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A Visual Representation of the Observational Study of Extended Adjuvant Neratinib in HER2+Early Breast Cancer in the Context of the European Early Access Program (EAP)

NEAR Study Final Results

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CONTEXT AND OBJECTIVES

Neratinib is an oral pan-HER tyrosine kinase inhibitor approved since 2018 in the European Union for the extended adjuvant treatment of adults with HR+/HER2+EBC (early breast cancer) who completed adjuvant trastuzumab-based therapy less than 1 year ago[1].

Since 2017, an early access program (EAP) granted neratinib access to patients with HER2+EBC in Europe.

The NEAR study was designed to describe the extended adjuvant neratinib use in patients treated in the context of this EAP from December 2017 to July 2022[2].

METHODS

The retrospective, longitudinal, multi-country NEAR study included adult patients who had received at least one dose of extended adjuvant neratinib for HER2+EBC between 1 August 2017 and 31 December 2020, in the context of the EAP and were followed-up until 5 July 2022.

Data on patient and tumor characteristics, previous cancer treatments, neratinib treatment patterns, reason for discontinuation, and adverse events (AEs), occuring during the study period were used.

Here, results are presented using advanced visualization techniques:

- Sequences of anti-HER2 treatments and neratinib use were visualized through time sequence analysis with K clustering (TAK)[3].
- A Heatmap by quarter is another way to visualize treatment sequence before and after neratinib initiation.
- The time to adverse events onset was presented on a span chart diagram. The span chart shows the distribution of the occurrence of adverse events over time.

CONCLUSION

The results of this study are consistent with known extended adjuvant neratinib treatment pattern and safety profile. The visualization methods allow to represent the use of neratinib throughout the entire treatment journey of patients with early-stage HER2-positive BC receiving neratinib as well as the use of concomitant therapy in the context of the EAP.

Reference

[1] Chan A, et al. Clin Breast Cancer. 2021;21(1):80–9.

[2] ClinicalTrials.gov. NCT05599334. https://tinyurl.com/2v76j4u7 (accessed 9 October 2024).

[3] Tredan O. et al. 2022; Cancer Inform. 2022 Jan;21:117693512211351

Glossary

AE: Adverse events ; **EAP:** Early Access Program ; **EBC:** Early breast cancer ; **HER2:** Human epidermal growth factor receptor 2 ; **HR:** Hormon Receptor; **TAK:** Time sequence analysis through K-clustering

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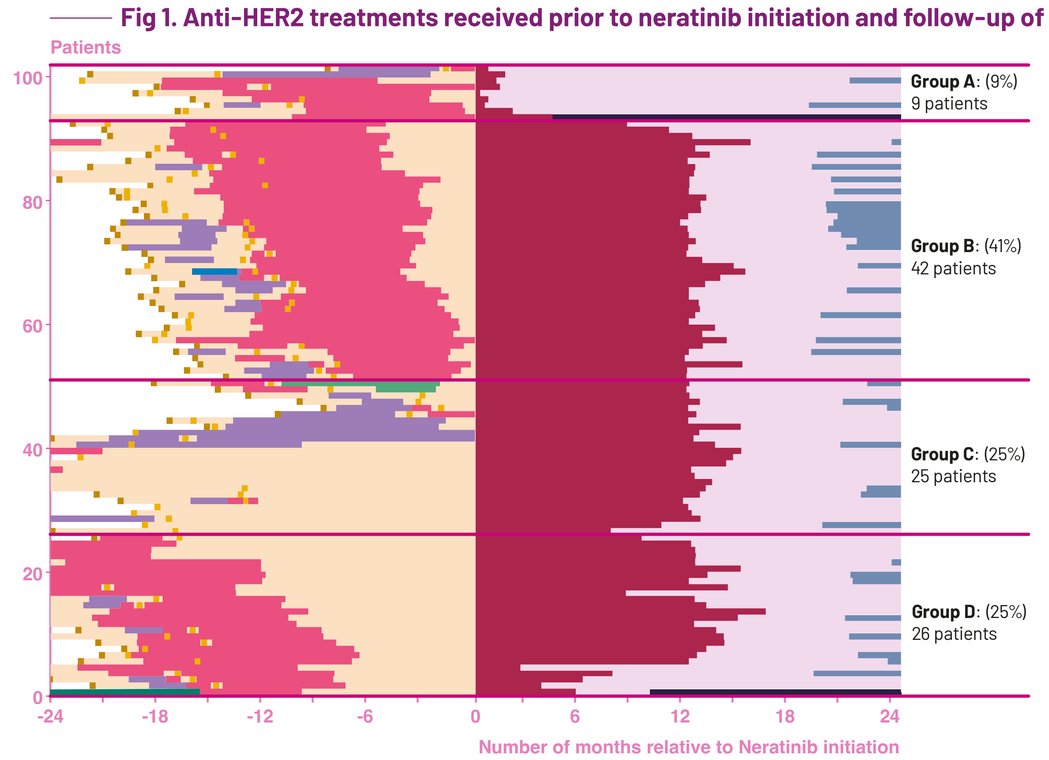
Poster Designed by Heva

RESULTS

Description of treatment patterns

Pertuzumab
Trastuzumab
Pertuzumab + Trastuzumab
T-DM1
T-DM1 + Trastuzumab
Neratinib
Primary surgery
Diagnosis
Death
No Neratinib treatment
No anti-HER2 Treatment
End of follow-up / study

Fig 1. Anti-HER2 treatments received prior to neratinib initiation and follow-up of neratinib treatment (truncated at two years)



Vizualization was truncated two years before and two years after neratinib initiation
N= 102 patients (6 patients had missing duration of treatment)
One additionnal patient died more than two years after neratinib initiation (three deaths in total)

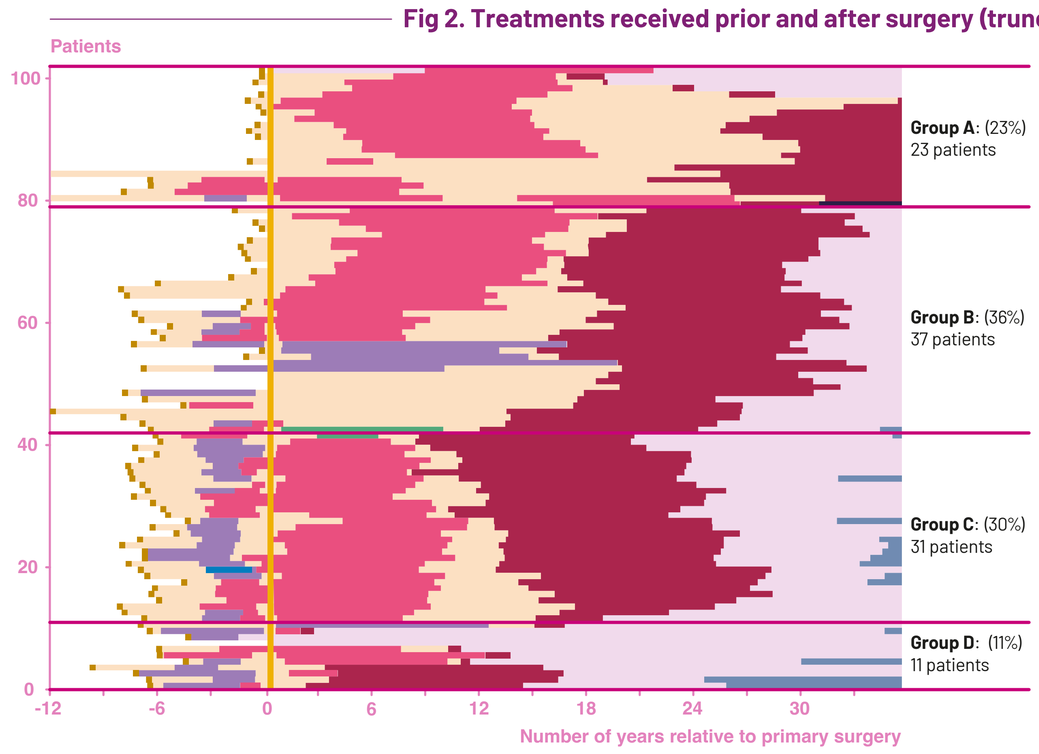
Key results

- This visualization provides a full picture of anti-HER2 treatment prior neratinib initiation
- It also provides a good overview of follow-up after neratinib initiation.
- All patients received trastuzumab-based treatment before neratinib initiation, excepted for few patients with contra-indication (no anti-HER2 therapy).

4 groups can be identified based on the length and the type of anti-HER2 treatment received :

A) Early neratinib interruption
B) Short period between trastuzumab adjuvant completion and neratinib initiation
C) Patients with either no anti-HER2 adjuvant treatment or combination trastuzumab /pertuzumab
D) Longer period between anti-HER2 adjuvant completion and neratinib initiation

Fig 2. Treatments received prior and after surgery (truncated at three years)



Vizualization was truncated two years before and three years after surgery
N = 102 patients (6 patients had missing duration of treatment)
Two additional patients died more than three years after surgery (three deaths in total)

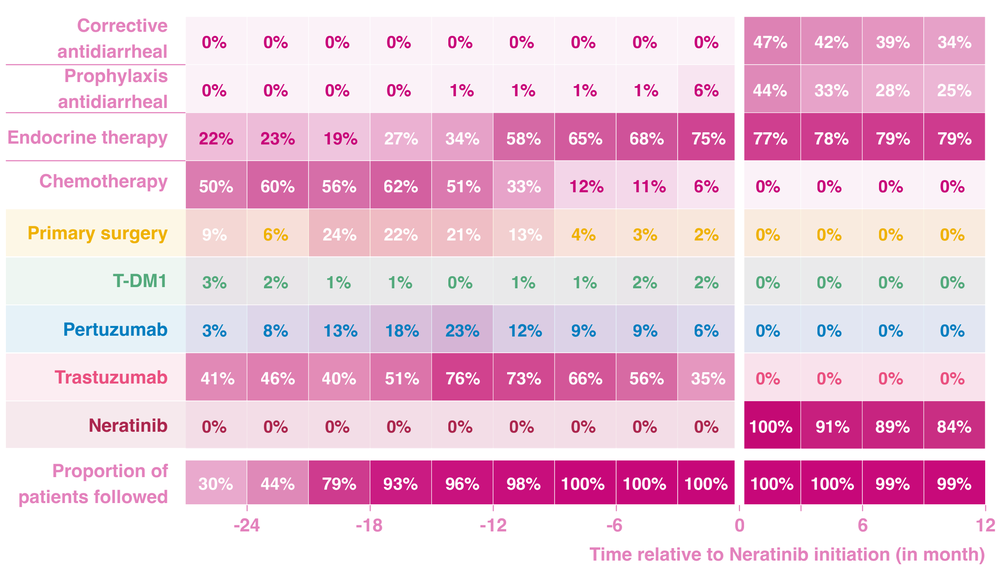
Key results

This other vizualisation is aligned on time of of surgery (T0).

4 groups can be identified based on the length and the type of diagnosis and treatment received before and after surgery:

A) Short period between diagnosis and surgery OR longer period between anti-HER2 adjuvant completion and neratinib initiation
B) Longer period between surgery and neratinib initiation
C) Neo-adjuvant treatments and short period between trastuzumab in adjuvant setting and neratinib initiation
D) Neratinib initiated shorly after surgery

Fig 3. Distribution of treatments received prior, at the same time and after neratinib initiation (Heatmap per quarter)



N=108 patients pre-neratinib initiation, N=102 patients post-neratinib initiation; 6 patients had missing duration of neratinib treatment
Vizualization was truncated two years before and 1 year after neratinib initiation
To be noted that some patients started the prophylaxis few days before the Neratinib start day

Key results

- Trastuzumab was used more frequently than pertuzumab and T-DM1
- A gradient of endocrine therapy is observed before and after neratinib initiation
- The frequency of prophylactic and corrective antidiarrheal treatments was highest in the 6-months following neratinib initiation

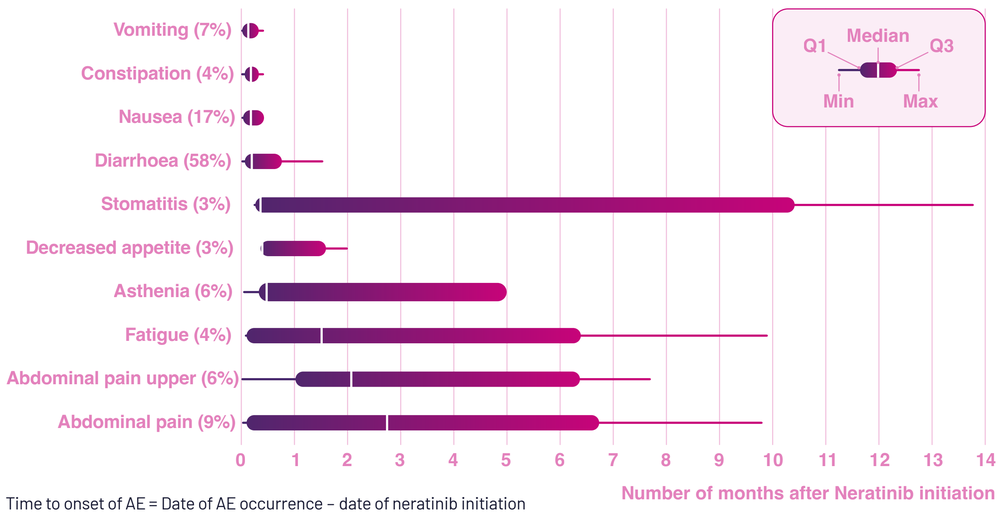
How to interpret this figure

This visualization provides an overview of the percentage of different treatment events considering temporality from neratinib initiation (T0)

Higher percentage corresponds to darker color

Time to onset of adverse events

Fig 4. Time to AE onset represented with a Span Chart by AE type (all grades)



Time to onset of AE = Date of AE occurrence – date of neratinib initiation
Percentages presented considering all patients as denominator (N=108)
Maximum values presented exclude values above 1,5 X (Q3-Q1)

Key results

- Adverse events (all grades) mainly occured in the first month after neratinib initiation.
- The most frequent adverse event (all grades), diarrhea, occurred mainly within 2 months of initiation of neratinib.

How to interpret this figure

This Span chart represents the distribution of adverse event over the study period

This figure can be read as a box plot: the beginning of the box correspond to the first quartile, the break in the line represents the median, and the end of the box represents the 3rd quartile of the distribution.