ACCESS-HER: Assessing Consequences of Standard-of-Care Gaps in HER2-Positive Breast Cancer in the Brazilian Healthcare System

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INTRODUCTION

Dual HER2 blockade with pertuzumab and trastuzumab, followed by adjuvant trastuzumab-emtansine (T-DM1) for residual disease, has been the undisputed global standard of care for high-risk HER2-positive early breast cancer (EBC). These regimens have demonstrated significant improvements in pathological complete response and overall survival in pivotal trials. However, neither pertuzumab nor T-DM1 is currently available in the Brazilian Unified Health System (SUS), leading to a critical gap between internationally recommended treatment and what is offered to patients in the public sector. This disparity may lead to worse oncological outcomes, including increased mortality.

AIM

The present study aimed to estimate the number of preventable deaths associated with the lack of access to these therapies in Brazil.

METHOD

- **Study Design:** Retrospective, scenario-based modeling study
- **Data Source:** Real-world data from DATASUS (Brazilian national public health database)
- **Study Population:** Women (≥18 years) initiating treatment for stage II/III HER2-positive early breast cancer (EBC) within the SUS in 2023.
- **Treatment scenarios** (for residual disease)
  1. SUS Standard: Neoadjuvant, followed by adjuvant trastuzumab alone.
  2. T-DM1 Scenario: Adjuvant trastuzumab emtansine (T-DM1).
  3. Global Standard: Neoadjuvant dual blockade (pertuzumab + trastuzumab) followed by adjuvant T-DM1 (if no pCR).
- **Analysis**: Calculation of preventable deaths (defined as the difference in mortality between the SUS Standard and the two alternative scenarios) among patients with residual disease post-neoadjuvant treatment.
- **Model Parameters:** Total pathologic complete response (tpCR) rates and 7-year overall survival (7y OS).
- **Parameter Source:** Derived from the pivotal NeoSphere and KATHERINE trials.
- **Primary Endpoint:** Estimated 7-year mortality per scenario.

STUDY DESIGN AND PARAMETERS

Figure 1. Study Design Decision Three

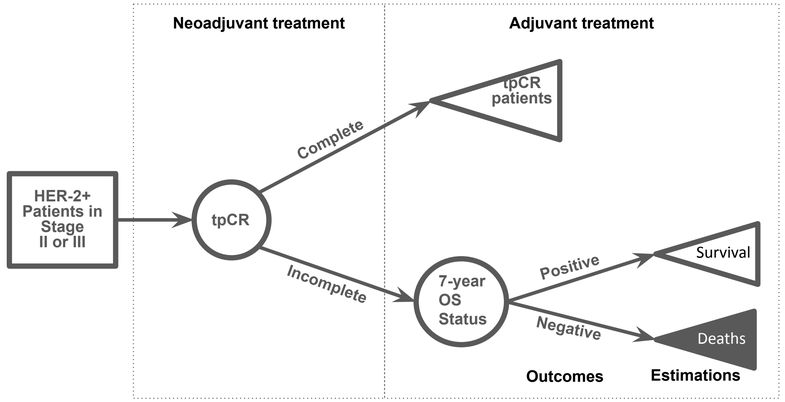


Table 1. Model Parameters

Model Parameters	Values (%)	95% CI	Source
tpCR – Neoadjuvant trastuzumabe	21.5	14.1 - 30.5	[1]
tpCR – Neoadjuvant double blockage	39.3	30.0 - 49.2	[1]
7y OS – Residual disease (trastuzumabe)	84.4	81.6 - 87.2	[2]
7y OS – Residual disease (T-DM1)	89.1	86.8 - 91.5	[2]

CONCLUSIONS

This analysis demonstrates that the absence of pertuzumab and T-DM1 from the Brazilian public health system may lead to over 340 preventable deaths annually among patients with high-risk HER2-positive early breast cancer. The estimated reductions in long-term mortality with access to standard-of-care regimens underscore the urgent need to align national treatment protocols with internationally accepted guidelines. Incorporating these therapies into the SUS is essential to address systemic inequities in breast cancer care and to improve survival outcomes for patients treated in the public sector in Brazil.

RESULTS

We identified 6,061 patients in 2023 SUS cohort

Scenario Model: 7-Year Mortality Projections

- **Projected Deaths:**
  - SUS Standard: 744.
  - T-DM1 Scenario: 520.
  - Global Standard: 402.
- **Relative 7-Year Mortality Reduction (vs. SUS Standard):**
  - T-DM1: ~30%.
  - Global Standard: ~46%.

Preventable Deaths (vs. SUS Standard)

- **T-DM1 Scenario:**
  - Stage II: 51 deaths prevented.
  - Stage III: 173 deaths prevented.
  - Total: 224 preventable deaths per annual cohort.
- **Global Standard Scenario** (Neoadjuvant Pertuzumab + Adjuvant T-DM1):
  - Stage II: 78 deaths prevented.
  - Stage III: 264 deaths prevented.
  - Total: 342 preventable deaths per annual cohort.

Figure 2. Clinical Stage Distribution (N=6,061)

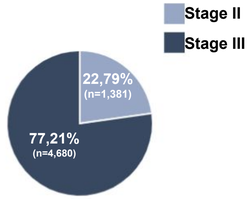


Figure 3. Projected 7-Year Deaths by Treatment Scenario and Clinical Stage

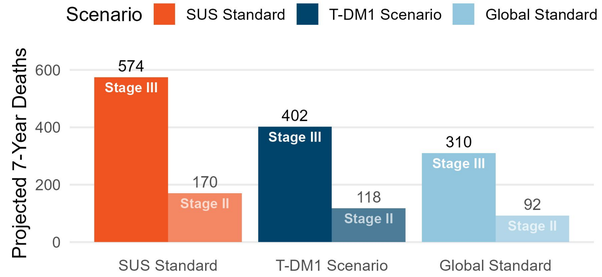
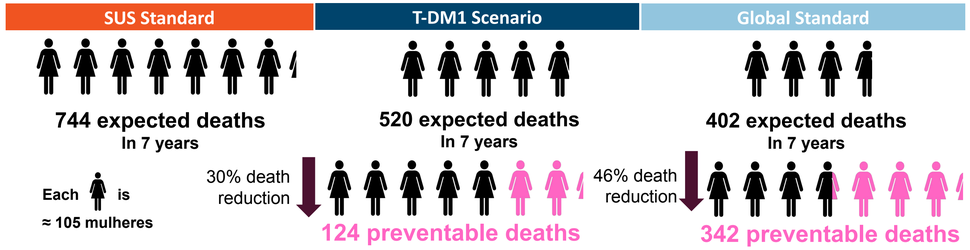


Figure 4. Preventable Deaths by Scenario



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Acknowledgement

- Cintia Kurokawa La Scala for scientific support
- Henrique Lima for their meticulous assistance with poster formatting.

References

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