

# P4-09-29: PR status cannot predict Oncotype DX Recurrence Score®: a study in a Greek cohort of N0M0/ER+/PR-/HER2- breast cancer patients tested with Oncotype DX

Venizelos V.<sup>1</sup>, Iosifidou R.<sup>2</sup>, Markopoulos C.<sup>3</sup>, Xepapadakis G.<sup>4</sup>, Tsoulos N.<sup>5</sup>, Giannoulakis S.<sup>5</sup>, Kapetsis G.<sup>5</sup>, Psyrris A.<sup>6</sup>, Saridaki Z.<sup>1</sup>, Natsiopoulos I.<sup>7</sup>, Nikolaidi A.<sup>8</sup>, Savvidou A.<sup>9</sup>, Mpoutis A.<sup>2</sup>, Mpoukovinas I.<sup>10</sup>, Kotsakis A.<sup>11</sup>, Christopoulou A.<sup>12</sup>, Saloustris E.<sup>11</sup>, Mavroudis D.<sup>13</sup>, Aggelaki S.<sup>13</sup>, Assi A.<sup>14</sup>, Tzanninis D.<sup>3</sup>, Grosomanidis D.<sup>8</sup>, Fountzilas E.<sup>9</sup>, Lala E.<sup>2</sup>, Ignatiadou E.<sup>14</sup>, Skondra M.<sup>14</sup>, Zagouri F.<sup>15</sup>, Koumariou A.<sup>6</sup>, Kosmidis P.<sup>16</sup>, Douvetzemis S.<sup>17</sup>, Papazisis K.<sup>18</sup>, Anastasakou K.<sup>17</sup>, Pavlidou F.<sup>2</sup>, Kampletsas E.<sup>19</sup>, Poulakaki F.<sup>3</sup>, Simpilidis G.<sup>2</sup>, Triantafyllidou S.<sup>20</sup>, Stathouloupoulou M.<sup>1</sup>

1. Metropolitan Hospital, Athens, Greece, 2. Theagenio Hospital, Thessaloniki, Greece, 3. Athens Medical Centre, Athens, Greece, 4. IASO Hospital, Athens, Greece, 5. Genekor Medical S.A, Athens, Greece, 6. Attikon University Hospital, Athens, Greece, 7. Interbalcan European Medical Centre, Thessaloniki, Greece, 8. Mitera Hospital, Athens, Greece, 9. Agios Loukas Hospital, Thessaloniki, Greece, 10. Bioclinic, Thessaloniki, Greece, 11. University General Hospital, Larissa, Greece, 12. St Andrews General Hospital, Patras, Greece, 13. University Hospital of Heraklion, Crete, Greece, 14. Henry Dunant Hospital, Athens, Greece, 15. Alexandra General Hospital, Athens, Greece, 16. Hygeia Hospital, Athens, Greece, 17. Metropolitan General, Athens, Greece, 18. Euromedica clinic, Thessaloniki, Greece, 19. Ioannina University Hospital, Ioannina, Greece, 20. Genesis Clinic, Thessaloniki, Greece



## Abstract

The Oncotype DX assay is a widely utilized genomic test that helps predicting the risk of breast cancer recurrence and the potential benefit of chemotherapy in early-stage, hormone receptor-positive (HR+) breast cancer patients.

Low/absent expression of PR in ER-positive breast tumors is associated with more proliferative and aggressive disease, poorer prognosis<sup>1</sup> and recurrence. However, the predictive value of progesterone receptor (PR) status in determining chemotherapy benefit remains unclear.

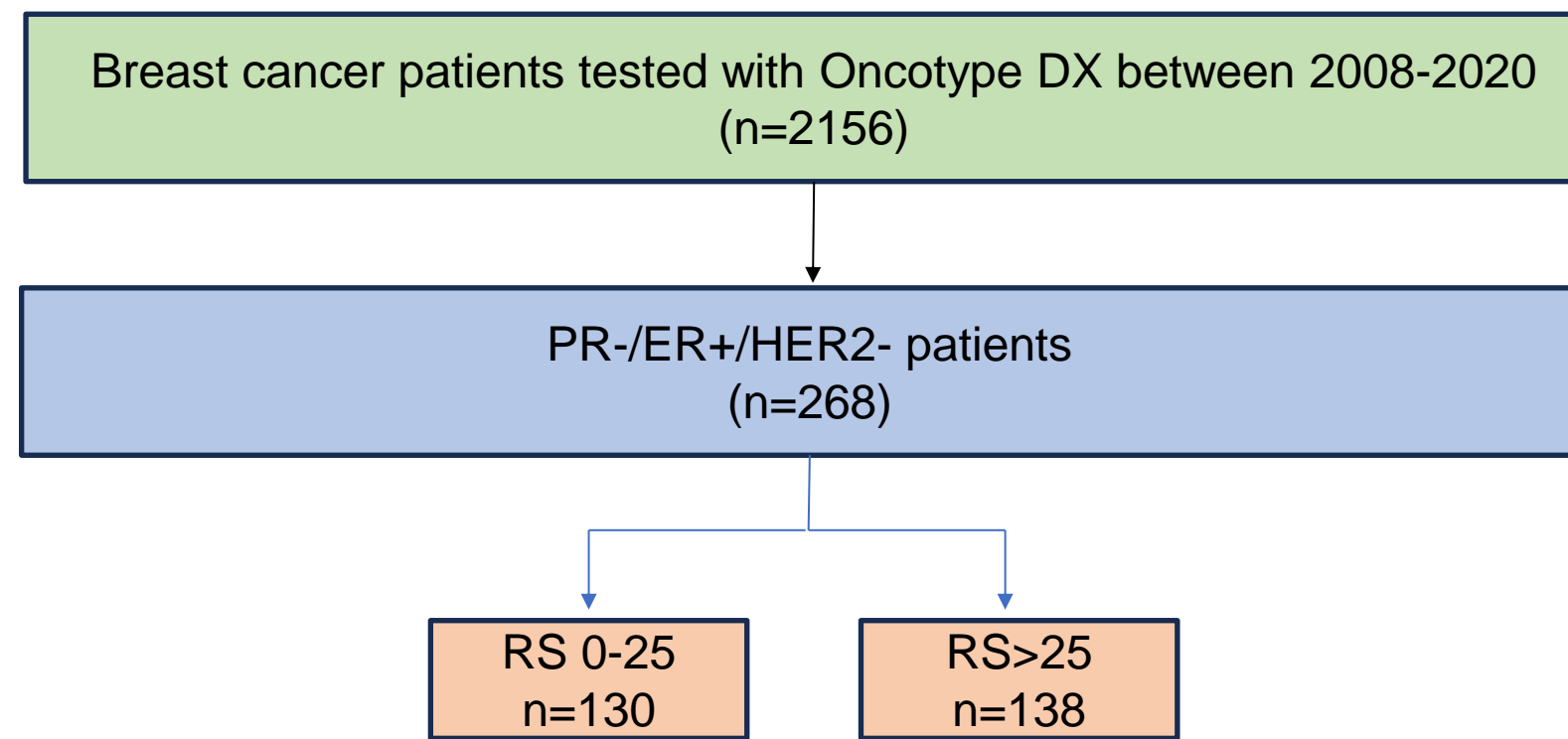
We retrospectively analyzed data from a Greek cohort of 268 pT1-3N0, cM0/ER+/PR-/HER2- breast cancer pts who underwent Oncotype DX testing between 2008 and 2020. Pts were categorized based on their Oncotype DX Recurrence Score (RS) into low (0-25) and high (>25) risk groups. The mean RS was 20.3. (Mean RS reported in TailorX<sup>2,3</sup> study regardless of PR status was 18.2).

RS 0-25 was reported in 130 (48,5%) of them, while 138 (51,5%) had a RS >25. In PR-negative, pT1-3N0, cM0/ER+/HER2- breast cancer pts, PR status alone does not predict the RS and hence, the benefit of chemotherapy. These findings underscore the importance of using Oncotype DX scores rather than PR status alone to guide chemotherapy decisions in PR-negative breast cancer patients.

## Introduction

PR-negative status has been associated with poorer prognosis in ER+ breast cancer pts compared to those that are PR-positive. The Oncotype DX<sup>®</sup> assay is a 21-gene assay used to predict the risk of breast cancer recurrence and the potential benefit of chemotherapy in early-stage, hormone receptor-positive (HR+) breast cancer patients. In TAILORx clinical study, PR-negative pts represented 10% of the total cohort. PR-negative pts have been correlated with higher RS<sup>4</sup>. Nevertheless, the predictive value in determining chemotherapy benefit of PR status has not been proven in clinical trials. This study focuses exclusively on PR-negative breast cancer pts to assess whether PR status can predict chemotherapy benefit using Oncotype DX scores.

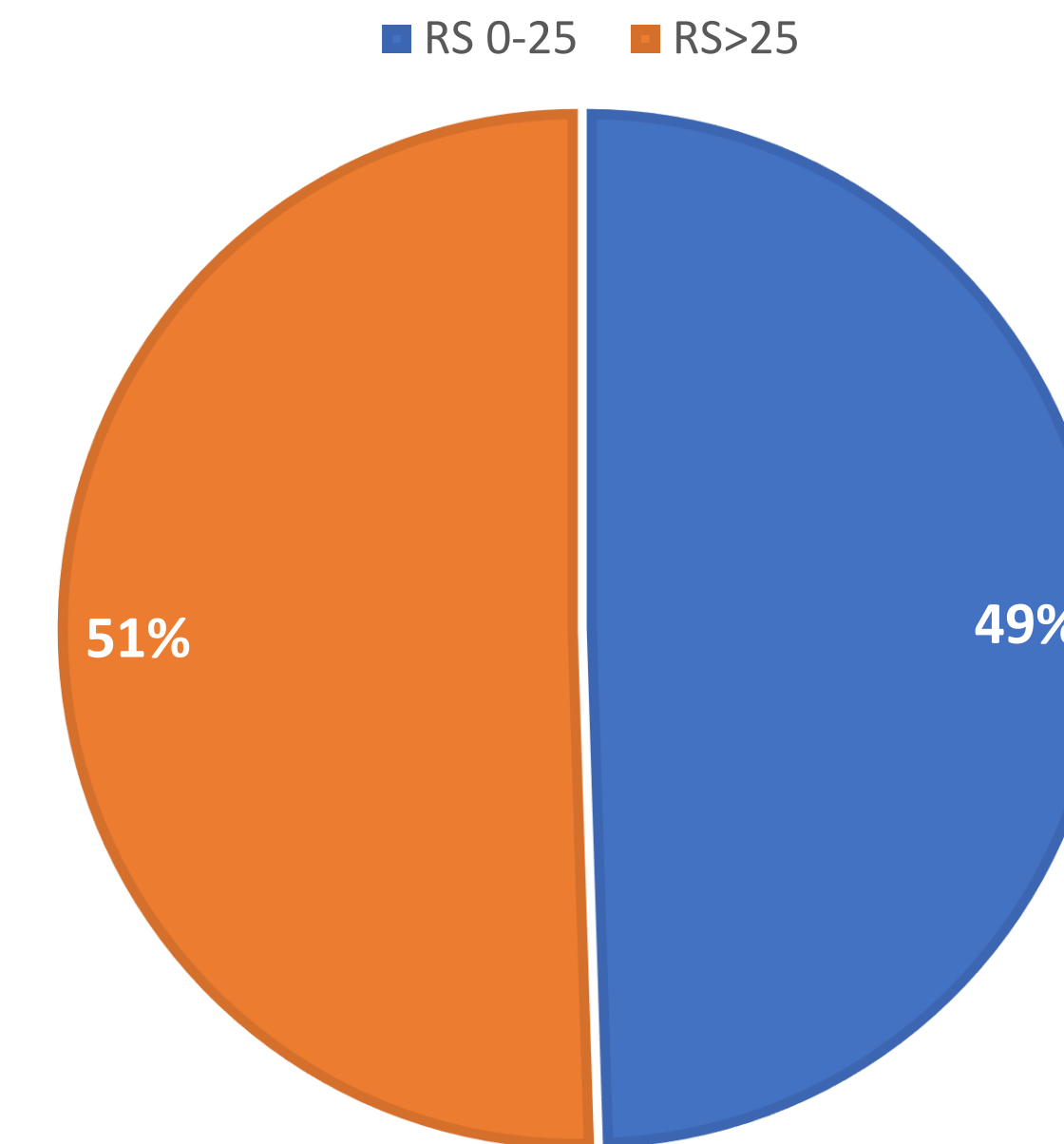
Figure 1. Study design



## Methods and Materials

We retrospectively analyzed data from a Greek cohort of 2156 breast cancer pts who underwent Oncotype DX testing between 2008 and 2020. Taking into consideration the ER,PR,HER2 status from the quantitative single-gene scores in the Oncotype DX report, we identified a total of 268 PR-negative (PR quantitative score <5.5) pT1-3N0, cM0/ER+/HER2- cases (Figure 1). The median age of the cohort was 57,5 and 49 pts (18,3%) were ≤ 50years old. Pts were categorized based on their Oncotype DX recurrence scores (RS) into low (0-25) and high (>25) risk groups.

Chart 1. RS in 268 pT1-3N0, cM0/ER+/HER2-/PR-negative breast cancer patients.



## Results

In the total of 268 pT1-3N0, cM0/ER+/HER2-/PR-negative breast cancer pts, the mean RS was 20.3. RS 0-25 was reported in 130 (48,5%) of them, while 138 (51,5%) had a RS >25 (Chart1).

## Discussion

In PR-negative, pT1-3N0, cM0/ER+/HER2- breast cancer pts, PR status alone does not predict the RS and hence, the benefit of chemotherapy.

Although low/absent expression of PR in ER-positive breast cancer pts has been associated with more aggressive disease and poorer prognosis, almost half (48,5%) of the pts in our cohort had a RS<0-25.

## Conclusions

These findings underscore the importance of using Oncotype DX scores rather than PR status alone to guide chemotherapy decisions in PR-negative breast cancer patients.

## Contact

Vasileios Venizelos  
Metropolitan Hospital, Athens, Greece  
Email: bennievenizelos@gmail.com  
Website: <https://www.vvenizelos.gr/>  
Phone: +306932201100

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