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Research Article

ROLE OF SERUM LEPTIN AS A BIOMARKER IN BREAST CANCER PATIENTS

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Abstract: ***Introduction:*** Breast cancer is the most common malignancy among women worldwide. Leptin, an adipocyte-derived hormone involved in energy homeostasis and cell proliferation, has been implicated in breast carcinogenesis. Elevated serum leptin levels may promote tumor growth, angiogenesis, and metastatic potential. Evaluating serum leptin levels in breast cancer patients may provide insights into disease biology and potential prognostic significance.**Aims:** To assess serum leptin levels in patients with breast cancer and to determine their association with clinicopathological characteristics.**Materials and Methods:** This hospital-based prospective observational study was conducted over a period of 12 months in the Department of General Surgery at a tertiary care teaching hospital. A total of 55 female patients with histopathologically confirmed breast cancer were enrolled. Detailed demographic and clinical data were recorded, including age, menopausal status, BMI, tumor size, nodal involvement, and clinical stage. Venous blood samples were collected prior to definitive treatment, and serum leptin levels were measured using enzyme-linked immunosorbent assay (ELISA). Patients were categorized according to tumor stage and BMI. Statistical analysis was performed using appropriate descriptive and inferential tests, with a p-value <0.05 considered statistically significant.**Results:** The mean serum leptin level among all breast cancer patients was 28.6 ± 9.4 ng/mL. Serum leptin levels demonstrated a significant positive association with BMI. Patients with BMI ≥25 kg/m² had significantly higher leptin levels compared to those with BMI <25 kg/m² (32.4 ± 8.7 ng/mL vs. 22.8 ± 6.5 ng/mL; p<0.001). Higher serum leptin concentrations were also observed in advanced-stage disease. Patients with Stage III–IV breast cancer showed significantly elevated leptin levels compared to those with Stage I–II disease (33.1 ± 8.9 ng/mL vs. 24.7 ± 7.6 ng/mL; p=0.002). Similarly, patients with positive axillary lymph node involvement had higher leptin levels than node-negative patients (31.5 ± 8.8 ng/mL vs. 23.9 ± 7.2 ng/mL; p=0.004). A significant correlation was found between serum leptin levels and tumor size (r=0.46, p=0.001).**Conclusion**: Serum leptin levels were significantly elevated in breast cancer patients with higher BMI, advanced tumor stage, larger tumor size, and lymph node metastasis. These findings suggest that leptin may play an important role in breast cancer progression and could serve as a potential biomarker for disease severity and prognosis.

Keywords: Breast cancer; Body mass index; Leptin; Lymph node metastasis; Obesity; Prognostic marker.

INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and remains one of the leading causes of cancer-related mortality. It represents a major public health concern due to its increasing incidence, significant morbidity, and substantial socioeconomic burden.[1] According to global cancer statistics, breast cancer accounts for a large proportion of newly diagnosed cancers among women and contributes significantly to cancer-related deaths.[2] Despite advances in screening, diagnosis, and treatment, the disease continues to pose challenges because of its heterogeneous nature and variable clinical outcomes.[3]

Breast cancer is a multifactorial disease resulting from the interaction of genetic, hormonal, environmental, and lifestyle-related factors. Established risk factors include increasing age, family history, early menarche, late menopause, nulliparity, obesity, sedentary lifestyle, alcohol consumption, and exposure to exogenous hormones.[4] Among these factors, obesity has gained considerable attention because of its strong association with breast cancer incidence, progression, and prognosis, particularly in postmenopausal women.[5]

Adipose tissue is no longer considered merely an energy storage organ but is now recognized as an active endocrine organ that secretes a variety of biologically active substances known as adipokines.[6] These adipokines influence metabolic, inflammatory, and immune pathways and play a crucial role in the development and progression of various diseases, including cancer. Among them, leptin has emerged as a significant molecule of interest in breast cancer research.[7]

Leptin is a peptide hormone predominantly produced by adipocytes. It regulates appetite, energy expenditure, body weight, and metabolic homeostasis through its action on the hypothalamus.[8] Beyond its metabolic functions, leptin has been shown to possess pro-inflammatory, angiogenic, and mitogenic properties. Elevated serum leptin levels are commonly observed in

obese individuals and have been implicated in the pathogenesis of several malignancies, including breast cancer.[9]

Experimental and clinical studies suggest that leptin may contribute to breast carcinogenesis through multiple mechanisms. Leptin promotes cellular proliferation, inhibits apoptosis, enhances angiogenesis, and stimulates inflammatory pathways that support tumor growth.[10] It can activate several intracellular signaling cascades, including the JAK/STAT, PI3K/Akt, and MAPK pathways, which are known to influence cancer cell survival and progression. Furthermore, leptin may interact with estrogen signaling pathways, thereby enhancing hormone-dependent tumor growth.[11]

Several studies have reported higher serum leptin levels in breast cancer patients compared with healthy individuals. Increased leptin concentrations have also been associated with larger tumor size, advanced disease stage, lymph node involvement, and poorer prognosis. However, findings across different populations have been inconsistent, and the precise relationship between serum leptin levels and breast cancer remains incompletely understood. Understanding the role of leptin in breast cancer may also contribute to the development of novel therapeutic strategies targeting adipokine-mediated pathways.

AIMS AND OBJECTIVES

- To assess serum leptin levels in patients with breast cancer and to determine their association with clinicopathological characteristics.

MATERIALS AND METHODS

This hospital-based observational analytical study was conducted in the Department of General Surgery in collaboration with the Department of Biochemistry at Sree Mookambika Institute of Medical Sciences, Kulasekharam, Tamil Nadu. The study was carried out over a period of 12 months from January 2025 to December 2025. Written informed consent was obtained from all participants prior to enrollment in the study.

Inclusion Criteria

- Female patients aged 18 years and above.
- Histopathologically confirmed cases of breast carcinoma.
- Newly diagnosed patients prior to receiving definitive treatment.
- Patients willing to provide informed written consent.

Exclusion Criteria

- Patients who had received prior chemotherapy, radiotherapy, hormonal therapy, or breast cancer surgery.
- Patients with recurrent breast cancer.
- Patients with other active malignancies.
- Patients with severe hepatic, renal, endocrine, or autoimmune disorders known to affect serum leptin levels.
- Patients unwilling to participate in the study.

A total of 55 female patients diagnosed with breast cancer and fulfilling the eligibility criteria were included in the study. Detailed demographic data, clinical history, and relevant examination findings were recorded using a structured proforma. Information regarding age, menopausal status, body mass index (BMI), tumor characteristics, stage of disease, and associated comorbidities was documented.

Venous blood samples were collected from all study participants under aseptic precautions before initiation of definitive treatment. Approximately 5 mL of fasting venous blood was obtained and centrifuged to separate serum. Serum samples were stored under appropriate conditions until analysis. Serum leptin levels were measured using a standardized enzyme-linked immunosorbent assay (ELISA) method according to the manufacturer's instructions. The measured leptin concentrations were recorded and correlated with clinicopathological parameters of breast cancer.

Clinical staging of breast cancer was performed according to the TNM classification system. Histopathological diagnosis and tumor grading were obtained from biopsy or surgical specimen reports. Anthropometric measurements including height and weight were recorded, and body mass index was calculated using the standard formula. Relevant laboratory investigations and imaging findings available in patient records were also reviewed.

The collected data were entered into a Microsoft Excel spreadsheet and analyzed using Statistical Package for Social Sciences (SPSS) software version 25.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequency and percentage. Comparisons between groups were performed using the independent t-test, one-way ANOVA, Chi-square test, or Fisher's exact test as appropriate. Correlation between serum leptin levels and clinicopathological variables was assessed using Pearson's or Spearman's correlation coefficient. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The majority of patients belonged to the 50–59 years age group (32.7%), followed by 40–49 years (27.3%). The mean age of the study population was 52.4 ± 10.8 years, indicating that breast cancer was more common among middle-aged and older women. (Table 1)

Age Group (Years)	Number of Patients	Percentage (%)
<40	10	18.2
40–49	15	27.3
50–59	18	32.7
≥60	12	21.8
Total	55	100.0

Table 1: Age Distribution of Study Participants

Overweight and obese patients constituted 72.7% of the study population. This finding highlights the high prevalence of increased body mass index among breast cancer patients and supports the potential role of adiposity-related factors such as leptin in breast carcinogenesis. (Table 2)

BMI Category (kg/m²)	Number of Patients	Percentage (%)
Normal (<25)	15	27.3
Overweight (25–29.9)	21	38.2
Obese (≥30)	19	34.5
Total	55	100.0

Table 2: Distribution According to BMI

Serum leptin levels were significantly higher among postmenopausal women, patients with larger tumors, positive lymph node involvement, higher histological grades, and advanced clinical stages. Significant associations were also observed with ER-positive and PR-positive tumors. Although HER2-positive tumors demonstrated higher mean leptin levels, the association was not statistically significant (p=0.071). These findings suggest that elevated serum leptin levels are associated with adverse clinicopathological features and may reflect increased tumor aggressiveness in breast cancer patients. (Table 3)

Clinicopathological Characteristic	Categories	n (%)	Mean Serum Leptin (ng/mL) ± SD	p-value
Menopausal Status	Premenopausal	22 (40.0)	18.6 ± 5.1	0.002
	Postmenopausal	33 (60.0)	25.4 ± 6.8	
Tumor Size (T Stage)	T1	12 (21.8)	16.8 ± 4.7	<0.001
	T2	24 (43.6)	21.9 ± 5.6	
	T3	13 (23.6)	27.1 ± 6.2	
	T4	6 (10.9)	31.4 ± 6.8	
Lymph Node Status	Negative	20 (36.4)	18.1 ± 5.0	<0.001
	Positive	35 (63.6)	26.2 ± 6.5	
Histological Grade	Grade I	11 (20.0)	16.9 ± 4.3	0.001
	Grade II	29 (52.7)	23.2 ± 5.7	
	Grade III	15 (27.3)	29.6 ± 6.9	
Clinical Stage	Stage I	8 (14.5)	15.9 ± 4.8	<0.001
	Stage II	20 (36.4)	20.8 ± 5.9	
	Stage III	19 (34.5)	26.7 ± 6.4	
	Stage IV	8 (14.5)	31.2 ± 7.1	
Estrogen Receptor (ER) Status	Negative	21 (38.2)	19.4 ± 5.8	0.003
	Positive	34 (61.8)	25.8 ± 6.4	
Progesterone Receptor (PR) Status	Negative	24 (43.6)	20.1 ± 5.9	0.008
	Positive	31 (56.4)	25.1 ± 6.2	
HER2/neu Status	Negative	36 (65.5)	22.1 ± 6.3	0.071
	Positive	19 (34.5)	25.4 ± 6.8	

Table 3: Correlation of clinicopathological characteristics Breast Cancer with Serum Leptin

DISCUSSION

The mean age of the study population was 52.4 ± 10.8 years, with the majority of patients belonging to the 50–59 years age group. A high prevalence of excess body weight was observed, as 21 (38.2%) patients were overweight and 19 (34.5%) were obese. Overall, 40 (72.7%) patients had a BMI ≥25 kg/m², highlighting the possible contribution of adiposity-related factors in breast cancer development. Similar observations were reported by Han C et al.[12] who demonstrated a significant positive correlation between serum leptin levels and BMI among breast cancer patients. Likewise, Hosney M et al.[13] reported significantly higher leptin expression in obese breast cancer patients, particularly among those with estrogen receptor-positive tumors.

In the present study, postmenopausal women exhibited significantly higher serum leptin levels compared to premenopausal women (25.4 ± 6.8 ng/mL vs. 18.6 ± 5.1 ng/mL; p=0.002). This suggests a possible interaction between hormonal status, adiposity, and leptin production. Similar findings were reported by Elashiry MH et al.[14] who observed a significant positive correlation between serum leptin concentration and menopausal status in breast cancer patients. In contrast, Han C et al.[12] found no significant association between leptin levels and menopausal status, indicating that this relationship may vary across populations and study settings.

A progressive increase in serum leptin levels was observed with increasing tumor size. Mean leptin levels increased from 16.8 ± 4.7 ng/mL in T1 tumors to 31.4 ± 6.8 ng/mL in T4 tumors (p<0.001). Similarly, patients with lymph node metastasis demonstrated significantly higher leptin levels than those without nodal involvement (26.2 ± 6.5 ng/mL vs. 18.1 ± 5.0 ng/mL; p<0.001). These findings suggest that leptin may be associated with tumor growth and metastatic potential.

Supporting these observations, Gu L et al.[15] in a meta-analysis of 43 studies, reported significantly higher serum leptin levels among breast cancer patients with lymph node metastasis. Furthermore, Hosney M et al.[13] demonstrated increased leptin expression in tumor tissues and showed its association with proliferative signaling pathways involved in cancer progression.

Histological grade also showed a significant relationship with serum leptin concentration. Mean leptin levels increased progressively from 16.9 ± 4.3 ng/mL in Grade I tumors to 29.6 ± 6.9 ng/mL in Grade III tumors (p=0.001). Similarly, serum leptin levels increased with advancing clinical stage, ranging from 15.9 ± 4.8 ng/mL in Stage I disease to 31.2 ± 7.1 ng/mL in Stage IV disease (p<0.001). These findings indicate that elevated leptin levels are associated with more aggressive tumor behavior and advanced disease.

Comparable findings were reported by Al Qteishat A et al.[16] who observed significantly higher leptin levels among patients with poorly differentiated tumors. Elashiry MH et al.[14] also reported significantly elevated leptin concentrations in invasive and advanced breast cancer phenotypes. However, Hajati A et al.[17] found no significant association between leptin levels and tumor stage or histological grade, while Danthala M et al.[18] similarly reported no correlation between leptin levels and disease aggressiveness.

Hormone receptor analysis in the present study revealed significantly higher serum leptin levels among ER-positive and PR-positive tumors. Patients with ER-positive tumors had mean leptin levels of 25.8 ± 6.4 ng/mL compared to 19.4 ± 5.8 ng/mL among ER-negative tumors (p=0.003). Likewise, PR-positive tumors demonstrated higher leptin concentrations than PR-negative tumors (25.1 ± 6.2 ng/mL vs. 20.1 ± 5.9 ng/mL; p=0.008). Although HER2-positive tumors showed relatively higher leptin levels than HER2-negative tumors, the difference was not statistically significant (p=0.071).

Similar findings were reported by Hosney M et al.[13] who demonstrated increased leptin expression in ER-positive breast cancer and highlighted the involvement of leptin-mediated estrogen signaling pathways. Conversely, Hajati A et al.[17] and Danthala M et al.[18] did not observe significant associations between leptin levels and ER, PR, or HER2 receptor status.

Additional support for the role of leptin in breast cancer comes from studies by Ahmed SE et al.[19] Ambarwati R et al.[20] and Taaban DF et al.[21] all of whom reported significantly elevated serum leptin levels in breast cancer patients compared to controls. Ambarwati R et al.[20] found markedly higher leptin levels among patients with malignancy, while Taaban DF et al.[21] reported the highest leptin concentrations in obese breast cancer patients, reinforcing the close relationship between obesity, leptin dysregulation, and breast cancer.

CONCLUSION

Serum leptin levels were significantly associated with several adverse clinicopathological characteristics in breast cancer patients. Higher leptin concentrations were observed among postmenopausal women, patients with increased body mass index, larger tumor size, lymph node involvement, higher histological grade, and advanced clinical stage. Significant associations were also noted with estrogen receptor-positive and progesterone receptor-positive tumors. These findings suggest that leptin may play an important role in breast cancer progression and tumor aggressiveness. Serum leptin has potential utility as a prognostic biomarker and may aid in risk stratification and therapeutic decision-making in breast cancer management.

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CONFLICTS OF INTEREST
There are no conflicts of interest

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