INVESTIGATING THE ACCESSIBILITY OF GENE BASED ASSAYS IN EVERY DAY PRACTICE: THE CASE OF ONCOTYPEDx ASSAY in GREECE

Siskou O[1*]., Kikilias N[2]., Kaitelidou D[3]., Galanis P[4]., Tsoulos N[5]., Kalogeropoulou M[6]., Vafiadis J[7]., Prezerakos P[8]., Liaropoulos L[9]

[1] Senior Researcher RN, MSc, PhD. Center for Health Services Management and Evaluation-Faculty of Nursing-National and Kapodistrian University of Athens-GREECE, olsiskou@nurs.uoa.gr
[2] Head of Primary Care Division, MSc. Organization for the Provision of Health Services (EOPYY)-Athens – GREECE, nkikilias@gmail.com
[3] Assistant Professor RN, MSc, PhD. Center for Health Services Management and Evaluation-Faculty of Nursing-National and Kapodistrian University of Athens-GREECE, dkaitelid@nurs.uoa.gr
[4] Senior Researcher RN, MSc, PhD. Center for Health Services Management and Evaluation-Faculty of Nursing-National and Kapodistrian University of Athens-GREECE, pegalan@nurs.uoa.gr
[5]Chief Executive Officer Clinical Biochemist Genekor, Athens GREECE, ntsoulos@GENEKOR.com
[6]Researcher RN, MSc, PhD. Center for Health Services Management and Evaluation-Faculty of Nursing-National and Kapodistrian University of Athens-GREECE, makaloger@yahoo.gr
[7] Chief Executive Officer MD,MSc,PhD. . Organization for the Provision of Health Services (EOPYY)- Athens – GREECE, jvafiadis57@gmail.com

[8] Associate Professor RN, MSc, PhD. Faculty of Nursing. University of Peloponnese-Sparta GREECE,prezerpot@gmail.com
* Corresponding Author

Abstract

The aim of this study is to investigate the accessibility of Greek women to OncotypeDx assay by comparing the number of the potentially eligible breast cancer women for undertaking the assay with the real number of women who undertook it (from April 2011 to 2014). For the purposes of the study administrative data from National Organization for the Provision of Health Services and data from international bases (e.g Globocan and OECD) were used. It was estimated that *1,100 patients* were potentially appropriate for conducting the OncotypeDX assay (taken in mind the age criterion of 65 years old). In case, that we pass over the age criterion then the potentially eligible number of women for undertaking the assay was increasing to *2,500.* The real number of women undertaking the assay was found steadily increasing from 176 in 2012, to 222 in 2013 and 340 in 2014, but it is still remarkable lower than the potentially ones. Concerning the burden of the assay on households' budgets, it was reported that women must fully pay the test and after some months get

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reimbursed 80% of the cost, which leaves them with a €650 out of pocket expense. Reimbursement policy reforms which will reduce the burden of cost sharing for patients and cancellation of the age criterion, is expected to facilitate the accessibility to the assay.

Keywords: Breast Cancer, Gene Based Assays, OncotypeDx

1. INTRODUCTION

Oncotype DX consists a widely used breast cancer assay, involved in the decision making process concerning the planning of the therapeutic path for women suffering from early stage breast cancer with estrogen receptor (ER) positive and node lymph (NL) negative. It calculates the risk of breast cancer distant recurrence and consequently predicts the clinical benefit with the administration of additional adjuvant chemotherapy (Paik et al.,2006; Malo et al., 2012).

The recurrence score is calculated between 0-100 which corresponds to a particular breast cancer recurrence probability at 10 years. When the recurrence score is <18, the recurrence risk is low, when the value is between 18 and 30, the risk is intermediate and when the score is >31, the recurrence risk is high. Women with low recurrence scores should avoid chemotherapy, whereas women with high risk recurrence scores should receive it. It is still unclear however whether or not chemotherapy is beneficial to women with intermediate recurrence scores (Lee et al., 2014).

It does not cause any problems to the patient, given the fact that for carrying out the procedure only a small amount of tissue is required, which is removed during surgery.

In June 2012 a Ministerial Decision was issued in Greece describing the clinical profile of potentially eligible women to be reimbursed by National Organization for Health Provision –EOPYY with 80% of the total cost of the assay (€3,250). According this entitlement and in order to avoid overuse of the assay, only women ≤65 years old were determined as eligible for being reimbursed for the assay, although the international guidelines do not refer to age criteria. However, the reimbursement policy regarding the test was not consistent. From 23.04.13 to 10.09.2013 the test was not reimbursed according to a ministerial decision which was later on revoked under a different Minister of Health.

This inconsistency of the reimbursement policy may constitute one of the main reasons for the underuse of the test until today, although its adoption was proven as a cost-effective choice (Vanderlaan 2011; Kikilias et al., 2014).

1.2 Aim

The aim of this study is to compare the number of the potentially eligible breast cancer women for undertaking the assay with the real number of women who undertook it (from April 2011 to 2014). Moreover, we try to bring on light obstacles which possibly limit the accessibility to the assay (e.g reimbursement practices).

2. METHODS

The breast cancer patients considered potentially appropriate for the assay application was determined according international guidelines (National Comprehensive Cancer Network-NCCN) and the 2012 Health Ministerial Decision. It included early stage breast cancer women with hormone receptor positive and lymph node negative. Although international guidelines don't refer to age criteria, the Ministerial Decision in Greece set a cutoff for women older than 65 years in order to avoid over-use of the assay. Cancer incidence was derived from Hellenic Statistical Authority-ELSTAT and OECD health data bases, while some assumptions were made concerning the disease stage of the population. The age structure was derived from the Globocan 2014 data base. The real number of women who undertook the assay, data for the total cost (€3,250) and the description of reimbursement policies

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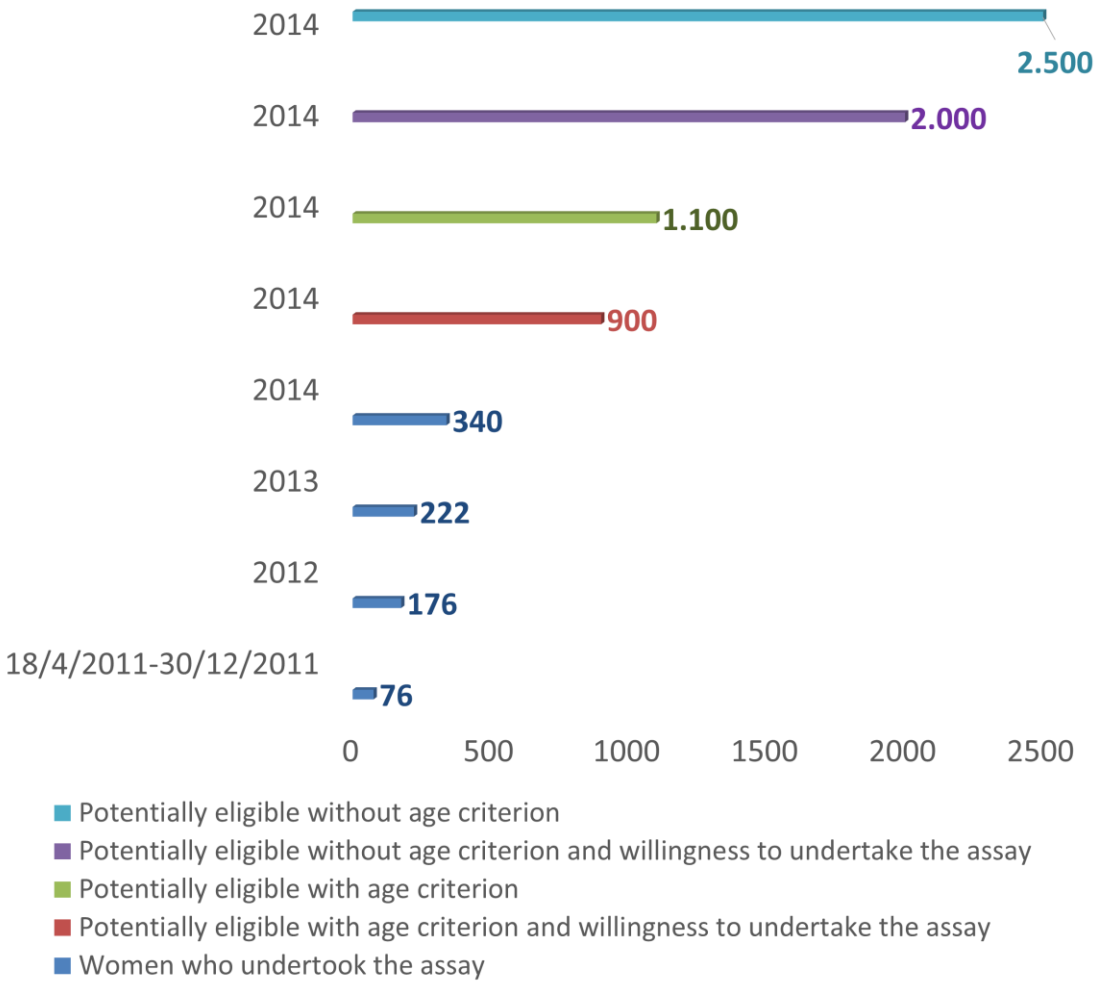
Figure 1: Nb of women who undertook the assay and potentially eligible number of women to undertake the assay under different scenarios



3. RESULTS

Based on the incidence of female Breast Cancer in Greece, approx. 5,000 new cases per year, the percentage of women with positive hormone receptors and negative lymph nodes (approx. 50%) and the age structure of the breast cancer suffering women in Greece (43.8% of breast cancer women <65years old) it was estimated that *1,100 patients* were potentially appropriate for conducting the OncotypeDX assay. In case, that we pass over the age criterion then the potentially eligible number of women for undertaking the assay is increasing to *2,500.* However, by making the assumption that 20% of eligible women don't agree to undertake the test, the eligible numbers are limited to about **900** (with age criterion) and **2,000 without age criterion**, respectively. The real number of women undertaking the assay is steadily increasing from 176 in 2012, to 222 in 2013 and 340 in 2014.

Concerning the burden of the assay for households' budgets, it was reported that women must fully pay the test and after some months get reimbursed 80% of the cost, which leaves them with a €650 out of pocket expense.

4. DISCUSSION- CONCLUSIONS

Although the number of women undertaking the assay is increasing, just 38% (N=340 in 2014) of the potentially eligible women (N=900 taking also in mind the age criterion and the fact that about 20% of eligible women will be unwilling to contact the assay), undertook the test in 2014. Reimbursement policy reforms

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which will reduce the burden of cost sharing for patients and cancellation of the age criterion, is expected to facilitate the accessibility to the assay

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