The EQ-5D Index of Elderly Patients with HER2-Positive Breast Cancer: Results from the N-SAS BC 07 Trial for Adjuvant Trastuzumab with and without Chemotherapy

Yasushiro Hagiwara1, Naruto Taira2, Tsuyoshi Saito3, Shinichi Baba4, Kokoro Kobayashi5, Takuya Kawahara6, Takeru Shiraiwa7, Takashi Fukuda8, Kojiro Shimozuma9, Yukari Uemura10, Hirofumi Mukai11, Yasuo Ohashi11, Masataki Sawaki11

1The University of Tokyo, 2Chiyamaya University Hospital, 3Japanese Red Cross Saitama Hospital, 4Sagara Hospital, 5The Cancer Institute Hospital of the Japanese Foundation for Cancer Research, 6The University of Tokyo Hospital, 7National Institute of Public Health, 8Ritsumeikan University, 9National Cancer Center Hospital East, 10Chuo University, 11Aichi Cancer Center Hospital

INTRODUCTION

• As population is aging especially in developed countries, more elderly patients receive anti-cancer treatments.
  • Elderly patients with cancer often have comorbidities and/or declined physical functions.
  • Standard adjuvant therapy for HER2-positive breast cancer is trastuzumab plus chemotherapy.
  • N-SAS BC 07 trial showed that omitting chemotherapy results in only slight loss of disease-free survival in elderly patients with that disease [1].
  • Effects of omitting chemotherapy on health status would inform decision making for treatment.
  • Health utility also inform cost-utility analysis.

• To compare EQ-5D index of adjuvant trastuzumab monotherapy with that of trastuzumab plus chemotherapy in N-SAS BC 07 trial.

METHODS

• N-SAS BC 07 trial was a randomized controlled trial.
  • Patients
    - Women aged 70–80 years old
    - HER2-positive primary invasive breast cancer
    - Stage I to IIIA after curative surgery
    - ECOG performance status 0–1
  • Treatment (unblinded)
    - 1-year trastuzumab (once at 8 mg/kg and then 6 mg/kg every 3 weeks) in both groups
    - 3–6-month concurrent or preceding chemotherapy (selected from PTX, DTX, TC, AC, EC, FEC, CMF, TCbH) in H+CT group
  • EQ-5D Assessment (Japanese EQ-5D 3L [2, 3])
    - At enrolment, 2 months, 12 months, and 36 months after treatment initiation
    - Calculating EQ-5D index based on societal preferences in general population of Japan [4]
  • Statistical Analysis
    - Analysis population: patients with baseline EQ-5D index in full analysis set
    - Mean EQ-5D index profiles were compared using linear mixed effect models for repeated measures, adjusting for baseline EQ-5D index.
    - Proportions of the deteriorated and improved EQ-5D index based on minimally important difference (MID) of 0.1 and 0.05 [5] were compared.

RESULTS

• Of randomized 275 patients, 233 patients were included in the analysis population.

Completion Rates of EQ-5D

<table>
<thead>
<tr>
<th>Completion Rates (months)</th>
<th>H (n=120)</th>
<th>H+CT (n=113)</th>
</tr>
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<tbody>
<tr>
<td>2 months</td>
<td>107/120</td>
<td>97/119</td>
</tr>
<tr>
<td>12 months</td>
<td>90/107</td>
<td>81/97</td>
</tr>
<tr>
<td>36 months</td>
<td>80/80</td>
<td>75/75</td>
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Mean EQ-5D Profiles

At 2 months: 0.067 (0.028 to 0.105)
At 12 months: 0.034 (~0.007 to 0.075)
At 36 months: 0.049 (0.003 to 0.094)

DISCUSSIONS

• This study revealed positive effects of omitting adjuvant chemotherapy on EQ-5D index in elderly patients with resected HER2-positive breast cancer.
  • Negative effects of chemotherapy seemed to be persistent even after end of chemotherapy, despite absence of such persistent effects in many adjuvant trials in younger populations.
  • QALY may be longer with trastuzumab monotherapy than with trastuzumab plus chemotherapy.
  • Baseline mean EQ-5D index in this population was similar to that of the Japanese population norm of women aged 70 years or older [6].
  • After treatment initiation, however, mean EQ-5D index with trastuzumab monotherapy was better than that of the norm.

CONCLUSION

• Adjuvant trastuzumab monotherapy resulted in improved health status measured by the EQ-5D during adjuvant treatment period and even thereafter.

REFERENCES


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