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Single Center Clinico-Epidemiological study of Female Patients with Breast Cancer

Sara Mohammed Abd Elkader Ayoub (MSC), Bahaa Said Ebrahim (MD), Nehal Mohamed ElMashad (MD), Alaa Mohamed Maria (MD),

Clinical Oncology & Nuclear Medicine Department, Faculty of Medicine, Tanta University, Egypt
Email: saraa.ayooub@gmail.com

Abstract: **Aim of the Work:** describe the clinico-epidemiological and pathological pattern of breast cancer (BC). **Patients and Methods:** This retrospective descriptive Hospital based epidemiological study for female patients with breast cancer presented at Clinical Oncology Department, Tanta University Hospitals throughout the period between January 2014 to 1st of January 2019. **Results:** Female breast cancer represented 28.3% of patients presented during the period of study. The median age was 51 years. Supra-areolar position was present in 74% of patients and 5% had multicentric lesions. Stage II was the most prevalent (42.6%). Invasive ductal carcinoma was the most common pathological subtype and grade II was the most frequent. Intraductal component, lympho-vascular invasion (LVI) and perineural invasion (PNI) were missing in a large number of pathological reports. More than 60% were hormone receptor (HR) positive & HER2 was positive in 14.2%. expression of KI-67 was unknown in 42.5%. Surgery was done in the majority of patients with modified radical mastectomy (MRM) followed by conservative breast surgery (CBS) in 57.4% & 33.9% respectively. Chemotherapy was offered in most cases. Radiotherapy whether adjuvant or palliative was offered in most cases. Hormonal therapy was offered in almost all HR positive patients. Over 90% of cases were still alive by the end of the study. The median OS was 141 months, the median DFS was 66.5 months and the median PFS was 26 months. **Conclusion:** Breast cancer is a heterogenous disease that needs to be fully understood to tailor the best strategy to fight and overcome it. Screening programs are needed and defining risk categories will help in designing better screening methods for each category. Registry of cases will help to understand the disease burden in our region so that we become able to better define our problem and find the best solution.
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1. Introduction:

In 2020, Female breast cancer has surpassed lung cancer as the most commonly diagnosed cancer, followed by lung then colorectal cancer in both sexes. Female breast represents 6.9% of all cancer mortality coming in the fifth place **(Sung et al, 2021)**.

In Egypt, 15.41% of cancer patients in both sexes are diagnosed with breast cancer, with 32% of female cancer patients diagnosed with BC as the highest incidence, while in males BC represents 0.51% of all cancers and 25% of female cancer mortality in Egypt is attributed to breast cancer. Regarding breast cancer rates in Gharbiah, it accounts for 38.8% of malignancies in females versus 0.6% in males **(Ibrahim et al, 2007, Ibrahim et al, 2014, Ferlay et al, 2019).**

Breast cancer may be invasive or non-invasive. Non-invasive neoplasms of the breast are broadly divided into two major types, lobular carcinoma in situ (LCIS) and ductal carcinoma in situ (DCIS). Pathologists broadly divide invasive breast cancer into ductal (IDC, 50-70%) and lobular (ILC, 10%) histologic types. Other rare types include medullary, tubular and mucinous **(Alkabban and Ferguson, 2022).**

There are five main molecular subtypes of BC based on gene expression of cancer cells that include luminal A, luminal B, triple-negative or basal-like, HER2-enriched and normal-like **(Cejalvo et al, 2018).**

Risk factors of BC can be classified into: demographic (age as BC significantly increases with age and reaches its peak around the menopause then gradually decreases or remains constant, gender), reproductive (late menopause, pregnancy characteristics), hormonal (hormonal contraceptive methods, postmenopausal hormone therapy), hereditary (genetic, positive family history), breast related (lactation duration, benign breast disorders), lifestyle which affects prognosis of the disease and is an independent predictor of overall survival(obesity and overweight, alcohol consumption, smoking, diet) and other factors that include air pollution, night work,

socioeconomic status as BC is relatively higher in women with higher socioeconomic status as an association with sedentary lifestyle, diabetes and radiation **(Momenimovahed et al, 2019).**

Breast cancer is a preventable disease through modulation of risk factors. Strategies to decrease BC generally focus on addressing environmental factors, genetic and histo-pathologic risks whether directly or indirectly **(Sauter, 2018).**

This study aimed to describe the clinico-epidemiological and pathological pattern of breast cancer.

2. Patients and Methods:

This retrospective descriptive Hospital based clinico-epidemiological study for female patients with breast cancer presented at Clinical Oncology Department, Tanta University Hospitals throughout the period between January 2014 to 1st of January 2019.

- **Patient evaluation:**

All medical files were revised for history taking, clinical examination, laboratory investigations, radiological investigations, pathological findings and line of treatment. Details of the follow up either clinical, radiological or laboratory was revised evaluating response, progression and complication of the treatment.

- **Privacy and Ethical consideration:**

Privacy of all patients' data was guaranteed and every patient had a file with a private code number including all investigations. Approval from Ethical Committee of Tanta Faculty of Medicine was obtained before starting the study and collected data were not and will not be used for any purpose.

- **Statistical Analysis:**

The data was collected, complied and analyzed using percentage, mean and median using statistical package for social science (SPSS) version 21. The date of final analysis was in December 2021. Disease free survival was calculated from the start of treatment that the patient survives without any signs or symptoms of the disease till disease recurrence. Progression free survival was calculated from the date of diagnosis till the occurrence of disease progression. Overall survival was calculated from the date of diagnosis till death from any cause or date of last follow up using Kaplan Meier analysis and log rank test.

3. Results:

Among 9869 patients presented, there were 2788 (28.3%) female breast cancer patients that their files were revised and all documented data were classified. Files with missed data were neglected, and the remaining files of 2023 patients were included in the data analysis, (table 1).

Table (1): Presentation of breast cancer cases for each year

	All cases	Breast cases	Cases for analysis
2014	2616	833 (31.8%)	522/833 (62.7%)
2015	2154	638 (29.6%)	480/638 (75.2%)
2016	1810	462 (25.5%)	322/462 (69.7%)
2017	1787	482 (26.9%)	354/482 (73.4%)
2018	1502	373 (24.8%)	345/373 (92.5%)
All cases	9869	2788 (28.3%)	2023/2788 (72.6%)

Patient characteristics

Bilateral cases were around 1%. Unilateral cases either right or left were around 50% each with supra-areolar location in 74%. Solitary lesions represented 87.8%, multifocal lesions represented 7.2% and multi-centric lesions represented 5%. T2 & N1 were the commonest stages (66.5% & 32.0% respectively) and 8.4% had metastasis at first presentation with bone metastasis as the commonest site (4.3%). The commonest presenting stage was stage II (42.7%), IDC represented 82.5% and pathological grade II represented 86.3% of all cases. Pathological reports were lacking information regarding lympho-vascular invasion (LVI), perineural invasion (PNI), and intra-ductal component in 37.9%, 44.1% & 40% respectively. Hormonal receptors were positive in 69.2% & 62.9% for ER & PR respectively and 14.2% were HER2 positive. KI-67 was unknown in 42.5% of cases. Most cases were luminal A (39.8%) followed by luminal B (30.1%). Triple negative cases represented 14.4% & unknown cases were 8.5% of all cases (table 2).

Line of treatment

The line of treatment for included patients either surgery, chemotherapy or radiation therapy was reported in table (3). Most cases (92.4%) were subjected to surgery with MRM done in 57.4% and conservative surgery in 33.9% of cases. Most cases received chemotherapy in their treatment course (89.5%) whether curative (neoadjuvant & adjuvant) or palliative. Regarding herceptin administration, only 43.2% of HER2 positive patients received herceptin (6.1% of all cases) & hormonal therapy was offered in 68.9%. Of all included patients, 80.7% received adjuvant radiation with the median duration between surgery & start of radiation was 211 (range 13-560) days and the median time gap during radiation was 4 (range 0-109) days.

Postmenopausal patients represented 52.5% of all cases and most cases were married (82.8%). Hypertension was the most coexisting comorbid illness followed by diabetes mellitus (DM) (18.3% and, 14.0% respectively). Positive family history of breast cancer was higher than other malignancies (7.6% vs 4.1%).

Table (2): Patients characteristics

		All Cases (2023 cases)	
		N	%
Age of patients	Min	23	
	Max	90	
	Median	51	
Menstrual status	Premenopausal	961	(47.5%)
	Postmenopausal	1062	(52.5%)
Marital status	Married	1676	(82.8%)
	Divorced	18	(0.9%)
	Widow	257	(12.7%)
	Single	72	(3.6%)
Comorbid illness	Hypertension	371	(18.3%)
	Diabetes Mellitus	283	(14.0%)
	Cardiac	64	(3.2%)
	Hepatitis C	56	(2.8%)
	Others	184	(9.1%)
Family history of malignancy	breast cancer	154	(7.6%)
	Other malignancies	83	(4.1%)
	No	1786	(88.3%)
Laterality of the affected breast	Right	986	(48.7%)
	Left	1018	(50.3%)
	Bilateral	19	(1.0%)
Tumor location at the affected breast	Supra-areolar	1498	(74.0%)
	Retro-areolar	198	(9.8%)
	Infra-areolar	226	(11.2%)
	Multi-centric	101	(5.0%)
Number of focal lesions	Solitary	1777	(87.8%)
	Multifocal	145	(7.2%)
	Multicentric	101	(5.0%)
T stage	Tis	25	(1.2%)
	T1	338	(16.7%)
	T2	1346	(66.5%)
	T3	217	(10.7%)
	T4	71	(3.5%)
	pT0	26	(1.3%)
N stage	0	575	(28.4%)
	1	648	(32.0%)
	2	441	(21.8%)
	3	359	(17.7%)
Metastasis at first presentation (M stage)	0	1853	(91.6%)
	1	170	(8.4%)
Sites of Metastasis at first presentation	No	1853	(91.6%)
	Bone	88	(4.3%)
	Visceral	38	(1.9%)
	Both	44	(2.2%)
Staging of all cases at first presentation	0	32	(1.6%)

	I	137	(6.8%)
	II A	448	(22.1%)
	II B	415	(20.5%)
	III A	458	(22.6%)
	III B	36	(1.8%)
	III C	327	(16.2%)
	IV	170	(8.4%)
Pathological types	IDC	1668	(82.5%)
	ILC	130	(6.4%)
	Mixed	73	(3.6%)
	DCIS	21	(1.0%)
	Mucinous	26	(1.3%)
	Medullary	22	(1.1%)
	Phyllodes	6	(0.3%)
	Others	20	(1.0%)
	Unknown	57	(2.8%)
Pathological grade	Unknown	57	(2.8%)
	I	39	(1.9%)
	II	1745	(86.3%)
	III	182	(9%)
Lympho-vascular invasion	No	657	(32.5%)
	Yes	600	(29.6%)
	Unknown	766	(37.9%)
Perineural invasion	No	824	(40.7%)
	Yes	307	(15.2%)
	Unknown	892	(44.1%)
Intra-ductal component	No	701	(34.7%)
	Yes	512	(25.3%)
	Unknown	810	(40.0%)
Estrogen Receptor expression	-ve	453	(22.4%)
	+	178	(8.8%)
	++	421	(20.8%)
	+++	802	(39.6%)
	Unknown	169	(8.4%)
Progesterone Receptor expression	-ve	578	(28.6%)
	+	359	(17.7%)
	++	465	(23.0%)
	+++	449	(22.2%)
	Unknown	172	(8.5%)
HER2 Receptor expression	-ve	1553	(76.8%)
	+++	287	(14.2%)
	Unknown	183	(9.0%)
KI-67 expression	≤15%	423	(20.9%)
	>15%	740	(36.6%)
	Unknown	860	(42.5%)
Molecular types	Luminal A	806	(39.8%)
	Luminal B	608	(30.1%)
	Her2	146	(7.2%)
	Triple –ve	291	(14.4%)
	Unknown	172	(8.5%)

Table (3): Line of treatment

		All Cases (2023 cases)	
		N	%
Surgical interference	No	153	(7.6%)
	Yes	1870	(92.4%)
Types of surgery	Conservative	685	(33.9%)
	MRM	1162	(57.4%)
	Excision biopsy	23	(1.1%)
Use of Chemotherapy	No	213	(10.5%)
	Yes	1810	(89.5%)
The aim of chemotherapy	Induction	109	(5.4%)
	Adjuvant	1371	(67.8%)
	Indu+Adju	234	(11.6%)
	Palliative	96	(4.7%)
Administration of Herceptin	No	1899	(93.9%)
	Yes	124	(6.1%)
The aim of radiation therapy	No	234	(11.5%)
	Palliative	157	(7.8%)
	Adjuvant	1632	(80.7%)
Duration between surgery & adjuvant radiation therapy	Min	13	
	Max	560	
	Median	211	
Time gap during radiation therapy	Min	0	
	Max	109	
	Median	4	
Hormonal therapy	Yes	1394	(68.9%)
	No	518	(25.6%)
	Unknown	111	(5.5%)

Survival analysis

At the time of study termination, 1843 (91.1%) patients were alive with 14 months median follow up for all patients (range 1-328 months). As regard the survival outcome, the median OS was 141 months (95% CI, 127.9–154.1). The 3-year OS rate was 90.7% & 5 year OS rate was 84.5% for all patients (Fig 1).

Of 1853 non-metastatic patients at first presentation, 478 (25.8%) patients developed metastases during follow-up (13.6% solitary site & 12.2% multiple sites) with the median DFS was 66.5 months (95% CI, 58.1–74.9). The 3-year DFS rate was 69.4% & 5-year DFS rate was 52.9% for all patients (Fig 2).

Of 170 metastatic patients at first presentation, 72 (42.4%) patients developed progression of the disease during follow-up with the median PFS was 26 months (95% CI, 19.9–32.1). The 2-year PFS rate was 53.5% (Fig 3).

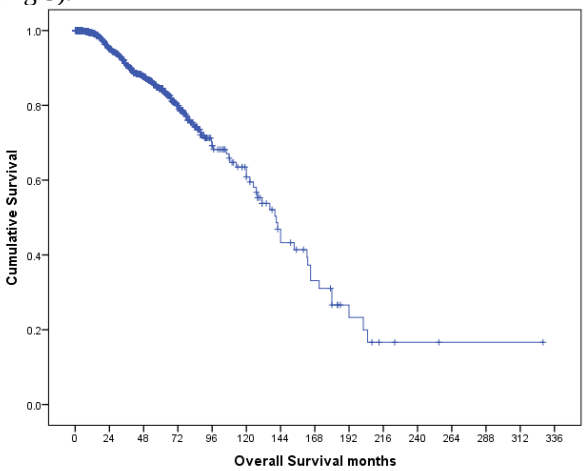

Figure (1): Overall survival

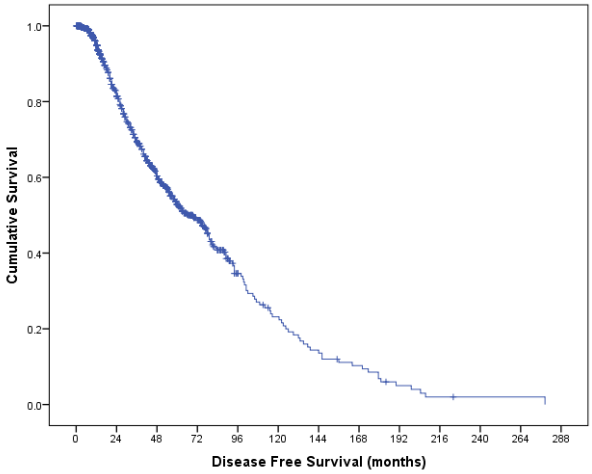

Figure (2): Disease Free Survival

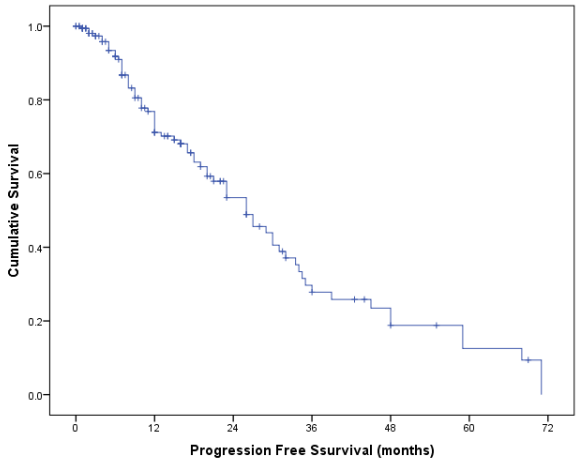

Figure (3): Progression Free Survival

4. Discussion:

Breast cancer is the most common cancer among women and one of the most important causes of death among them. Breast cancer incidence, mortality, and survival rates vary considerably among different parts of the world, which could be due to many factors such as population structure, lifestyle, genetic factors, and environment. Classification of women based on risk factors for breast cancer can be effective in improving risk-free methods and designing targeted breast cancer screening programs **(Momenimovahed et al, 2019)**.

Our study is a retrospective study that included all female breast cancer patients presented at Clinical Oncology Department – Tanta University throughout the period between Jan 2014 to 1st Jan 2019. Of all 9869 cancer patients presented, there were 2788 (28.3%) female breast cancer with 765 files neglected due to data shortage and loss of follow up, and the remaining files of 2023 patients were included in our analysis. In a study based on the Gharbia Population-based Cancer Registry, patients with breast cancer were 6624 through the period from 1999 to 2007. The large number may be due to longer study duration & inclusion of many centers **(Zeeneldin et al, 2013)**.

The median age of our patients was 51 years (range 23-90) versus 49.5 years (range 42-57) in the study of **Zeeneldin et al, 2013** and 52 years in **Jang et al, 2020** study. Postmenopausal patients represented 52.5% of all cases versus 77.6% & 54% in the studies of **Kotsakis et al, 2019** and **Sofi et al, 2019** respectively. Regarding marital status, 82.8% of cases were married versus 24.1% in the study of **Balekouzou et al, 2016** and 57.3% in **Martínez et al, 2017** study.

Hypertension was the most coexisting comorbid illness representing 18.3% followed by DM (14%). **Kotsakis et al, 2019** reported that 16.1% of their patients had vascular disorders, 13.5% had cardiac disorders and 13.2% had endocrinal disorders.

In our study, 7.6% of patients had positive family history of breast cancer and 4.1% had positive family history of other cancers which is lower than other studies. In Haiti, 22% of patients had positive family history **DeGennaro et al, 2018** and **Sofi et al, 2019** reported that 15% of patients had family history of breast cancer.

Left breast cancer represented 50.3% of cases, followed by right breast cancer representing 48.7% and bilateral cases were 1% which is compatible with other studies. In **Zeeneldin et al, 2013** study, 53.6% of cases were left-sided and 46.4% were right-sided. In the study of **Kotsakis et al, 2019**, 50.3% had left breast cancer, 47.6% had right breast cancer and 2.1% had bilateral breast cancer. In **Mehta et al, 2021** study, 50% of patients were right-sided, 47.7% were left-sided, 0.6% were bilateral and 1.7% were unknown.

Supra-areolar location of the tumor was reported in 74% of included patients versus 56.5% & 67.1% in the studies of **Zeeneldin et al, 2013** and **Rummel et al, 2015**. Most lesions (87.8%) were solitary versus 5% multicentric. **Zeeneldin et al, 2013** and **Neri et al, 2015** reported that multicentric lesions represented 18% & 5.2% respectively.

Regarding T stage, T2 was the most common T representing 66.5% of included patients versus 59.9% & 33.5% in the studies of **Zeeneldin et al, 2013** and **Kim et al, 2022**. Regarding N stage, N1 was the commonest N in included patients (32%), while N0 was the commonest in **Kim et al, 2022** study (65.7%) & was N1 in **Zeeneldin et al, 2013** study (29.6%). In our study 91.6% of patients were non-metastatic and 8.4% were de-novo metastatic. In **Zeeneldin et al, 2013** reported that 13.1% were metastatic. **DeGennaro et al, 2018** reported that 28.4% were de-novo metastatic which may be due to delay in seeking medical advice. Bone metastasis represented 51.8%, followed by 25.9% had both bone & visceral and 22.3% had visceral metastasis of all de-novo metastatic patients. While **Wang et al, 2019** reported that 39.8% had bone, 19.79% had visceral (liver, lung & brain) and 40.41% had both.

Regarding stage, 6.8% had early stage (stage I) that is compatible with **Zeeneldin et al, 2013** (4.1%) & lower than reported in **Martínez et al, 2017** study (45.4%) & **Sofi et al, 2019** study (14%). This may be due to lack of screening programs.

Invasive ductal carcinoma was the most common pathological subtype accounting for 82.5% of patients. In **Zeeneldin et al, 2013** study, IDC represented 90% & 83.2% in **Ibrahim et al, 2022**. **Balekouzou et al, 2016**, reported that IDC represented 64.9% and in the study of **Jang et al, 2020**, IDC represented 86.3% and **DeGennaro et al, 2018** reported that IDC represented 87.3%. In our study, pathological grade II was the most frequently represented grade (86.3%). In **Zeeneldin et al, 2013** study, 76.6% were grade II. **Kim et al, 2022** reported that grade II represented 48%. In **DeGennaro et al, 2018,** 48.2% were grade II.

In our study, LVI was unknown in 37.9%. It was positive in 29.6% and negative in 32.5%. That is different from the findings of **Kim et al, 2022** in which LVI was negative in 62%, positive in 20% and unknown in 18%. The PNI was unknown in 44.1%, not present in 40.7% and present in 15.2% of cases. In a tertiary cancer center in Turkey, PNI was not present in 85.9%, unknown in 9.3% and present in 4.9% of patients **(Yekedüz et al, 2022)**. Intra-ductal component was unknown in 40%, not present in 34.7% and present in 25.3% of cases. While **Walsh et al, 2019** found extensive intraductal component in 7.4% and was not present in 92.6%.

Concerning HR status, 69.2% were ER positive, 22.4% were ER negative while unknown cases were 8.4%, versus 88.4%, 9.3% & 2.3% respectively in **Walsh et al, 2019** study. In **Zeeneldin et al, 2013** study, 71.1% were ER positive and 28.9% were ER negative. In our study, 62.9% of cases were PR positive, negative (28.6%) and 8.5% were unknown, versus 78.7%, 18.7% & 2.6% respectively in **Walsh et al, 2019** study. In **Zeeneldin et al, 2013** study, 64.1% were PR positive and 35.9% were PR negative.

Most of our cases were HER2 negative representing 76.8%, 14.2% were HER2 positive and 9% were unknown. In **Kim et al, 2022** study, 69.3% of cases were HER2 negative, 26.5% were positive and 4.2% were unknown and **Walsh et al, 2019** reported that 88.7% were negative, 8% were positive and 3.3% of patients were unknown. In **DeGennaro et al, 2018**, 19.6% of patients were positive.

The expression of KI-67 was unknown in 42.5%. It was high (>15%) in 36.6% and low (≤15%) in 20.9%. **Soliman et al, 2016** found that 66.2% had low KI-67 and 33.8% had high KI-67. **Nigam et al, 2021** reported that KI-67 was positive (>10%) in 82.9% and negative (<10%) in 17.1%.

In our study, 69.9% of cases were luminal (39.8% were luminal A& 30.1% were luminal B) followed by triple negative cases 14.4%, unknown cases were 8.5% and Her2 enriched represented 7.2% of all cases. **Ibrahim et al, 2022** reported that 55.1% of cases were luminal (41.2% & 13.9% for A & B respectively), 28.5% were TNBC and 19.4% were HER2 enriched. In the study of **Jang et al, 2020**,

luminal cases represented 53.4% followed by TNBC 32.1%, unknown 14.5% of cases. Luminal cases were 67.3%, followed by TNBC 16.7%, Her2 enriched 12.9% and unknown cases were 3.1% in the study of **Kim et al, 2022**. In **Martínez et al, 2017** study, 70.4% were luminal, 14.2% were unclassified, 10.4% were TNBC and 5% were HER2 enriched. **Yekedüz et al, 2022** reported that 59.6% were luminal, 18% were HER2 enriched, 13% were TNBC and 9.4% were missing.

In our study, 92.4% underwent surgical procedures. **Balekouzou et al, 2016** reported that surgery was done in 95.4% and in 92.7% in the study of **Martínez et al, 2017**. The MRM was done in 57.4% of our cases and CBS in 33.9% versus 60.6% and 38.2% respectively in **Jang et al, 2020** study, 42% and 58% in the study of **Kim et al, 2022**, 38.7% and 54% in **Martínez et al, 2017** study and 21.1% and 78.9% in **Yekedüz et al, 2022** study.

Chemotherapy was delivered to 89.5% of our patients versus 91.4% in **Balekouzou et al, 2016** study, 58.6% in **Kim et al, 2022** study, 44.3% in **Martínez et al, 2017** study and 23.4% in **DeGennaro et al, 2018** study. In our study, 6.1% of patients received Herceptin (only 43.2% of HER2 positive cases) which may be due to financial issues versus 8.7% in **Kim et al, 2022** study and 10.1% in **Yekedüz et al, 2022** study.

In our study, 80.7% received adjuvant radiotherapy, 11.5% did not receive any radiotherapy and 7.8% received palliative radiotherapy, versus 68.9%, 5.1%, 47.5%, 66.1% &30.4% received RT in the studies of (**Yekedüz et al, 2022, DeGennaro et al, 2018, Martínez et al, 2017, Kim et al, 2022, Balekouzou et al, 2016**) respectively. The patients who did not receive RT represented 30.9%, 52.4%, 33.3% & 69.6% in the studies of (**Yekedüz et al, 2022, Martínez et al, 2017, Kim et al, 2022, Balekouzou et al, 2016**) respectively.

Hormonal therapy was offered in 68.9% of our cases, 25.6% did not receive hormonal therapy and 5.5% of patients were unknown. This is in agree with others received treatment 67.8% & 68.6% in the studies of (**Kim et al, 2022** and **Yekedüz et al, 2022**) respectively. Patients who did not receive hormonal therapy represented 31.2% & 30.9% in the studies of (**Kim et al, 2022, Yekedüz et al, 2022**) respectively.

At the time of study termination, 91.1% of patients were alive. As regard the survival outcome, the median OS was 141 months (95% CI, 127.9–154.1). The 3-year OS rate was 90.7% & 5-year OS rate was 84.5%. **Balekouzou et al, 2016** reported that 84.5% of patients died, 12.1% were still alive, 3.4% lost follow up and in **DeGennaro et al, 2018** study, the 12-month mortality rate was 18.4% overall.

Of 1853 non-metastatic patients at first presentation, 478 (25.8%) patients developed metastases during follow-up with the median DFS was 66.5 months (95% CI, 58.1–74.9). The 3-year DFS rate was 69.4% & 5-year DFS rate was 52.9% for all patients. In **Yekedüz et al, 2022** study, 74.7% of patients developed metastasis & 25.3% were missing.

Of 170 metastatic patients at first presentation, 72 (42.4%) patients developed progression of the disease during follow-up with the median PFS was 26 months (95% CI, 19.9–32.1). The 2-year PFS rate was 53.5%. **Kotsakis et al, 2019** reported that median PFS of the overall population was 22.4 months and all-cause mortality rate was 37.7%.

Conclusion:

Breast cancer is a heterogenous disease that needs to be fully understood to tailor the best strategy to fight and overcome it. Screening programs are needed and defining risk categories will help in designing better screening methods for each category. Registry of cases will help to understand the disease burden in our region so that we become able to better define our problem and find the best solution.

Conflict of interest:

Authors have no conflict of interest to declare.

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