Research Article

PROSPECTIVE ANALYSIS OF MANAGEMENT OF BREAST CANCER PATIENTS – A QUALITY OF LIFE-BASED STUDY

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ABSTRACT
Background: The present research work is based on prospective analysis of management of breast cancer patients for their quality of life during the time of disease condition and its treatment. **Objective:** We are more focused on studying diagnosis, medications and mental stress level of the patients through a questionnaire, which we have prepared for this prospective study. **Methods:** In this research study, the Quality of life of the patients was evaluated using "Quality of Life Assessment Questionnaire for the Patients with Breast Cancer". The questionnaire was designed in 4 different languages: English, Hindi, Telugu and Urdu. The questionnaire consists of 21 questions divided in 2 domains. Domains include: Mental health and social health status. **Result:** The data later was statistically analysed and mean of physical health was found to be 1.84, for mental health, it was 2.04, for social health, it was 2.56 and lastly, for Pharmacotherapy status, mean was found to be 3.29. The total mean was found to be 2.30. **Conclusion:** It can be concluded that breast cancer has a negative impact on patient's quality of life limiting patient's physical health, severely affecting mental and social health. As most of the patients were found to be of daily wage worker background belonging to inferior and middle class socioeconomic status it was very difficult for the patients to cope up with the disease and treatment.

KEYWORDS: Quality of life, Breast Cancer, Mental health and social health status.

INTRODUCTION
Breast cancer has devastating effects on a patient's life. Apart from the inconvenience of the disease, breast cancer poses serious challenges in accomplishing daily activities.[1] The person diagnosed with breast cancer is challenged physically, psychologically and socially. Despite the advances in modernization of society, the social stigma remains the same. The patients may get conscious about the unavoidable long term physical changes. This also tends to have a great impact on the mental health and social health of the patient. Illiteracy, lower socioeconomic status just adds up to the problems.[2] The treatment is not affordable by every individual. Government schemes, online donations seem to help patients to cope up with the disease. There is an absolute need of a therapist and counselors to improve the mental and physical health of the patients. In this regard, the quality of life of the patients was assessed with the help of "Quality of life assessment questionnaire for the patients with breast cancer."

Selected analysis
To analyse the impact of the prescribing pattern of the chemotherapeutic agents and their subsequent effect on the quality of life of the patient.

Prospective elements
- To assess the prescribing pattern of the chemotherapeutic agents – single or combination used.
- To assess the quality of life of patients based on the management of disease.
- To check the rational use of drugs.
- To assess the prescriptions for polypharmacy.
- To detect the various ADR's and their management.
- To educate the patient regarding the disease, its management and medication adherence.

METHODOLOGY
Study Site: Cancer speciality hospital.

Study Design: It is a prospective observational study conducted in a tertiary care Cancer speciality hospital at Hyderabad for 6 months from September 2019 to February 2020. During this period a total of 203 patients were questioned with our set of diagnostical, medicinal and stress questions in the form of a questionnaire are collected and analysed.

Study Period: This study is conducted for 6 months.

Sample Size:203 **Study Criteria:**

Inclusion criteria
- In-patients of cancer specialty hospital.
- Patients above the age of 16 year.
- Patients with other co-morbidities are also included.

Exclusion criteria
- Patients below the age of 16 years.
- Patients having HIV AIDS as co-morbid condition.
- Patients who did not comply with the objectives of the study were excluded such as treatment regimen and quality of life questionnaire.

Sources of Data:
All the necessary data was collected from
1. Case sheets
2. Lab reports
3. Quality of life questionnaire

Data Collection
The study was conducted in a cancer speciality hospital in Hyderabad, India. The data was collected using patient profile forms and the quality of life questionnaire, designed to meet the parameters of the study. The data was collected for a period of 6 months.

Monitoring
Research information was gathered everyday and followed, and the resources, quality/quantity of activities reviewed frequently. This helped to identify gaps and problems which could be solved early and avoid affecting the research.

Statistical Analysis
The data collected was compiled using Microsoft Excel 2007 and analysed using version 20 of SPSS software to obtain the graphs and results, the correlation for the quality of life data was done using Pearsons co-efficient.

RESULTS
AGE DISTRIBUTION

Mean ± SD is 48.92±11.22

Table 1: Age Distribution.

Age Interval	N	%(years)
21-30	12	6
31-40	40	20
41-50	75	37
51-60	46	23
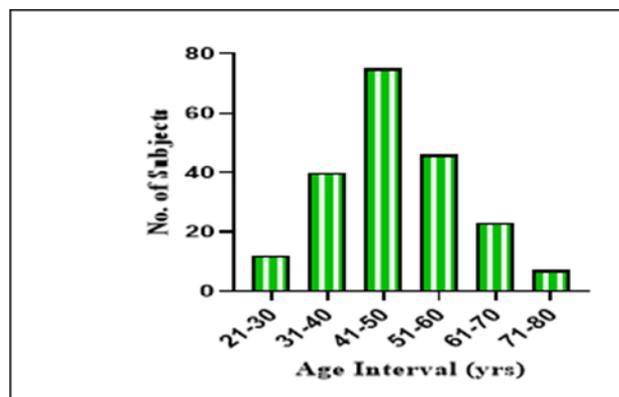
Figure 1: Age Wise Distribution.

All the patients above 16 years were considered for the study and it has been found that the highest number of patients (N=75) fell under the age group of 41-50 years with a total percentage of 37%. The least number (N=7) was found between the age group of 71-80 years with a percentage of 3%. The age groups: 51-60, 31-40, 61-70 and 21-30 had patients with percentages of 23%, 20%, 11% and 6% respectively.

GENDER DISTRIBUTION
Male and female patients were considered for the study and it has been found that out of a total of 203 patients, 100% of the patients (N=203) were female. It has also been studied that the cases of male breast cancer were rare. In a year, not more than 4 patients were diagnosed with breast cancer. As the cases were out of the study period of 6 months, those patients were excluded from the study.

BREAST AFFECTED
Table 2: Breast Affected.

Breast	N	%
Bilateral	4	2
Left	93	46
Right	10	52

Out of a total of 203 patients, 52% of the patients (N=106) had developed cancer in the right breast, whereas 46% of the patients (N=93) had developed cancer in the left breast. It has also been found that patients with bilateral breast cancer were relatively less with a total number of 4 patients giving a percentage of 2%.

CATEGORIZATION OF BREAST CANCER

Out of 203 patients, 194 patients had Invasive ductal cell carcinoma, 5 patients had Ductal carcinoma in situ, 2 patients had a combination of Invasive ductal cell carcinoma and Ductal carcinoma in situ and lastly, 2 patients had histological Invasive lobular carcinoma with percentages of 96%, 2%, 1%, and 1% respectively. It has been found that Invasive ductal cell carcinoma was greatly exceeded amongst the patients when compared to the other histopathological type of cancer. Invasive lobular carcinoma was found to be the least.

TNM STAGING OF CANCER

Based on the Union Internationale Centre le cancer and the American Joint Commission staging, Out of 203 patients, The highest number of the patients were diagnosed at Stage III (N=79) with a total percentage of 38%. This is followed by stage II (N=63), Stage IV (N=55) and Stage I (N=6) showed a total percentage of 32%, 27%, and 3% respectively.

TNM STAGING OF CANCER- EARLY/ ADVANCE

Statistically, it has been found that out of a total number of 203 patients, 56% of the patients (N=113) were diagnosed at the early stage of cancer and 44% of the patients (N=90) were diagnosed at the late stage of cancer.

METASTASIS STATUS

Out of 203 patients, it has been statistically found that in 31% of the patients (N=62) cancer had metastasized to different sites, whereas in 69% of the patients (N=141) there was no metastasis found.

SITE OF METASTASIS

The extent of metastasis in the affected patients. Out of 203 patients, 31% (N=62) had cancer metastasized to different sites which include Bone (N=41), Lung (N=20), Liver (N=17), Brain (N=7) and Lymph nodes (N=2) with respective percentages of 47%, 23%, 20%, 8%, and 2%. Bone was the highest metastasized site whereas, Lymph node metastasis was found to be the least. In the Bone; scapular metastasis (N=2), skull metastasis (N=1) and spine metastasis (N=1) show 2%, 1%, 1% percent respectively.

BI-RADS SCORING

Out of 203 patients, Breast Imaging Reporting and Data System (BI-RADS) score was found in 92 patients (44%). About 19% of the patients (N=19) had score IV, 17% of the patients (N=35) had score V whilst score III (N=8), II (N=7) and VI (N=2) was found in 4%, 3%, and 1% respectively.

MBRS GRADING

Out of 203 patients, Modified Scarff-Bloom-Richardson Grading System (MBRS) was found in 89 patients, 44%. About 24% of the patients (N=48) had grade 7, 13% of the patients (N=26) had grade 6, 4% of the patients (N=9) had grade 8, 2% of the patients (N=4) had grade 5 and lastly, 1% of the patients (N=2) had grade 9.

MASTECTOMY STATUS

Out of 203 patients, 64% of the patients (N=129) had undergone surgery, whereas 36% did not (N=74). Amongst the patients with surgery, 57% of the patients (N=115) had undergone Modified radical mastectomy, while 5% of the patients (N=10) had undergone Breast conserving surgery. About 2% of the patients (N=4) had undergone breast conserving surgery followed by Modified radical mastectomy.

TREATMENT PLAN

The treatment choice depends on the patient's disease progression, Mastectomy history, and Metastasis status. Out of a sample size of 203 patients, it has been statistically analyzed that 41% of the patients (N=84) had undergone Adjuvant Chemotherapy, 24% of the patients (N=48) had undergone Neoadjuvant Chemotherapy and 21.5% of the patients (N=44) hadreceived Palliative Chemotherapy. Combination use of different treatment plans was also seen as the disease progressed to higher stages. 6% of the patients (N=12) received Adjuvant Chemotherapy which was followed by Palliative as the disease progressed to the Metastasis stage. In 6% of the patients (N=12) NACT was followed by Adjuvant Chemotherapy. 1% of the patients (N=2) had NACT followed by Adjuvant followed by Palliative Chemotherapy. In 1 patient, disease entered stage IV post NACT giving out a percentage of 0.5%.

TREATMENT REGIMEN

The different therapeutic regimens amongst breast cancer patients. It has been statistically analyzed that out of 203 patients, 97% of the patients (N=196) were prescribed chemotherapy. 21% of the patients (N=43) were subjected to radiation therapy. Furthermore, hormonal therapy was prescribed for 30 patients and immunotherapeutic agents were prescribed for 19 patients which gives out a percentage of 15% and 9% respectively.

CHEMOTHERAPEUTIC AGENTS DISTRIBUTION
Table 3: Chemotherapeutic Agents.

S.No	Drug	N	%
1	Paclitaxel	85	42
2	Ibandronic acid	1	0.5
3	Capecitabine	6	3
4	Docetaxel	17	8
5	Methotrexate	1	0.5
6	Gemcitabine	1	0.5
7	Lipophilic Doxorubicin	1	0.5
8	Zoledronic acid	24	12
9	Palbociclib	1	0.5
10	Eribulin	1	0.5
11	Doxorubicin+Cyclophosphamide	119	59
12	Epirubicin+Cyclophosphamide	24	12
13	Nab Paclitaxel+Carboplatin	3	1
14	Cisplatin+Paclitaxel	1	0.5
15	Carboplatin+Paclitaxel	4	2
16	Carboplatin+Docetaxel	2	1
17	Epirubicin+Cyclophosphamide+5-Flurouracil	9	4
18	Doxorubicin+Cyclophosphamide+5-Fluorouracil	16	8
19	Cyclophosphamide+5-Fluorouracil+Methotrexate	1	0.5

The treatment plan for 203 patients diagnosed with breast cancer includes a diverse selection of chemotherapeutic agents amongst which the combination of Doxorubicin and Cyclophosphamide was found to be the highest (N=119) with a percentage of 59%. This is followed by single agent paclitaxel (N=85), Epirubicin + Cyclophosphamide (N=24), Zoledronic acid (N=24), Doxorubicin+ Cyclophosphamide + 5-Fluorouracil (N=16), Docetaxel (N=16), Epirubicin+Cyclophosphamide+5 Fluorouracil (N=9), Capecitabine (N=6), Carboplatin+ Paclitaxel (N=4), Carboplatin+Docetaxel (N=2), Nab. Paclitaxel+Carboplatin (N=3),Cyclophosphamide+5-Fluorouracil+Methotrexate (N=1),Cisplatin+Paclitaxel (N=1), Palbociclib (N=1), Eribulin (N=1), Gemcitabine (N=1), Methotrexate (N=1), Lipophilic Doxorubicin (N=1) and Ibandronic acid (N=1) with respective percentages of 42%, 12%, 12%, 8%, 8%, 4%, 3%, 2%, 1%, 1%, 0.5%, 0.5%, 0.5%, 0.5%, 0.5%, 0.5%, 0.5% and 0.5%.

IMMUNOTHERAPY AGENTS DISTRIBUTION
Out of 203 patients, it has been statistically observed that 17 patients were prescribed with Trastuzumab while Denosumab was prescribed for 2 patients which brings out a percentage of 8% and 1% respectively.

HORMONAL THERAPY AGENTS DISTRIBUTION
Out of 203 patients, it has been statistically found that 12 patients were prescribed with Tamoxifen. This is followed by Letrozole which was prescribed for 10 patients and Anastrazoleprescribed for 9 patients displaying percentages 6%, 5%, and 4% respectively.

MENTAL HEALTH

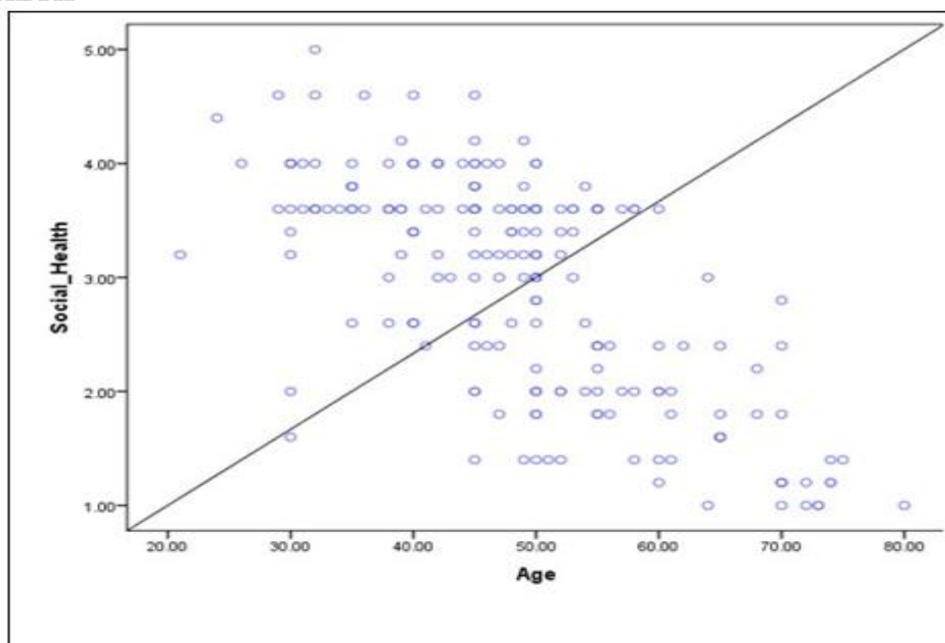

$$y= 0.05 * x + 0$$
$$r= -0.612*$$
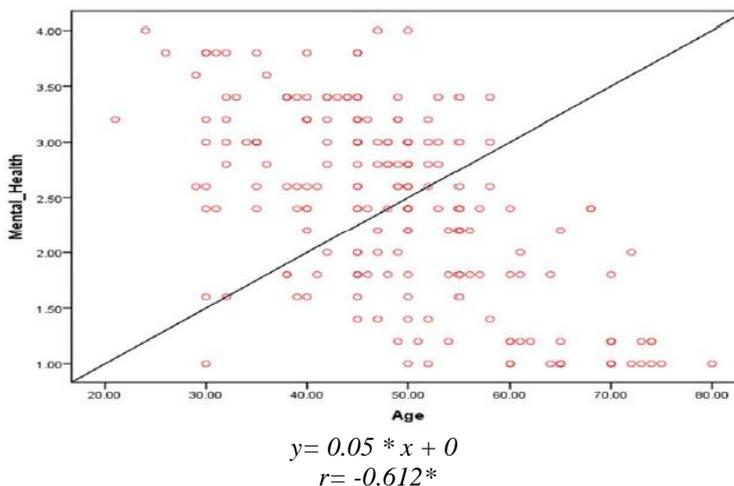
Figure 2: Correlation between Age and Mental Health.

The above graph illustrates the correlation between Age and Mental Health. The data was analyzed statistically and correlation was done using Pearson Correlation. The Correlation Coefficient was found to be negative indicating an inverse correlation($r = -0.612*$). As the patient's age increases, the mental health decreases. The asterisk denotes a significant correlation. Thus, "A significant inverse correlation was found".

SOCIAL HEALTH

$$y = 0.0667 * x + -0.3333$$
$$r = -0.674*$$
Figure 3: Correlation between Age and Social Health.

The above graph reflects the correlation between Age and Social Health. The data was analyzed statistically and correlation was done using Pearson Correlation. The Correlation Coefficient was found to be negative indicating an inverse correlation($r = -0.674*$). As the patient's age increases, the social health decreases. The asterisk denotes a significant correlation. Thus, "A significant inverse correlation was found".

DISCUSSION
In this research study, female patients were considered and 100% of the patients were above 16 years of age. The mean age of the patients was found to be 48.92 years. The incidence of breast cancer in less than 30 years patients was found to be relatively less (6%). The incidence of unilateral breast cancer is far greater (98%) than bilateral breast cancer (2%). It has also been found that the right breast was slightly more affected (52%) than the left breast (46%). Most of the patients were diagnosed at Stage III cancer (38%) and Stage II (32%) followed by Stage IV (27%) and Stage I cancer (3%). 56% of the diagnosed patients were in early stage of breast cancer, whereas 44% of the patients were in late stage of breast cancer.

In this research, a very high number of the patients were diagnosed with Invasive ductal cell carcinoma (96%). 2% of the patients were diagnosed with Ductal carcinoma in situ. 1% of the patients were diagnosed

with a combination of Invasive ductal cell carcinoma and Ductal carcinoma in situ and lastly, 1% of the patients were diagnosed with Invasive lobular carcinoma. In 69% of the patients, the cancer has not metastasized to any part of the body, whereas in 31% of the patients cancer had metastasized to Bone (47%), Lung (23%), Liver (20%), Brain (8%) and Lymph nodes (2%).

In about 44% of the cases BI-RADS score was found. 19% of the patients had Score IV, 17% of the patients had score V, 4% of the patients had Score III, 3% of the patients had score II and 1% of the patients had score VI. In about 44% of the cases MBRS grade was found. 24% of the patients had grade 7, 13% of the patients had grade 6, 4% of the patients had grad 8, 2% of the patients had grade 5 and lastly, 1% of the patients had grade 9.

In this research study, about 64% of the patients had undergone surgery. 57% of the patients with surgery had undergone Modified radical mastectomy, 5% of the patients had undergone Breast conserving surgery and 2% of the patients had undergone Breast conserving surgery followed by Modified radical mastectomy.

The choice of treatment in this study includes Neoadjuvant chemotherapy, Adjuvant chemotherapy

and Palliative chemotherapy. About 41% of the patients had received adjuvant chemotherapy, 24% of the patients had received neoadjuvant chemotherapy, 21.5% of the patients had received Palliative chemotherapy. In immunotherapy, trastuzumab was prescribed to 8% of the patients and denosumab was prescribed to 1% of the patients. In hormonal therapy, tamoxifen was prescribed to 6% of the patients, letrozole was prescribed to 5% of the patients and anastrazole was prescribed to 4% of the patients.

The treatment of cancer comes with its unavoidable adverse drug reactions, one of which being chemotherapy induced nausea and vomiting. To manage this, antiemetic drugs are must to be prescribed. Ondansetron was the choice of drug which was prescribed to 90% of the patients, Granisetron was prescribed for 3% of the patients and Metoclopramide was prescribed for 1% of the patients.

In this research study, the Quality of life of the patients was evaluated using "Quality of Life Assessment Questionnaire for the Patients with Breast Cancer". The questionnaire was designed in 3 different languages: English, Telugu and Urdu. The questionnaire consists of 21 questions divided in 2 domains. Domains include: Mental health and social health status.

Mental health domain has 5 questions and social health domain has 5 questions. Each question is given a score of 1 to 5, 1 being poor and 5 being excellent health status. At the end of the questionnaire a total score is given which is the mean score of the quality of life of the patient. The total score is given as 1 to 5. 1 indicates very poor, 2 indicates poor, 3 indicates OK, 4 indicates good and 5 indicates excellent quality of life.

The quality of life questionnaire was explained to all the patients and their response was noted. The data later was statistically analysed and mean of physical health was found to be 1.84, for mental health, it was 2.04, for social health, it was 2.56 and lastly, for Pharmacotherapy status, mean was found to be 3.29. The total mean was found to be 2.30.

Correlation between age and physical health, mental health and social health was done using Pearsons correlation. The correlation coefficient of physical health was found to be negative indicating a significant inverse correlation (r=-0.744*). As the patient's age increases, the physical health decreases.

The correlation coefficient of mental health was found to be negative indicating a significant inverse correlation (r=-0.612*). As the patient's age increases, the mental health decreases. The correlation coefficient of social health was found to be negative indicating a significant inverse correlation (r=-0.674*). As the

patient's age increases, the social health decreases.

As most of the patients were of lower and middle class socioeconomic status, patients were not well versed with the disease or about their condition. In our research study, patient education was done based on the patient's knowledge regarding disease and the response given in the questionnaire with the help of breast cancer pamphlets which was designed in 3 different languages: English, Telugu and Urdu. Patient education plays a key role in patient's understanding about the disease, to burst myths about breast cancer and improves overall adherence to the therapy.

CONCLUSION
This research study was conducted at a cancer specialty hospital in Hyderabad. In the duration of 6 months, a total of 220 patients were approached out of which 203 patients complied with the study and were considered for the study. Most of the patients in this study fell under the age group of 41 to 50 years. All the patients in this study were found to be females. It has also been known that the incidence of male breast cancer was rare and not more than 4 cases were diagnosed at the hospital in the year of 2019. The prescribing pattern of various single and combination drugs was assessed based on patient's progression of the disease. The incidence of various adverse drug reactions and its management was assessed which helps in patient compliance with the therapy given.

During this research study, the rationality of the drugs being prescribed was evaluated and was found to have positive impact on patients who were adherent to the therapy given. Medication adherence posed a serious problem as most of the patients who were non-adherent had found to develop metastatic breast cancer. Lack of knowledge regarding the seriousness of the disease and medications, limitation of resources and transportation were found to be the barriers for non-adherence. In about 5% of the cases polypharmacy was seen mostly in the management of pain, constipation.

Based on the evaluation done with the help of "Quality of life assessment questionnaire for the patients with breast cancer", it can be concluded that breast cancer has a negative impact on patient's quality of life limiting patient's physical health, severely affecting mental and social health. As most of the patients were found to be of daily wage worker background belonging to inferior and middle class socioeconomic status it was very difficult for the patients to cope up with the disease and treatment. Various Government schemes helped patients to bear the expenses of the treatment decreasing the mortality rate. Patients are also at a high risk of developing depression and anxiety. Patient counselling, various therapies will greatly enhance mental health and physical health of the patients.

Patient education was done with the help of breast cancer pamphlets designed in 4 different languages. Patient education greatly empowers the patient and will have a positive impact on patient's quality of life. It also helps in improving medication adherence, bursting myths, manage stress and break superstitions.

Through this research study we aim to analyse the management and quality of life of breast cancer patients. This study also aims to empower patients by patient education. As patients undergo drastic physical changes it is very often that patients don't find themselves aesthetically appealing and this has a major effect on their social life. Through this research we intend to remove social stigma and improve the quality of living of the patients.

ACKNOWLEDGMENTS

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