graph demonstrates the suitability of chemotherapy and the actual offer of chemotherapy. There is good correlation in between results of the test and actual offer of chemotherapy.



Graph 5.shows eligibility of Oncotype Dx testing with relation to age comparison in between groups

Conclusion

This study has shown that the compliance with NICE guidelines in our unit is quite poor. Only 43% of patients eligible and 55% of patients in total have been offered Oncotype Dx testing. It would be interesting to compare these results to other unit in the country.

The patients whose NPI scored above the limit of 3.4 were not offered testing due to various reasons. These mainly included old age and frailty and co morbidities which would very likely not make them good candidate for chemotherapy regardless.

All these decisions have been made by multidisciplinary team (MDT) meetings with at least 2 consultant oncologists present. The decisions have been based on the consultants experience and supported by clinical review from the breast surgeons. This review consists of general health and frailty assessment giving performance score and list of co morbidities to the MDT panel. Performance score in our unit uses Zubrod scale as shown bellow.[6]

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Performance score

PERFORMANCE SCORE	LEVEL OF ACTIVITY
0	normal activity
1	symptomatic and ambulatory, cares for self
2	ambulatory >50% of time, occasional assistance
3	ambulatory <50%, nursing care needed
4	bedridden

Table 3.shows performance score as per Zubrod

Discussion

Our study shows that Oncotype Dx is good quality genetic testing and predictive tool for right patients. It gives both patients and clinicians good scale and probability score and guidance towards chemotherapy. It also makes it easier for the patients to understand the probability of recurrence and benefits of surgery.

Unfortunately on the grand scale it does not take into account other patients' factors which may influence the outcome.

We think that it is very useful to do performance score or similar other assessment in view to get idea about patients' general health. This is good predictive factor for potential chemotherapy. We have to agree with our oncology colleagues that performing testing on patients that would not be candidate for chemotherapy is generally not very good use of time and money.

We believe that Oncotype is great tool while used on the right subgroup of patients. At present as the NICE guidelines states, our unit is unlikely to follow for all patients.

We would be interested to see the practice of other breast cancer units within or outside UK.

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