

the 2 (c) categories with the 3 (g) groups; the timing of recurrences; and the putative benefit of EET for each genomic group.

Methods: All ER+/HER2- BC pts with MP data diagnosed between 2012-2017 at Vall d'Hebron University Hospital were selected. cLow risk was defined as in MINDACT trial. To study the benefit of EET, a landmark analysis at 5y from ET initiation was conducted.

Results: 140 pts were identified. Baseline features: 47.8% premenopausal; stage I/II: 74%/26%; histological grade 1/2/3: 19.6%/74.9%/6.5%. cLow/cHigh: 67%/33%; gUL/gLow-Non-Ultralow (LNUL)/gHigh: 11.4%/53.6%/35%. PgR and Ki67 tended to correlate with MP g risks, but only the IHC-subtype reached statistical significance. Systemic adjuvant treatments [N(%): ET 138/98.5%; ovarian function suppression for premenopausal pts 23/35%; CT: 45/32%; EET: 49/35.8%. After 8y-median FU, 15 DFS events and 11 DMFS were observed. DMFS in cHigh/gLow (UL+LNUL) without CT was 90.6% [81.1%; 100%]. DFS/DMFS rates by each c/g category are depicted in the table. Only 4 DMFS events occurred after 5 years, precluding to explore EET role by RC.

Conclusions: In our series, DMFS rate in cHigh-gLow pts without CT was similar to that reported in MINDACT trial. In line with prior reports, gUL pts had excellent survival, while cHigh-gHigh group showed significantly poorer outcome. Albeit limited by small sample size, classification in 6 RCs instead of 4 seems useful to redefine prognosis. Additional FU is warranted to determine the EET benefit in each RC.

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116P Time and motion randomised study of a subcutaneous (SC) pertuzumab and trastuzumab fixed-dose combination (PH FDC) for the treatment of HER2-positive early breast cancer (HER2 EBC): PHaTiMa

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Background: In oncologic monotherapy, SC compared to intravenous (IV) route brings advantages like patients' (Pts) and healthcare professionals (HCP) preference and improved healthcare efficiency, thanks to reductions of both time and use of resources.

Methods: During adjuvant dual blockade for HER2 EBC, trained observers measured time used in various treatment activities for 3 cycles (2nd to 4th) of pertuzumab (Perjeta or P) IV and trastuzumab (Herceptin® or H) IV or SC (Group A: P-IV+H-IV; Group B: P-IV+H-SC) and later for subsequent 3 cycles (5th to 7th) of PH FDC SC (Phesgo). The objectives were to assess time saved by Pts and HCP and what resources were used with PH FDC SC versus P-IV+H-IV or P-IV+H-SC.

Results: In 10 Spanish centres, 34 women were randomised (n=17 in Groups A and B). Per cycle, PH FDC SC saved 71% and 63% of Pts time in treatment room (-119 and -87 min, both p<0.0001) and 75% and 69% in chair (-121 and -90 min, both p<0.0001) compared with P-IV+H-IV and P-IV+H-SC, respectively. Active HCP time was reduced by 49% and 48% (-22.9 and -23.0 min, both p<0.0001), including preparation (-6.05 min p<0.0001 and -2.05 min p=0.1112) and administration (-16.9 min p=0.0006 and -20.8 min p<0.0001). Active times were reduced both for pharmacists (-2.10 min p=0.0185 and -1.46 min p=0.0488) and nurses (-18.3 min p=0.0004 and -20.0 min p<0.0001). PH FDC SC reduced use of consumables and avoided drug waste. Safety data up to cycle 7 (in 2025 ends 3-year follow-up) reported 20 Pts with 38 adverse events related to study treatments (only 2 Grade 3: diarrhoea and a serious [SAE] drug hypersensitivity).

Conclusions: PH FDC SC significantly saved Pts and HCP times and reduced use of healthcare resources. In dual therapies, the advantages of the SC route are added to those of fixed dose combination, versus administering drugs separately. Preliminary safety data indicated that the study treatments were overall well tolerated. Together with previous findings showing comparable efficacy and safety profiles and Pts preference of PH FDC SC versus P-IV+H-IV in (neo)adjuvant settings, these results encourage the use of PH FDC SC for dual blockade treatments.

Clinical trial identification: EudraCT 2020-004241-36.

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