SAFETY AND EFFECTIVENESS OF TRASTUZUMAB EMTANSIN IN LOCALLY ADVANCED OR METASTATIC HER 2 POSITIVE BREAST CANCER

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OBJECTIVE:
To evaluate the effectiveness and safety of TDM-1 in patients with advanced/metastatic HER2-positive breast cancer.

MATERIAL AND METHODS:
• Design: observational retrospective study.
• Population: patients that received treatment with TDM-1 in unresectable or metastatic breast cancer who have previously received Trastuzumab and taxane separately or in combination, from January-2015 to June-2018.
• Treatment: TDM-1 was administered intravenously (3.6 mg/kg) every 3-week cycle.
• Variables collected: gender, age, hormone receptor expression (HR), previous lines, progression and death date, adverse events (AD), treatment discontinuation and dose reductions.
• Progression free survival (PFS) and Overall survival (OS) were measured from the time of beginning treatment with TDM-1 to the date of first progression or death, respectively. PFS and OS were calculated by Kaplan-Meier analysis.

RESULTS:
- 40 patients: women with a mean age of 55 years (SD=±13.7).
- 80% RH+.
- The median number of previous chemotherapy lines was 2 (range 1-6).

- Previous HER2-targeted therapies included:

- Mean follow-up was 15 months.
- Median PFS was 7 months (95% CI 4.3-9.7).
- No statistically significant differences were found in PFS according to HR status, age>65 years, number of previous lines or anti-HER2 therapy previously administered.
- Median OS was not reached, the 12-month OS was 73%.
- AD occurred in 82.5% of patients — 15% dose reduction — 17.5% discontinued treatment

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>44</td>
</tr>
<tr>
<td>Hepatotoxicity</td>
<td>42,5</td>
</tr>
<tr>
<td>Astenia</td>
<td>27,5</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>17,5</td>
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<tr>
<td>Peripheral neuropathy</td>
<td>15</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>12,5</td>
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</tbody>
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CONCLUSION:
Our results show lower median PFS and 12-month OS than those from randomized trials. Most patients presented AD. Toxicity profile was similar to previously described in clinical trials.