

**The total character count for a single abstract is 2,000.** Characters include everything in the title, abstract body, and table but **do not include spaces.** Author names and institutions also are not included in the total. There is **no maximum length for the title.** However, the characters in the title will count toward your total character count.

The maximum number of authors is **20.** **One authoring group** may also be included along with the individual author names. The group name will appear as the last author of the author string.

### **Deadline**

The deadline for abstract submissions is 11:59 PM (EST) on **February 5, 2013.**

\*\*\*\*\*

### **Safety of trastuzumab in HER2 positive primary breast cancer in Japan; Initial safety report for the large scale cohort study (JBCRG C-01)**

N. Yamamoto<sup>1</sup>, H. Yamashiro<sup>2</sup>, H. Iwata<sup>3</sup>, N. Masuda<sup>4</sup>, S. ohtani<sup>5</sup>, M. Takahashi<sup>6</sup>, K. Yamazaki<sup>7</sup>, M. Kato<sup>8</sup>, S. Ohno<sup>9</sup>, K. Kuroi<sup>10</sup>, K. Yamagami<sup>11</sup>, T. Morimoto<sup>12</sup>, Y. Hasegawa<sup>13</sup>, T. Takano<sup>14</sup>, H. Shigematsu<sup>15</sup>, M. Hosoda<sup>16</sup>, H. Abe<sup>17</sup>, S. Morita<sup>18</sup>, S. Yasuno<sup>19</sup>, M. Toi<sup>20</sup>

<sup>1</sup>Breast Surgery, Chiba Cancer Center, Chiba,

<sup>2</sup>Breast Surgery, NHO Kure Medical Center and Chugoku Cancer Center, Hiroshima,

<sup>3</sup>Breast Oncology, Aichi Cancer Center Hospital, Aichi,

<sup>4</sup>Surgery, Breast Oncology, NHO Osaka National Hospital, Osaka,

<sup>5</sup>Breast Surgery, Hiroshima City Hospital,

<sup>6</sup>Breast Surgery, NHO Hokkaido Cancer Center, Sapporo,

<sup>7</sup>Sapporo-Kotoni Breast Clinic, Hokkaido,

<sup>8</sup>Kato breast surgery clinic, Shiga,

<sup>9</sup>Breast Oncology, NHO Kyusyu Cancer Center, Hukuoka

<sup>10</sup>Surgery, Tokyo Metropolitan Cancer and Infectious diseases Center Komagome Hospital, Tokyo,

<sup>11</sup>Breast Oncology, Shinko Hospital, Hyogo,

<sup>12</sup>Breast Surgery, Yao Municipal Hospital, Osaka,

<sup>13</sup>Breast Surgery, Hirosaki Municipal Hospital, Aomori,

<sup>14</sup>Department of Clinical Oncology, Toranomon Hospital, Tokyo,

15Breast Surgery, Hiroshima Univesity Hospital, Hiroshima

16Breast and Endocrine Surgery, Hokkaido University Hospital, Hokkaido,

17Breast and General Surgery, Shiga University of Medical Science Hospital, Shiga

18Department of Biostatistics and Epidemiology, Yokohama City University Medical Center, Kanagawa

19EBM Research Center Kyoto University, Kyoto,

20Breast Surgery, Kyoto University Hospital, Kyoto,

**Background:**

The global randomized trials with trastuzumab (H) shows increased cardiotoxicity in patients (pts) with HER2 positive early breast cancer (BC). Safety in Japanese has not been fully evaluated. We evaluated the safety, especially focused on cardiotoxicity, of H adjuvant (adj) therapy in an observational study in Japan (UMIN000002737).

**Methods:**

Pts with histopathologically confirmed HER2 positive invasive BC were registered. Women with stage I-IIIc disease who received H as neo-adj and/or adj therapy were eligible. Mean LVEF at 3, 6, 9 and 18 months (M) was evaluated. The time points represent examination on day 60-120, 150-210, 240-330 and 455-635, respectively.

**Results:**

A total of 2024 pts were registered from 56 institutes between July 2009 and June 2011. Data of 1875 pts were collected and finalized by September 2012, and 1800 of them were analyzed for safety. The median follow-up was 35 M. The mean age was 54.5 years. Elderly pts  $\geq 60$  years were 32.7%. Treatments after surgery were: concurrent chemotherapy (CT) and H in 20.1%, sequential CT and H in 43.5% and H monotherapy in 36.4%. Adverse events (AEs) associated with H were reported in 350 pts (19.4%) and Grade (G) 3/4 AEs in 12 pts (0.7%). G 3/4 cardiac toxicities were reported in 7 pts (dysfunction, 4pts; angina, 1 pt; myocardial infarction, 1 pt and heart failure, 1 pt). The mean baseline LVEF was 69.4% and the mean LVEF at 3, 6, 9, 18M were 66.9%, 66.3%, 65.3%, 66.3%, respectively. There was a significant difference compared with the mean baseline LVEF at all points ( $p < 0.0001$ ). LVEF decrease  $\geq 10\%$  occurred in 177 pts (during H treatment, 130 and after H treatment, 47). Follow-up data were available in 66 pts: 34 pts recovered to the baseline. Mean time to recover was 262 days. The univariate analysis showed using anthracyclin (odds ratio 2.312,  $p = 0.003$ ) was the only risk factor for cardiotoxicity. However, elderly, radiation concurrent/sequential treatment with CT and H had no impact.

**Conclusion:**

From our study, we found the AE profiles of H were consistent with previously known AEs and we found using anthracycline was the risk factor for cardiotoxicity at this moment. We should carefully follow pts and watch long-term safety.

(本体 : 1860 字 + title : 117 字 = 1977 字 / 2000 字)