

## Hormonal treatment in patients of breast cancer and their quality of life in western Indian scenario

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### Abstract

**Context:** Long term use of anti-hormonal therapy in breast cancers is effective for extending long term survival rates but simultaneously can lead to various side effects affecting quality of life.

**Aims:** Aim of this study was to assess the utilization of hormonal treatment in patients suffering from breast cancer with specific objective of reviewing their quality of life with relation to side effects.

**Settings and Design:** This was an OPD based cross sectional study, conducted in Shree Krishna Hospital, Karamsad.

**Methods and Materials:** Prior permission from institutional ethics committee was taken. Utilization part of the study was a record based study, from the case files available in record section of cancer OPD. For quality of life part of the study, written informed consent was taken from the participants and were interviewed according to quality of life questionnaires.

**Statistical Analysis Used:** Data were analyzed as per descriptive statistics and results were presented in form of percentage and range. Mean scores for various quality of life subscales were calculated using EORTC scoring manual.

**Results:** Out of total 38 patients of breast cancer, 26(68.42%) patients were on treatment with letrozole, 12(31.57%) were on tamoxifen. We found better role functioning and cognitive functioning subscales in breast cancer patients of tamoxifen group as reflected in the highest mean score of 93.74 in functional scale. Mean sexual functioning scores in both letrozole and tamoxifen groups were on lower side. Percentage of patients experiencing systemic therapy side effect (dry mouth, hot flushes, hair loss, headache, dysgeusia) were found to be more in tamoxifen group.

**Conclusions:** Overall, the parameters of quality of life in breast cancer patients on hormonal therapy, were found to be in better side, except for sexual functioning scores which were on lower side.

**Keywords:** Breast cancer, Hormonal therapy, Quality of life.

### Introduction

Breast cancer was the first neoplasm shown to be responsive to hormonal manipulation.<sup>1</sup> 1.67 million new breast cancer cases were diagnosed in 2012 worldwide including 144,937 from India.<sup>2</sup> Hormonal and antihormonal therapy with antiestrogens such as tamoxifen and Aromatase Inhibitors (AIs) have replaced estrogens or androgens for breast cancer and is currently the mainstay therapy in hormone receptor positive breast cancer patients after surgical resection or adjuvant chemotherapy.<sup>1</sup> Cancer and its treatment have a major impact on patients' lives which can lead to difficulties in performing daily activities, fulfilling family roles and participating in common social activities. Even when successfully treated, cancer may result in long-term physical and psychological consequences.<sup>3</sup> The treatment of hormone-dependent cancers with anti hormonal therapy is effective in shrinking tumor masses and extending long-term survival rates. However long term use of anti-hormonal therapy can lead to various side effects related to vasomotor symptoms, musculoskeletal symptoms, sexual functioning etc.<sup>4</sup> In India there are limited studies regarding utilization of hormones and their antagonists in treatment of patients of breast cancer and their quality of life. So the aim of this study was to assess the utilization of hormonal treatment in patients suffering from breast with a specific objective of reviewing their quality of life with relation to their side effects.

### Materials and Methods

This was a cross sectional study, spreaded over a period of one and half year from January 2017 to July 2018. The study was conducted in cancer OPD of Shree Krishna Hospital, Karamsad, after approval of Human Research Ethics Committee of H M Patel Center for Medical Care and Education, Karamsad. A total of 86 case files of the patients suffering from the breast cancer were screened from the record section of cancer OPD. Once selected as per our inclusion criteria, treatment history (medical and drug history) of participants were noted from the case files into clinical research form. For assessing the quality of life of patients suffering from breast cancer, patients visiting cancer OPD and meeting our inclusion criteria were selected. Once selected and after taking proper informed consent, they were interviewed according to European Organization for Research and Treatment of Cancer QoL questionnaire (EORTC QLQ C-30 and QLQ BR-23).<sup>5</sup> EORTC QLQ C-30 questionnaire addresses the physical, role, cognitive, emotional & social functioning and symptoms like fatigue, nausea /vomiting, pain, dyspnoea, insomnia, appetite loss and financial difficulties. EORTC QLQ BR-23 questionnaire addresses the body image, sexual activity, future perspective and breast cancer specific symptoms like systemic therapy side effects, breast symptoms, arm symptoms and upset by hair loss. A high score for a functional scale represented a high / healthy level of functioning, a high score for the global health status /

QoL represented a high QoL, but a high score for a symptom scale / item represents higher incidences of symptoms/ problems experienced. All patients diagnosed with breast cancer, planned for treatment with hormones and their antagonists and who were on treatment for at least three months were included in the study. A total of 41 case files, meeting our inclusion criteria were assessed for the utilization part of the study. In order to assess the quality of life out of them 26 patients who met our inclusion criteria were interviewed as per quality of life questionnaires. Data were analyzed as per descriptive statistics and results were presented in form of percentage and range. Mean scores for various quality of life subscales were calculated using EORTC scoring manual.<sup>6</sup> Microsoft word and excel were used to generate tables and figures.

## Results

A total of 86 case files of patients suffering from breast cancer were screened from the cancer OPD. Out of them 38 case files were selected for studying utilization of the hormones and their antagonists as per selection criteria. Mean age of 38 patients was found to be 55.23 years, the youngest was 30 years old and the oldest was 75 years of age. Mean weight of the 38 patients was 54.39 Kg, the lowest value recorded was 45 Kgs and highest value recorded was 70 Kgs. Mean haemoglobin level of the 38 patients was 10.53 g/dl. Mean creatinine level of the 38 patients was 0.69 mg/dl, the lowest value recorded was 0.22 mg/dl and the highest value recorded was 1.3 mg/dl. Mean SGPT levels of the 41 patients was 34.65 U/L, the lowest value recorded was 12 U/L and the highest value recorded was 78 U/L. Hormonal receptor sensitivity status of the tumor helps in deciding the treatment for breast cancer patients. Therefore testing the tumor sensitivity for estrogen (ER), progesterone (PR), human epidermal growth factor 2 (Her2) receptors is a standard part of breast cancer diagnosis. In this study among 38 patients, 60.52% were positive for both ER and PR, 21.05% positive for all three ER, PR and Her2; 7.89% were positive for ER and negative for PR, 2.63% were negative for ER but positive for PR and overall 28.94% patients were positive for Her2. Distribution of patients on hormonal therapy and their ER/PR/Her2 status is shown in table I. In this study before starting adjuvant hormonal therapy, out of 38 patients 55.26% patient underwent both modified radical mastectomy (MRM) and chemotherapy, 36.84% underwent modified radical mastectomy and chemotherapy followed by radiotherapy and 13.15% underwent only modified radical mastectomy. Out of the total 38 patients 26 (68.42%) were on Aromatase inhibitors (tablet Letrozole 2.5 mg once a day or Anastrozole 1mg once a day), 12 (31.57%) were on tablet Tamoxifen 20 mg once a day as shown in Fig. 1. Tablet Shelcal (Calcium 500 mg+Vitamin D3 250 IU) once daily and injection Zolendronic 4mg/100ml acid once in four weeks were prescribed as adjuvant drugs with hormonal therapy.

Quality of life for breast cancer patients was assessed by using EORTC QLQ-C30 version3 which was the core

questionnaire for cancer patients and a breast cancer specific questionnaire EORTC QLQ- BR 23. The QLQ- C30 is composed of both multi-item scales and single-item measures. These include five functional scales, three symptom scales, a global health status / QoL scale, and six single items. QLQ-BR23 is also composed of both multi-item scales and single- item measures. These include four functional scales and five symptom scales. All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level. Thus a high score for a functional scale represented a high / healthy level of functioning, a high score for the global health status / QoL represented a high QoL, but a high score for a symptom scale / item represents higher incidences of symptoms/ problems experienced. A total of 26 patients of breast cancer who were on hormonal therapy filled the quality of life questionnaires. Out of 26 patients 18 were found to be on treatment with letrozole and 8 were found to be on tamoxifen.

### Functional scale scores (QLQ-C30)

Mean scores for physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning with score range in brackets are shown in table 2. Mean scores for various functioning subscale scores were on higher side except emotional functioning. The highest score (93.74) in functional scale was for role functioning and cognitive functioning subscales in tamoxifen group, indicating that they were able to perform their routine work and daily activities without much limitation and were able to concentrate and remember things. Whereas the lowest score (74.99) was for emotional functioning subscale in tamoxifen group, which indicated that they were more worried and anxious about their health. Mean scores for social functioning 89.58 and 84.25 were on higher side in tamoxifen and letrozole groups respectively which indicated that their physical condition and medical treatment has not interfered much in their family life and social activities. Mean score for physical functioning 90.83 was on higher side in tamoxifen group which indicates that they were able to perform their daily physical activities like lifting shopping bag, walking long and short distance, eating, dressing etc without much trouble.

### Symptom Scale Scores (QLQ-C30)

Mean symptom scale scores with score range in brackets for fatigue, nausea /vomiting, pain, dyspnoea, insomnia, appetite loss and financial difficulties are shown in table 3. and the percentage of patients experiencing untoward symptoms in tamoxifen and letrozole groups are shown in Fig. 2. The highest mean score on symptom scale was for fatigue (28.97) followed by pain (27.77) in letrozole group which indicates that patients in letrozole group experienced more generalized musculoskeletal symptoms like tiredness, weakness, pain etc. However in the terms of percentage, 87.5% patients undergoing treatment tamoxifen and 83.33% patients undergoing treatment with letrozole experienced fatigue, whereas 88.88% patients in letrozole group and

62.5% patients in tamoxifen group experienced generalized pain. Overall the various mean symptom subscale scores were on lower side in both groups, indicating towards better quality of life due to lesser degree of symptoms. Some other symptoms like diarrhoea and constipation were experienced by 1 patient in tamoxifen group and 5 patients in letrozole group respectively.

**Breast cancer specific functioning scale scores (QLQ-BR23)**

Mean scores for breast cancer specific functioning with score range in brackets are shown in table 4. The highest mean score (96.29 and 94.79) were for body image in letrozole and tamoxifen group respectively which indicates that patients in both groups were satisfied with their body image. The lowest scores 4.62 and 8.33 were for sexual functioning in letrozole and tamoxifen group respectively which indicates that they were less sexually active. For future perspective subscale all the patients in both groups were worried about their future health.

**Breast cancer specific symptom scale scores (QLQ-BR23)**

Mean scores with score range in brackets for systemic therapy side effect, breast symptoms, arm symptoms and upset by hair loss are shown in table 5 and the percentage of patients experiencing these symptoms are shown in figure 3. The highest mean scores were for arm symptoms (arm swelling, arm pain etc) in letrozole group and systemic therapy side effects in tamoxifen group which indicated that arm symptoms were more in letrozole group and side effects like dry mouth, hot flushes, headaches and hair loss were more in tamoxifen group. Number of patients who were found to be positive for arm symptoms and underwent surgery, chemotherapy or radiotherapy are shown in table 6. In the terms of percentage 100% patients in tamoxifen group and 94.44% patients in letrozole group experienced systemic therapy side effects. The lowest score 7.29 for breast symptoms in tamoxifen group which indicated lesser

number of symptoms like breast swelling, skin problems in the area of affected breast in these patients. Overall the mean scores for various breast cancer specific subscales were on lower side indicating towards the better quality of life.

Percentage of patients experiencing systemic therapy side effects (dry mouth or painful eyes, hot flushes, hair loss, headache, dysgeusia) are shown in Fig. 4. All the patients in tamoxifen group complained of dysgeusia. In the terms of percentage of patients experiencing various systemic therapy side effects were found to be more in tamoxifen group.

**Global health status**

For measuring global health status of breast cancer patients, they marked their over health and quality of life during past week on a scale of 1 (very poor) to 7 (excellent). Mean global health status score for patients taking tablet tamoxifen was 86.45 (66.66-100) whereas for patients on letrozole was 76.84 (50-100), indicating that patients in tamoxifen group rated their overall health and quality of life in previous week towards higher side.

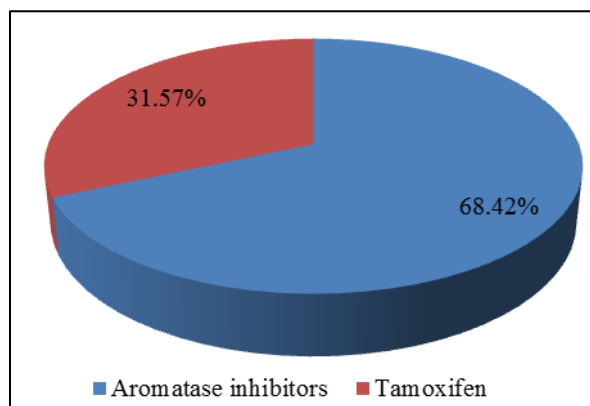


Fig. 1: Distribution of patients on hormonal therapy

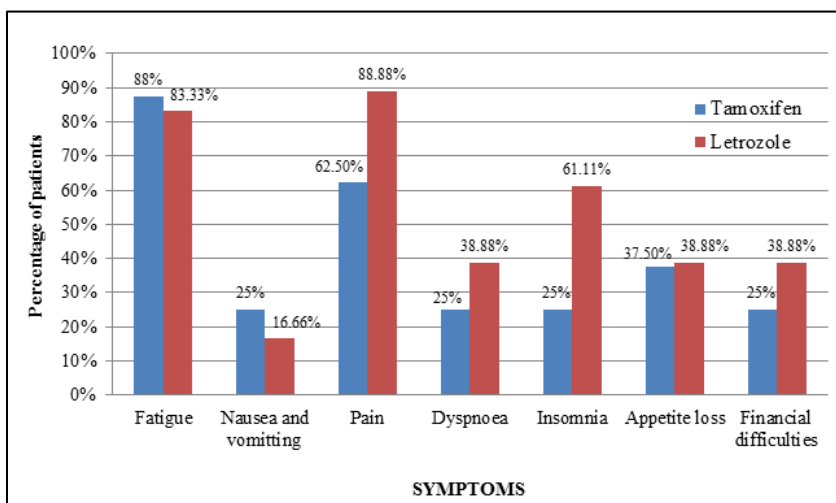


Fig. 2: Percentage of patients experiencing untoward symptoms

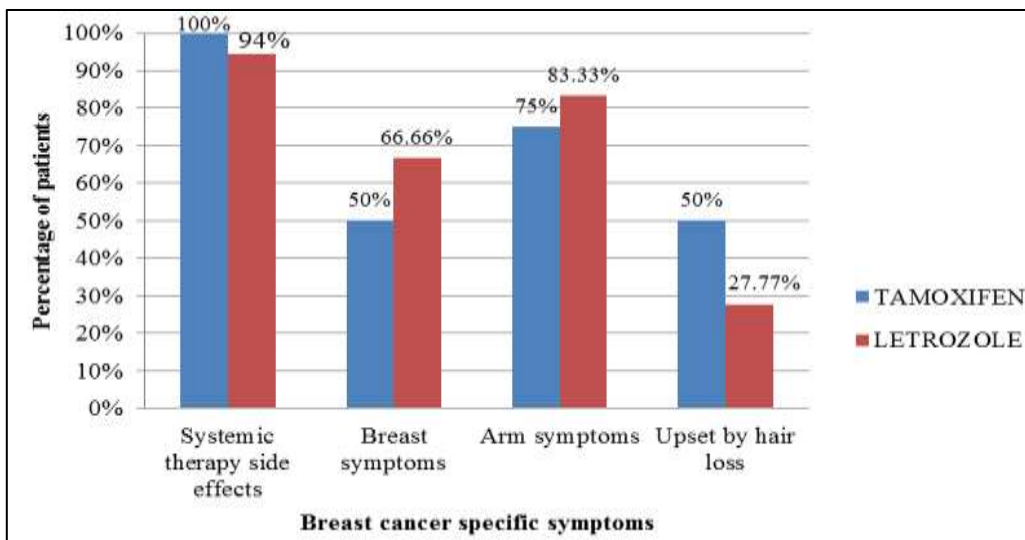


Fig. 3: Percentage of patients experiencing breast cancer specific symptoms

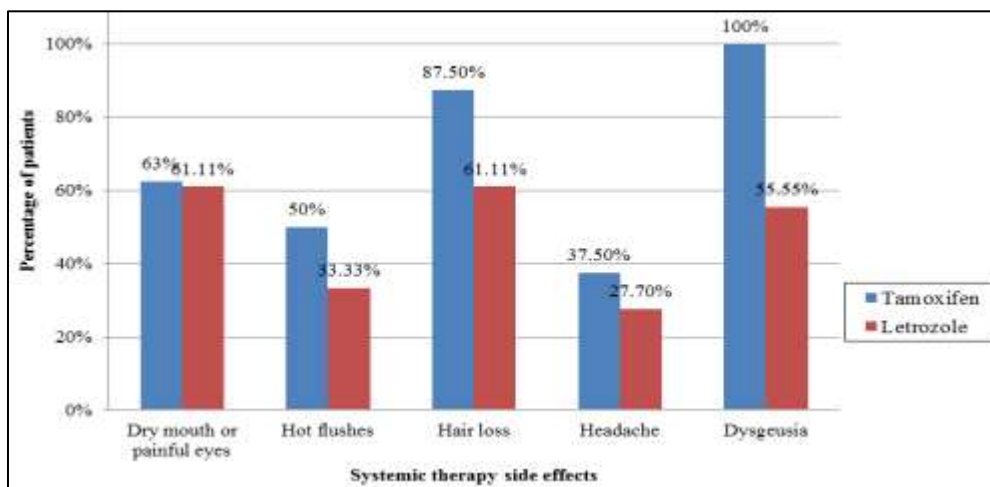


Fig. 4: Percentage of patients with systemic therapy side effects

Table 1: ER/PR/Her2 status with hormonal therapy

ER/PR/Her2 status	Number of patients	Hormonal/Antihormonal Therapy	
		Tamoxifen	Letrozole
ER+/PR+/Her2-	23(60.52%)	5(21.73%)	18(78.26%)
ER+/PR+/Her2+	08(21.05%)	3(37.5%)	5(62.5%)
ER+/PR-/Her2/-	03(7.89%)	2(66.66%)	1(33.33%)
ER-/PR+/Her2+	01(2.63%)	1(100%)	-
ER+/Her2+/PR-	02(5.26%)	1(50%)	1(50%)
ER-/Her2-/PR+	01(2.63%)	-	1(100%)

Table 2: Mean functioning scale scores measured by QLQ-C30

Functional scale	Mean score*	
	TAMOXIFEN(n=08)	LETROZOLE(n=18)
Physical functioning	90.83(66.66-100)	82.21(66.66-100)
Role functioning	93.74(66.66-100)	90.73(66.66-100)
Emotional functioning	74.99(41.66-91.66)	81.94(66.66-91.66)
Cognitive functioning	93.74(83.33-100)	89.81(66.66-100)
Social functioning	89.58(66.66-100)	84.25(66.66-100)

\*The higher value indicates higher level of functioning, min:0, max:100

**Table 3:** Symptom scale scores measured by QLQ-C30

Symptom scale	Mean score*	
	Tamoxifen(n=08)	Letrozole (n=18)
Fatigue	17.95 (0-44.33)	28.97(0-66.66)
Nausea and Vomiting	8.33(0-50)	2.77(0-16.66)
Pain	14.58 (0-33.33)	27.77(0-50)
Dyspnoea	4.16 (0-33.33)	14.81(0-66.66)
Insomnia	12.49(0-66.66)	24.07(0-100)
Appetite loss	16.65(0-66.66)	14.81(0-33.33)
Financial difficulties	8.33 (0-33.33)	12.96(0-33.33)

\*The higher value indicates higher degree of symptoms, min:0, max:100

**Table 4:** Breast cancer specific functioning scale scores measured by QLQ-BR23

Breast cancer specific Functioning scale	Mean Score*	
	TAMOXIFEN (n=08)	LETROZOLE (n=18)
Body image	94.79(75-100)	96.29(91.66-100)
Sexual functioning	8.33(0-33.33)	4.62(0-83.33)
Future perspective	66.66	72.21(66.66-100)

\*The higher value indicates higher level of functioning, min:0, max:100

**Table 5:** Breast cancer specific Symptom scale scores

Breast cancer specific symptom scale	Mean score*	
	TAMOXIFEN (n = 08)	LETROZOLE(n=18)
Systemic therapy side effects	20.74(19-23.66)	17.31(0-47.33)
Breast symptoms	7.29(0-25)	8.79(0-41.66)
Arm symptoms	15.20(0-33.33)	24.79(0-100)
Upset by hair loss	16.65(0-33.33)	9.25(0-33.33)

\*The higher value indicates higher degree of symptoms, min:0, max:100

**Table 6:** Number of patients with positive arm symptoms

Treatment before adjuvant hormonal therapy	Tamoxifen (n=8)	Letrozole(n=18)
Surgery + Chemotherapy + Radiotherapy	2	6
Surgery + Chemotherapy	2	5
Chemotherapy + Radiotherapy	1	-
Only surgery	-	4

## Discussion

Mean age of breast cancer patients in our study was 55.23 years which was nearly similar to the study by Patnayak et al,<sup>7</sup> where mean age was found to be 50.7 years for 389 cases. Age range in our study was nearly similar to another study by Taran et al,<sup>8</sup> in 149 patients with age range of 25-85 years and median age of 53 years.

Response to hormonal therapy depends on the Estrogen (ER), Progesterone (PR) and Her2 sensitivity status of the patients. Patients with ER and PR positive status have more likelihood to respond to hormonal therapy whereas ER and PR negative carcinomas don't respond to hormonal therapy.<sup>4</sup> In a study by Howalder et al,<sup>9</sup> 72.70% of patients were ER/PR positive and Her2 negative, 10.3% were triple positive which were nearly similar to our study where 60.52% were ER/PR positive/Her2 negative and 21.05% were triple positive.

Results from our study suggested that most of the patients, 68.42% were on treatment with aromatase

inhibitors, which were similar to results from a study by Kelly et al,<sup>10</sup> which suggested downward trends in tamoxifen use and upwards trend in aromatase inhibitors use in European countries. In our study it was observed that Letrozole was prescribed in those patients who attained menopause. This is found to be similar with BIG-198 trial in which aromatase inhibitors have been established as the preferred hormonal treatment for post menopausal women as adjuvant treatment due to small but significant benefits compared with tamoxifen in terms of reduced risk of recurrent disease.<sup>11</sup> Similarly in another study by Wu et al,<sup>12</sup> out of total 410 patients on hormonal therapy, 55% were initiated on aromatase inhibitors and 45% were initiated on tamoxifen for treatment of breast cancer which was nearly similar to our study.

In this study the mean scores for physical functioning, role functioning, cognitive functioning and social functioning of the patients suffering from breast cancer and are on hormonal therapy were found to be on higher side but the emotional functioning score was found to be on lower

side in patients on treatment with tamoxifen. In this study the highest mean score 93.74 was found to be for role functioning in tamoxifen group which was nearly similar to a study by Kilickap et al,<sup>13</sup> in which the highest mean score 83.3 was observed for role functioning in tamoxifen group. The high score for role functioning indicates that patients were not much limited in doing their daily routine activities. The lowest mean score 74.99 in this study was found to be for emotional functioning in tamoxifen group which was similar to the study by Kilickap et al<sup>13</sup> where the score for tamoxifen group was found to be 70.55. The low score for emotional functioning indicates that patients were more worried and anxious about their health condition. However the difference between the scores for physical functioning and cognitive functioning of this study and study by Kilickap et al<sup>13</sup> might be due to the difference in sample size which was much smaller in present study.

In this study the highest score on symptom scale were found to be for fatigue, pain and insomnia in letrozole group which was similar to the highest scores observed in study by Kilickap et al<sup>13</sup>. The high scores for fatigue, pain and insomnia indicates that patients in letrozole group experienced more generalized musculoskeletal symptoms like tiredness, weakness and disturbance in sleep. The musculoskeletal symptoms scores for pain and fatigue were more in letrozole group of present study was found to be similar to study by Ganz et al<sup>14</sup> who used BCPT symptom scale and observed musculoskeletal pain to be more in anastrozole group. Similarly the scores for other symptoms like appetite loss, nausea and vomiting were found to be on lower side (lesser degree of symptoms) in study by Kilickap et al<sup>13</sup> which were nearly similar to this study.

Results from a study by Ganz et al<sup>15</sup> suggested that patients on tamoxifen and aromatase inhibitors showed decline in mean sexual functioning scores which was similar to results found in this study. However this decreased score in sexual functioning might be due to more number of postmenopausal patients or due to cultural aspects. Similarly in an another study by Ribí et al<sup>16</sup> there was decline in sexual interest in patients on hormonal therapy.

Scores for body image in this study were on higher side in both tamoxifen and letrozole groups in this study, which suggested that these patients seemed to be satisfied with their body image and don't feel less attractive due to their disease or treatment. This might be due to more number of postmenopausal women in this study.

The mean scores for future perspective (worried about their health in future) were on lower side in this study in both groups, which indicated that these patients were anxious about their health.

In this study the highest score for breast cancer specific symptoms was for arm symptoms in letrozole group followed by systemic therapy side effects in tamoxifen group. However arm symptoms like arm swelling, pain in arm etc might be due to axillary lymph node dissection during surgical treatment of patients prior to starting of hormonal therapy. In addition to mastectomy and axillary lymph node dissection, radiotherapy has also been reported

as a risk factor of breast cancer related lymphadema.<sup>17</sup> In this study certain other adverse events like hot flushes were found to be more in tamoxifen group which was similar to findings in a study by Ganz et al.<sup>14</sup> Mean global health scores for patients on tamoxifen and letrozole in this study were 86.45 and 76.84 which indicates that patients rated their overall health and quality of life in previous week towards better side.

However in study by Kilickap et al,<sup>12</sup> mean scores for global health 66.5 and 63.0 for tamoxifen and anastrozole group were found to be on lower side compared to our study. The difference might be due to larger sample size in study by Kilickap et al.<sup>12</sup>

Overall, the mean scores for various functional subscales in breast cancer patients on hormonal therapy, were on higher side in this study indicating towards a better quality of life. However the mean scores for sexual functioning were on lower side in breast cancer patients as compared to international studies, indicating towards lower sexual activity which may be due to socio cultural factors or more number of postmenopausal breast cancer participants. Similarly the various symptom scale scores were on lower side indicating towards lesser degree of symptoms. However we were not able to compare the results of quality of life in Indian scenario due to dearth of such studies. Main limitation of our study was small sample size. Further long term studies are needed to demonstrate the other effects, if any, of hormonal therapy on quality of life of breast cancer patients.

**Conflict of Interest:** None.

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