ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH ME TASTATIC BREASTCANCER AND ITS PHARMACEUTICAL MANAGEMENT IN TERTIARY CARE HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract:
Instead of the progression that has been made in diagnosis and treatment of early stage breast cancer a significant proportion of patients still go on to develop incurable metastatic breast cancer that has spread to distant sites of body like lung ,liver, bone, brain. Patients may experience limitations in their daily activities and reduction in their quality of life (QOL) and may be threat of survival due to metastasis to different sites of the body. The purpose of this present study mainly focused to assess QOL in patients suffering with metastatic breast cancer and its pharmaceutical management in a tertiary care hospital. QOL is a multidimensional model which includes physical, social, and psychological well-being of the patient. Physical symptoms of the disease, side effects of treatment, social and family support may influence QOL. Treatment for the metastatic breast cancer is majorly palliative therapy rather than curative i.e main goal is to managing the symptoms as opposed to prolonging life. So it is important for health care providers to consider treatment in terms of not only managing symptoms, but also stabilizing or improving other factors that affect QOL. Here in this study we used self-designed and validated questionnaire (which was taken from European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer {EORTC QLQ-BR23} and Functional Assessment of Cancer Therapy-Breast Cancer {FACT-B}) was used to assess the quality of life in metastatic breast cancer patients which consists of 30 closed ended questions which represents the difference between the past and present Health status of patient.
Keywords: *Metastatic breast cancer, QOL, EORTC-QLQ-BR23,FACT-B.*

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INTRODUCTION:

Cancer is a disease of cells characterized by Progressive, Persistent, Purposeless and uncontrolled Proliferation of tissues. Breast cancer is number one cancer in India with age adjusted rate as 25.8 per 100.000 women and mortality 12.7 per 100,000 women[1].Instead of the disease progression that has been found in diagnosis and treatment of early stage breast cancer a significant proportion of patients still go on to develop incurable metastatic breast cancer . Metastatic breast cancer is a disease beyond the breast and regional lymph nodes i.e spread to distant sites of the body like lungs, liver, bone, brain metastasis in breast cancer usually happens through invasion of cancer cells near by healthy cells or penetration into circulatory or lymph system or any migration through circulation etc.[2]. Hormonal thera py plays an important role in treating metastatic breast cancer . bisphosphonates for bone metastasis is of significant benefit to patients with painful bone metastasis in breast cancer[3]. QOL is a multidimensional model which includes physical, social, and psychological well-being of the patient. physical symptoms of the disease, side effects of treatment, social and family support may influence QOL. Treatment for the metastatic breast cancer is majorly palliative therapy rather than curative i.e. main goal is to managing the symptoms as opposed to prolonging life. So it is important for health care providers to consider treatment in terms of not only managing symptoms, but also stabilizing or improving other factors that affect QOL[4]. Pharmaceutical Care is a patient-centered, outcomes oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient's other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective. The goal of Pharmaceutical Care is to optimize the patient's health-related quality of life, and achieve positive clinical outcomes[5].

AIM:

To assess QOL in patients with metastatic breast cancer and its pharmaceutical management.

OBJECTIVES:

- To assess the QOL in patients with metastatic breast cancer.
- To emphasize the pharmaceutical care in improving QOL.

METHODOLOGY:

A Prospective observational study was carried out in Government General Hospital, Guntur for duration of 6months i.e., September 2018 to February 2019 after obtaining approval from Institutional Ethics Committee. The Patients were screened based on inclusion and exclusion criteria. Inclusion criteria includes Patients whose origin of cancer (primary lesion) involved is breast , those who are diagnosed with metastatic breast cancer , who are willing to participate in the study and female patients with age >18yrs , who are taking chemotherapy and hormonal therapy for metastatic breast cancer , who are willing for regular follow up .Exclusion criteria includes Patients whose origin of cancer is other than breast , Patients with other than metastatic breast cancer, those who are <18yrs of age, those who are not willing to participate in the study , patients who are pregnant and lactating ,Patients who are not willing for regular follow up. Patients who satisfy inclusion criteria were included in the study after obtaining informed consent. The data was collected in the designed data collection form. After the necessary data was collected Assessment of quality of life was performed by using self-designed and validated questionnaire (which was taken from European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer {EORTC QLQ-BR23} and Functional Assessment of Cancer Therapy-Breast Cancer {FACT-B}) was used to assess the quality of life in metastatic breast cancer patients which consists of 30 closed ended questions which represents the difference between the past and present Health status of patient. These are again categorized into Painful site (Q: 7,11,12,13,21,26)), Symptoms (Q: 2,3,5,6,8,9,10,19,20,22,24,25,27), Functional status (Q14 to Q15) and psychosocial aspects (Q: 1,4,16,17,18,23,28,29,30). The data obtained was entered in advanced Microsoft excel spread sheet and evaluated. For statistical analysis, Graph Pad Prism 8.1.0 was used one sample t test and Paired t test was done with the 95% confidence interval at alpha value 0.05 and the p-value <0.05 are considered to be significant.

RESULT:

Age Vs No. of Subjects:
Based on the results obtained our study revealed that patients with metastatic breast cancer was found to be more predominant at age 51-60 years followed by 41-50 years ,31-40 years and 61-70 years , 21-30 years , 71-80 years respectively which was graphically represented in figure 1.
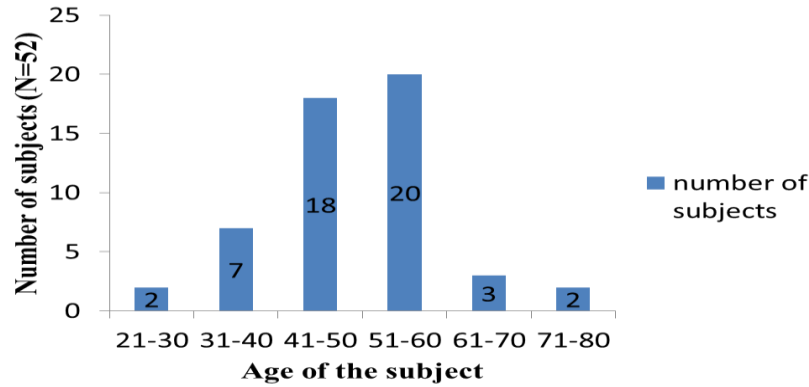
Figure 1: Age Vs Number of Subjects

Family history Vs Number of subject

Our study also found that there is no significant association (94.23%) of family history in development of metastatic breast cancer as shown in fig 2.
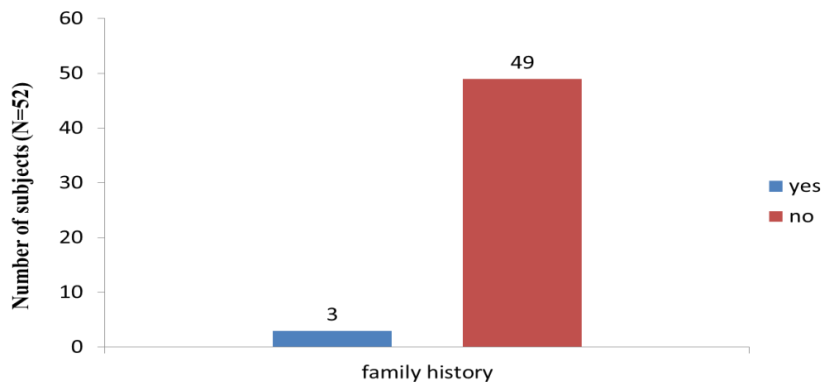
Figure 2 : Family history Vs Number of subjects

Menstrual irregularities Vs Number of subjects

Our study also found that there is no significant association (63.4%) of menstrual irregularities in development of metastasis in breast cancer . This was graphically represented in figure 3.
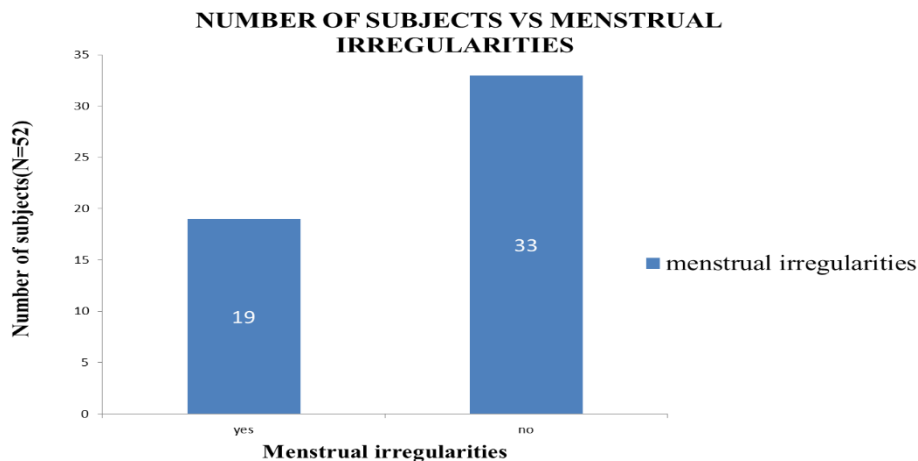

Figure 3 Menstrual irregularities Vs Number of subjects

Metastatic site Vs Number of subjects
Our study also found regarding the metastatic site which indicates that the most effected sites are bone (30.76%) followed by liver (17.30%) recurrence(17.30%) lung (11.53%) brain (5.77%) remaining(n= 9 ; 17.30

%) subjects were diagnosed with multiple site metastasis i.e lung ,bone (5.77%) bone,recurrence(1.92%) , liver,recurrence (1.92%) , liver ,brain (1.92 %),liver , lung (1.92%) bone, liver (1.92%) lung , bone ,liver (1.92%).this was graphically represented in figure 4.
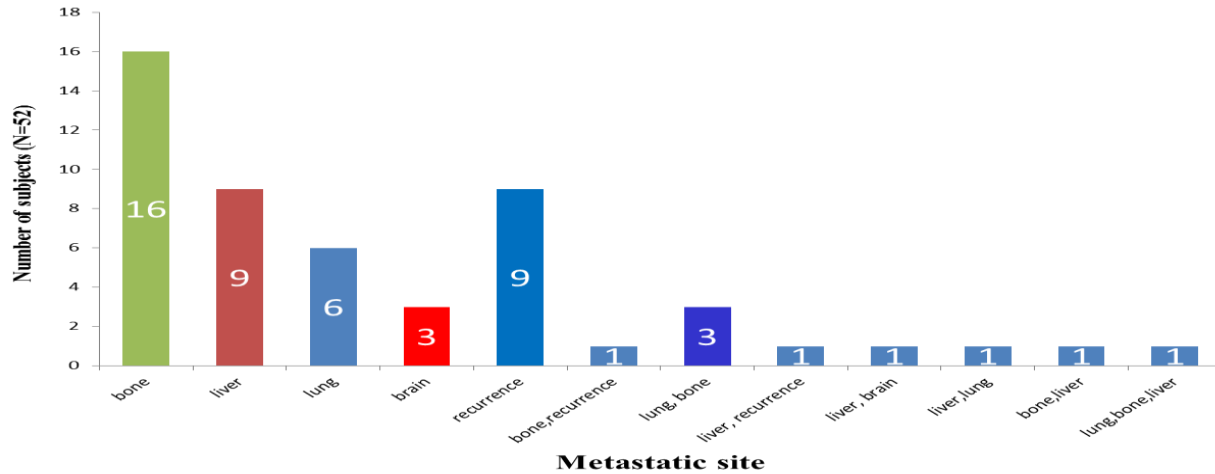
Figure 4 Metastatic site Vs Number of subjects

Table 1 to Table 4 depicts the results of self designed and validated questionnaire (which was taken from EORTC QLQ-BR23 and FACT-B) which consists of 30 closed ended questions which represents the difference between the past and present Health status of patient. These are again categorized into Painful site (Q: 7,11,12,13,21,26)), Symptoms (Q: 2,3,5,6,8,9,10,19,20,22,24,25,27), Functional status (Q14 to Q15) and psychosocial aspects (Q: 1,4,16,17,18,23,28,29,30).The

results were analyzed using Paired t-test and found to be Highly significant ($p<0.019$****).

Table 1 depicts before the treatment. most of the patients experiencing pain during bending/climbing followed by pain interfering sleep, pain while walking, pain while sitting, pain with strenuous activity, pain when trying to stand up, pain while lying down. After the treatment functional status of patients get improved.

Table 1: Functional interference Vs Number of subjects

Functional status (N=52)	Before treatment		After treatment	
	Yes	No	Yes	No
Pain while lying down	11(21.15%)	41(78.85%)	3(5.77%)	49(94.23%)
Pain while sitting	24(46.15%)	28(53.85%)	12(23.08%)	40(76.92%)
Pain when trying to stand up	18(34.61%)	34(65.39%)	10(19.23%)	42(80.77%)
Pain while walking	28(53.85%)	24(46.15%)	0(0%)	52(100%)
Pain during bending/climbing stairs	43(82.69%)	9(17.31%)	14(26.92%)	38(73.08%)
Pain with strenuous activity	2(3.85%)	50(96.15%)	11(21.15%)	41(78.85%)
Pain interfering sleep	38(73.08%)	14(26.92%)	19(36.54%)	33(63.46%)

Table 2 depicts before the treatment most of the subjects were worried about health in future followed by upset by loss of hair, felt isolated, trouble in communicating thoughts , changes in daily activities

due to illness, felt hopeful your pain will get better, felt positive about health , I am the content of QOL right now . After the treatment psychosocial aspects get improved.

Table 2: Psychosocial status Vs Number of subjects

Psycho-social status(N=52)	Before treatment		After treatment	
	Yes	No	Yes	No
Felt positive about health	9(17.31%)	43(82.69%)	52(100%)	0(0%)
Trouble in communicating thoughts	33(63.46%)	19(36.54%)	9(17.31%)	43(82.69%)
Felt isolated	36(69.23%)	16(30.77%)	8(15.38%)	44(84.62%)
Worried about health in future	38(73.08%)	14(26.92%)	10(19.23%)	42(80.77%)
Change in daily activities due to illness	12(23.08%)	40(76.92%)	2(3.85%)	50(96.15%)
Upset by loss of hair	37(71.15%)	15(28.85%)	5(9.61%)	47(90.39%)
Have you felt hopeful your pain will get better	12(23.08%)	40(76.92%)	44(84.62%)	8(15.38%)
I am content with quality of life right now	3(5.77%)	49(94.23%)	51(98.08%)	1(1.92%)

Table 3 depicts before the treatment that most of the subjects experiencing pain in , legs, arm/ shoulder, eyes ,stoma hand others . After the treatment pain at different sites get reduced

Table 3: Painful site Vs Number of subjects

Painful site (N=52)	Before treatment		After treatment	
	Yes	No	Yes	No
Stomach	0(0%)	52(100%)	0(0%)	52(100%)
Chest	39(69%)	13(25%)	91(17%)	30(57%)
Arm/shoulder	13(25%)	22(42%)	1(1.9%)	17(32%)
Legs	28(53%)	24(46%)	8(15%)	25(48%)
Eyes	10(19%)	47(90%)	3(5.7%)	42(80%)
Others	28(53%)	28(53%)	11(21%)	24(46%)

Table 4 depicts before the treatment symptoms experienced by the subjects that are nausea/vomiting,cough, tingling of hands or feet, headache, skin problems/in area of affected breast , dry mouth , drowsy during day time , trouble in controlling bladder, seizures, weight loss, hair loss, blurred vision , trouble in swallowing before the treatment. After the treatment symptoms get reduced.

Table 4 : Symptoms Vs Number of subjects

Symptoms (N=52)	Before treatment		After treatment	
	Yes	No	Yes	No
Nausea /vomiting	30(57.69%)	22(42.31%)	8(15.38%)	44(84.62%)
Hair loss	10(19.23%)	42(80.77%)	35(67.31%)	17(32.69%)
Cough	29(55.77%)	23(44.23%)	8(15.39%)	44(84.61%)
Dry mouth	24(46.15%)	28(53.855)	7(13.46%)	45(86.54%)
Weight loss	18(34.62%)	34(65.38%)	49(94.23%)	3(5.77%)
Trouble in swallowing	1(1.92%)	51(98.08%)	0(0%)	52(100%)
Tingling of hands or feet	29(55.77%)	23(44.23%)	11(21.15%)	41(78.85%)
Headache	29(55.75%)	23(44.23%)	17(32.69%)	35(67.31%)
Blurred vision	4(7.69%)	48(92.31%)	4(7.69%)	48(92.31%)
Seizures	18(34.62%)	34(65.38%)	2(3.85%)	50(96.15%)
Drowsy during day time	22(42.31%)	30(57.69%)	11(21.15%)	41(78.85%)
Skin problems / in area of affected breast	26(50%)	26(50%)	8(15.39%)	44(84.61%)
Trouble in controlling bladder	19(36.54%)	33(63.46%)	4(7.69%)	48(92.31%)

DISCUSSION:

A non-experimental prospective observational study was carried out on "**ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH METASTATIC B REAST CANCER AND ITS PHARMACEUTICA L MANAGEMENT IN TERTIARY CARE HOSP ITAL.**" 52 patients met the inclusion criteria and were included in the study. The data obtained was tabulated and analyzed. The information regarding distribution of patients within age groups of 21 to 80 years. Majority of patients were found within 51-60 years (38.54%) followed by 41-50 years (34.62%), 31-40 years (13.46%) and 61-70 years (5.77%), 21-30 years (3.85%) , 71-80 years (3.85%).

Our study also found that there is no significant association (94.23%) with family history for the development of metastasis in breast cancer and also there is no significant association (63.4%) with menstrual irregularities for the development of metastasis in breast cancer.

Based on the results obtained our study revealed that 16 (30.76%) of the 52 subjects the first distant metastasis was to bone. Of the 18 subjects whose first metastasis was to the viscera, the organ most often involved was the liver (n=9 ; 17.30%) followed by lung (n=6 ; 11.53%) and brain (n=3 ;5.77%) .These findings were in concordance with study done by Linda Vona-Davis et al., (2014) conducted a study on "Breast Cancer Pathology, Receptor Status, and Patterns of Metastasis in a Rural Appalachian Population[6]" and 9 out of 52 subjects were diagnosed with recurrence(17.30%) . remaining 9 subjects were diagnosed with multiple site metastasis i.e., out of 9 (17.30%) 3 subjects were diagnosed with lung ,bone (5.77%) and bone, recurrence(n=1 ;1.92%) , liver , recurrence (n=1 ; 1.92%) , liver ,brain (n=1 ; 1.92 %),liver , lung (n=1 ; 1.92%) bone, liver (n=1 ; 1.92%) lung , bone ,liver (n=1 ; 1.92%).

We also assessed quality of life (QOL) of patients suffering with metastasis in breast cancer whom being treated with bisphosphonates or chemotherapy or hormonal therapy. In this study we used self-designed and validated questionnaire (which was taken from EORTC QLQ-BR23 and FACT-B) questionnaire to assess the quality of life in metastatic breast cancer patients which consists of 30 closed ended questions which represents the difference between the past and present Health status of patient. We categorized the 30 questionnaires into functional status, psycho-social status, painful site and symptoms. We analysed the QOL by using paired t-test that functional status, psycho-social status, painful site and symptoms were

significantly improved (P=0.019) ; the difference is considered to be statistically significant) which indicated thus improvement in quality of life of patient after being treated with bisphosphonates (zoledronic acid) or chemotherapy , hormonal therapy. These results are similar to the study done by Fundação Antonio Prudente et al., (2006) conducted study on "Metastatic breast cancer: Do current treatments improve quality of life? A prospective study[7]."

CONCLUSION:

Based on the results obtained our study concludes that bone is the major site of metastasis in breast cancer followed by recurrence, liver, lung, brain. Bas ed on the results obtained our study strongly conclud es that the use of Bisphosphonates or chemotherapy a nd hormonal therapy(Tamoxifen, letrazole,anastrazol e etc.) are effective in improving QOL (P=0.019) in patients with metastatic breast cancer. Our study concludes that Pharmaceutical care and Psychosocial support and the provided patient information leaflet which was mainly focused on healthy diet plays a vital role in improving adherence to the therapy there by enhancing the QOL of patients with metastatic breast cancer being treated with Bisphosphonates or chemotherapy and hormonal therapy.

LIMITATIONS:

This study included only 52 patients to assess the "**ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH METASTATIC BREAST CA NCER AND ITS PHARMACEUTICAL MANAG EMENT IN TERTIARY CARE HOSPITAL.**". 3 subjects were excluded because of unavailability of subjects during follow up .This study has to be further extended with more number of patients to derive at a better conclusion.

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