Abstract

A prospective, evaluative, observational, follow up study was carried out on “Outcome of Pharmacological Management of Women with Breast Cancer in a Selected Tertiary Care Hospital.” The study was conducted in fulfillment for the award of doctor of Philosophy degree in pharmacy at Manipal College of Pharmaceutical Sciences, Manipal University.

The objective of the study was to explore the outcomes of pharmacological management of breast cancer in a tertiary care hospital in Udupi district of South Karnataka. An interview cum survey approach was used to collect the data. The study was conducted in the wards and day care centre of Shirdi Sai Baba Cancer Hospital and Research Center, Manipal after obtaining ethical clearance from institutional ethical committee (vide ref.no.IEC114/2009). The research tool used was socio-demographic proforma and EORTC-QLQ C 30 version 3 and EORTC QLQ-BR23.

Major findings of the study

The age of participants varied from 25-73 years, (mean age 47.23, SD=9.7). Out of 303 women, 53% were premenopausal and the rest of them were post menopausal. From 303 subjects studied 274 (90.4%) were married and cohabiting with their spouses and others were unmarried, widowed or separated. The economic background was categorized in to 3 classes as low income group (INR<5000/M), middle income group (INR-5000-10000/M) and high income group (INR >10000/M). The distribution of socio-economic status was low for 50.8% subjects, medium for 34% and high for 15.2 % of subjects. The educational qualification ranged from primary education and less 32.4%, 50.5% with 5th -10th class and 16.9 % college education. The stage wise distribution of breast cancer was stage I (2.6%), stage II (39.6%), stage III (39.6%) and stage IV (14.9%). Hormone responsiveness of tumors was found to be 57% as ER +ve. Majority, 93.7% of them had surgical intervention, out of which 70.9%
underwent Breast conserving surgery, 7.2% had mastectomy, 8.6% had lumpectomy and others had minor surgical procedures. Surgical interventions were supplemented with radiation therapy to chest wall. Among the subjects 81.5% were treated with chemotherapy by different drug regimens. All the ER/PR+ve cases were prescribed with tamoxifen /aromatase inhibitors for 5 years after the preliminary treatments, according to the menopausal status.

AC drug regimen(regimen I, adriamycin (60mg/m^2) and cyclophosphamide (600mg/m^2) was used for treating 26.7% of subjects. Subjects diagnosed at metastatic stage (16.8%) were treated with 6 cycles of 5 Fluorouracil (600mg/m^2), adriamycin and cyclophosphamide (FAC, regimen II). Another group, 47.2% who reported in advanced stages of the disease, were treated with 8 cycles (ACx4 + Taxol x 4 (60-75mg/m^2/kg) (ACT, regimen III).

The cost of treatment was computed for each pharmacological regimen and described as costs of consultation, drugs, investigations, surgical intervention, radiotherapy and other professional services charges and total direct cost of treatment. The total direct mean cost for treatment regimen I (AC x 4 cycles) was INR 114929/-, for regimen II INR 133073/- and for regimen III was INR 177037/-. The cost per QALY was identified as INR-11897/- for regimen I, INR 42789/- for regimen II and for INR- 285543/- for regimen III.

The symptom free survival was estimated for each regimen by Kaplan Meir Survival analysis. The survival curve for regimen I was 11.01yrs, for regimen II was 2.52 years and for regimen III was 1.10 years. Cox proportional hazards model regression analysis was used for finding the predictors of survival. The results confirmed statistically significant correlations between survival and adherence to treatment and stage of cancer at the time of diagnosis as survival predictors (Hazards Ratio=6.77, 95% CI=3.15-14.55, p=<0.001, and Hazards Ratio=0.10, 95% CI=0.05-0.22, P=<0.001 respectively for adherence and stage).

In the present study 264 (88%) subjects were adherent to the treatment and 12% was not adherent to the treatment suggestions. The logistic regression analysis showed that spouses support and distant /organ metastasis at the time of
diagnosis were significant predictors in adherence to treatment (Odds Ratio=37.47, 95% CI=1.06-1320.61, P=0.04, OR= 0.06, 95% CI=0.00 -0.99, P=0.04 for spouses support and distant metastasis at the time of diagnosis respectively).

The patient reported humanistic outcomes were measured during or after chemotherapy, for each pharmacological group by using EORTC QLQ C 30 and QLQ BR 23. Analysis revealed that there were differences in humanistic outcomes scores among different treatment groups. The overall functional scores for patients in regimens I, II and III were found to be in the order: regimen III, regimen I and regimen II; more or less ≥ 60% scores. Except social functioning and future perspective, all functional scores were ≥ 60 in regimen III (ACT regimen). Regimen II patients (FAC regimen) had low functional scores in different domains and in the overall quality of life, when compared with regimen I (AC regimen) and regimen III. Similarly the overall symptoms scores were found to be regimen III, regimen I and regimen II in the descending order. As a whole the overall quality of life of the study group was best in regimen III, of all 3 groups. Statistical evaluation by ANOVA amongst the 3 treatment regimens were found to be significant (p=<0.05) for quality of life in physical function, role function, emotional function and global health (P=< 0.05). Similarly the statistical analysis by ANOVA for symptoms scores revealed insignificant p values except for pain, constipation and upset by hair loss (P=<0.05). Post hoc analysis for multiple comparison revealed that there were differences in quality of life between regimen II and regimen III in functions and symptoms scores with significant P values.