

Comparison of adverse drug reactions and health related quality of life in Triple Negative Breast Cancer patients treated with AC-Taxane+carboplatin Vs AC-Taxane regimen: A prospective cohort study

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Anthracycline-Taxane containing regimen is the standard treatment for curative breast cancer chemotherapy from last two decades. Recent evidences showed improved efficacy when platinum compounds added to Anthracycline-Taxane containing regimen in any clinical setting (neoadjuvant, adjuvant and metastatic) for treating Triple Negative Breast Cancer (TNBC). But safety data on each regimen in TNBC is limiting although established data available on individual drug only. A crucial factor is to understand the impact of therapy on Quality of Life (QoL) of patients as it is influenced by every step of the treatment. In this prospective, cohort questionnaire based study, we evaluated whether ADRs and QoL from 2 different chemotherapy regimens differed in patients with triple negative breast cancer.

The study was conducted in the Dept. of Radiotherapy, Govt. Medical College, Calicut, India over a period of 8 months from January 2017 to August. Patients with TNBC who satisfied eligibility criteria were selected and divided into 2 groups based on their chemotherapy regimen. The patients who received Adriamycin and Cyclophosphamide (AC) followed by docetaxel (T) were assigned to group AC-T and those who received AC followed by docetaxel and carboplatin (Cb) were in group AC-TCb. List of ADRs were prepared using Cancer Care Ontario (CCO) drug formulary list. ADRs documented either from the patients or from their laboratory reports were graded as per NCI CTCAE guidelines. QoL mean scores were analyzed using EORTC QLQ C30 and EORTC QLQ BR23 questionnaires filled up by the patients during the study. Statistical analysis were done using PASW statistics 18, version 2009.

Data of 81 TNBC patients were collected in which 29 (35.8%) patients received AC-T and 52 (64.2%) AC-TCb regimens. Mean age of AC-T was 50.28±9.071 and 49.87±9.30 years for AC-TCb. Among thirteen system organ classification studied, ADRs in dermatological system, gastrointestinal (P value=0.644), cardiovascular (P value=0.131), ophthalmological (P value=0.533), neurological (P value=0.904), musculoskeletal (P value=0.066), auditory (P value=0.452), psychological (P value=0.303), hematological (P value=0.753), administration site (P value=0.252), respiratory (P value=0.094), were statistically insignificant. A statistically significant difference in ADRs under general disorders was confirmed among different chemotherapy regimens and confined to AC-TCb regimen (P value=0.011). Hand-foot syndrome, grade 3 was present in 1

subject from AC-T and 1 from AC-TCb; 1 subject from AC-T with grade 4. Vomiting, grade 4 type was present for one subject from AC-TCb. Constipation, grade 3 type was present for one subject from AC-TCb. Mucositis grade 4 type was observed from one subject each in AC-T and AC-TCb. Diarrhea, grade 3 was reported from a subject receiving AC-TCb. Although hematological reactions were a few, most of them belongs to grade 3/4. Anemia, grade 3/4 was reported in 1 from AC-T, 1 from AC-TCb.

Febrile neutropenia, grade 3/4 was observed in 4 subjects from AC-T and 5 from AC-TCb. 10 subjects from AC-T and 12 from AC-TCb had neutropenia, grade 3/4. 9 subjects from AC-T, 8 from AC-TCb had insomnia, grade 3/4. One subject from AC-T had hearing impaired, grade 4.

QoL mean score was insignificant among the regimen. Among EORTC QLQ C30 functional scale, emotional, cognitive and social domains shows significant difference; higher mean scores were observed for subjects receiving AC-TCb for all these three {(62.7, P = 0.046), (74.3, P=0.000) and (66.02, p=0.010) respectively}. Higher functional scale score indicates better functioning and quality of life. Among EORTC QLQ C30 symptom scale, a significant difference in the mean scores were observed in dyspnea and constipation domains; for both, the higher mean scores were reported for subjects receiving AC-T {(35.6, P = 0.001) and (48.7, P=0.046) respectively}. Higher symptom score indicates poor quality of life. All the domains from both functional and symptom scale in EORTC QLQ BR 23 found to be insignificant among the groups.

Both regimens were tolerated by the subjects reasonably very well with majority of adverse effects were mild. Severe (Grade 3 or 4) adverse effects were rare. In our study ADRs from two different taxane based chemotherapy regimens were observed statistically insignificant except in general disorders while QoL, functional domains of breast and disability due to breast symptoms were independent of the chemotherapy regimens showing that no regimen is superior to another. On the other hand, three variables from the functional and two from symptom scale indicate carboplatin based chemotherapy is better in TNBC compared to taxane alone. The major limitation of this study was the small sample size and shorter duration.

A more comprehensive study with a greater number of patients is required to get more conclusive results.

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