STUDY OF DOCETAXEL (BREXEL) AS SINGLE TREATMENT FOR METASTATIC BREAST CANCER AT DHARMAIS HOSPITAL, JAKARTA, INDONESIA

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Purpose: Breast cancer is the most common female's cancer in Indonesia. The majority of cases attended the hospital with metastatic diseases. From 2002-2007 there were 1.912 cases of breast cancer in Dharmais National Cancer Center and the operable cases were only around 100 cases. Brexel is the first generic docetaxel in Indonesia. Previously docetaxel has been reported to elicit 40-68% of response rate in the patients who have not been treated before and 30-57% response rate in the patients who have had chemotherapy for the treatment of metastatic diseases. The purpose of phase II clinical study in Dharmais Hospital Jakarta is to evaluate efficacy and safety of Brexel as single treatment for metastatic breast cancer.

Material and methods: Patients with advanced stage breast cancer, naive patients or recurrent disease with previously received chemotherapy, prior not receiving docetaxel-contained chemotherapy, patients with histologically confirmed breast cancer, patients have a WHO performance status of 0 to 2 and reveals tolerable range laboratory parameters were included in this study. Docetaxel 75 mg/m^{+} was administered every 3 weeks as a 1-hour infusion on day 1 with routine premedication for hypersensitivity reactions.

Results: From January 2008 to May 2009, 30 patients with metastastic breast cancer from 23 to 61 years of age were entered into the study. Twenty nine of the 30 patients were assessable for response, one patient could not be analyzed because diarrhea grade 4 and she was refused to continue the next cycles. Twenty four (80%) patients were received other chemotherapy previously, including 2 patients were exposed to paclitaxel. One complete response (CR) and 16 partial responses (PRs) were observed, for an overall response rate of 58.6%. Among 30 patients assessable for toxicity (155 cycles; the mean number of cycle of therapy was 5.2), the following hematology side effects were reported, neutropenia grade 3-4 (21 patients); febrile netropenia occurred in four patients; grade 3-4 anemia and no thrombocytopenia effect was occurred and for non- hematological toxicities were mild, excepts diarrhea grade 4 occurred in one patient, neuropathy grade 3 observed in 1 patient and one patient suffered severe neuropathy. Median time to progression was 5.28 months.

Conclusion: The results showed that the Docetaxel (Brexel) is highly active in metastatic breast cancer when used as a single agent in heavily treated chemotherapy and appears to have similar efficacy to original docetaxel with manageable toxicity.