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EndoPredict in patients with ER-positive, HER2-negative early-stage breast cancer: Real-world data from the prospective, international, multicenter RESCUE trial

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Background

RESCUE is a prospective, international, multicenter health care study on risk assessment by the clinicomolecular test EndoPredict® (EP) and long-term patient outcome in early luminal breast cancer. The trial recruited a total of 1191 patients (pt) in 45 sites. 49 pt were drop-outs. We describe the impact of the EP test result on adjuvant therapy recommendation and therapy compliance in real world by analyzing baseline and one year follow up data from RESCUE.

Methods

Data from 1142 (1133 female, 9 male) pt, who entered the RESCUE trial between July 2018 and September 2022 at 45 (42 German/3 Swiss) breast centers were collected via electronic case report forms. Pt were eligible, if they had been diagnosed with HR+/HER2- primary invasive breast cancer stage I/II, T1 to T3 with 0 to 3 positive lymph nodes and if they had an EP test within six months before inclusion. Data cut off for this analysis was May 7th, 2025. 1142 pt were analyzed.

Results

Median age was 57,0 years (range 26,0-82,0). Of the 1133 female pt, 395 were premenopausal and 733 postmenopausal. Nodal status was as follows: pN0: 615 (53.9 %) pN0(i+): 9 (0.8%) pN1mic: 76 (6.7%) pN1: 342 (30.0%) pNx: 5 (0.4%) N/A: 95 (8.3%). Tumor-Grading was reported as follows: G1 (137pt, 12,0%), G2 (892pt, 78,1%), G3 (112pt, 9,8%). Distribution of Ki-67 was recorded as follows: ≤10% (403pt, 35,3%), 11-24% (445pt, 39,0%), ≥ 25% (287pt, 25,1%). 62,8% (n=248) of premenopausal pt and 61,1% (n=448) of postmenopausal pt were recommended to undergo (neo)adjuvant CTX. Of the 696 female patients to whom (neo)adjuvant CTX was recommended, 550 (79,0%) were compliant, whereas 134 (19,3%) did not undergo chemotherapy. At the time of the one year follow up 1028 (96,5%) pt were still taking endocrine therapy ET, 27 (2,5%) had stopped ET. For 10 pt information on compliance ET was not available. EP results as well as correlation analyses between classical histopathological factors, and EP will be presented in detail at the meeting.

Conclusions

In the RESCUE trial cohort pt were extremely compliant regarding endocrine therapy during the first 12 month. CTX compliance was similar to already published earlier trials in this setting.

Clinical trial identification

DRKS00014051.

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Legal entity responsible for the study

North-Eastern German Society of Gynecological Oncology (NOGGO).

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Disclosure

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