ORIGINAL ARTICLE

CONTENTS

Correlation of serum tumor markers (CEA and CA15-3) with clinicopathological features in breast cancer patients in Iraq

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ABSTRACT

Aim: This research is aimed at looking into the relationship between the levels of the markers and the clinicopathological features of breast cancer patients in Iraq.

Materials and Methods: The study population consisted of 150 breast cancer patients in a cross-sectional correlation study. Demographic, clinical, and pathological data were collected including molecular subtypes, tumor staging and grading. The serum levels of CEA and CA15-3 were determined and the results correlated with patient characteristics. The statistical methods employed were ANOVA, t-tests, and Pearson correlation.

Results: Out of the total patients, 98.5% were females, 52.9% were over 50 years of age and 79.6% were married. The Luminal types were the most frequent (The Luminal types were the most frequent (Luminal A: 45.3%, Luminal B: 36.5%) while the triple-negative (10.1%) and HER2-positive (8.1%) subtypes were the least common. There was an increase in serum levels of CEA and CA15-3 in advanced tumor stage and high grade cancer, a significant difference in CA15-3 levels between the age groups (p=0.010). The marker levels varied according to the molecular subtypes with Luminal A demonstrating a greater CEA and Luminal B showing a higher CA15-3.

Conclusions: The levels of serum CEA and CA15-3 are indicative of the breast cancer patients' tumor stage, grade, and molecular subtype. The regular monitoring of these markers may provide better understanding of the disease progress and help in the formulation of patient-specific management plans.

KEYWORDS: breast cancer, CEA, CA15-3, molecular subtypes, tumor markers

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INTRODUCTION

Breast cancer still holds the number one spot as the most common cancer in women worldwide and it is still one of the major contributors to the cancer-related deaths [1-3]. The management of the disease is highly dependent on early detection and monitoring of its progression [2, 10]. Serum tumor markers like carcinoembryonic antigen (CEA) and cancer antigen 15-3 (CA15-3) are frequently used to evaluate disease activity, the effectiveness of treatments, and risk of recurrence [6, 9]. The presence of these tumor markers indicates that cancer cells are either releasing or the body is producing them in response to the tumor. Among them, CA15-3 derived from the MUC1 gene is found quite often in breast cancer and that too primarily in advanced stages, while CEA is considered to be a nonspecific marker linked to many adenocarcinomas [4, 6]. Therefore, higher blood levels of these markers are associated with larger tumors, presence of cancer in lymph nodes, and spread of disease to distant sites [2, 7]. Molecular subtyping has turned out to be an effective method for breast cancer classification. Luminal A, Luminal B, HER2-rich, and triple-negative are the main subtypes. These subtypes have different prognoses, responses to treatments, and biomarker profiles [11, 12]. Some studies indicate that the levels of serum tumor markers might differ based on the subtype, thus suggesting their potential role in clinical decision-making [14, 22]. Limited studies in Iraq have assessed the association between the levels of serum CEA and CA15-3 and the characteristics of breast cancer. The CEA/CA15-3 serum profile stands for one of the main clinical variables determining the prognosis of breast cancer. Moreover, the monitoring of these markers can lead to the development of personalized therapy based on the patient's individual profile [5-8, 16-19]. Internationally, CEA and CA15-3 have a clinically proven utility in breast cancer management; however, they are not routinely and systematically monitored in Iraq. Apart from being cost-effective, the monitoring of these tumor markers which are very much capable of providing valuable information in real-time disease

surveillance and treatment response assessment has been hindered by the resource limitations, the absence of universally accepted guidelines, and the fluctuation of laboratory facilities. The aforementioned situation underscores the necessity for clinical trials aimed at producing the evidence-based recommendations necessary for integrating serum tumor marker monitoring into the routine clinical workflow for breast cancer patients in Iraq. In addition to the already mentioned, in the case of the diagnostics of the disease, the markers' testing is a cheap and non-invasive procedure, which supports the results obtained by imaging or histopathology in the early detection and prognostication of the disease [15, 17]. CA15-3 has been connected with the recurrence and spread of cancer tumors, while CEA is a marker for aggressive phenotypes of tumors [18, 20]. Using both markers together might make the medical decision-making process better, especially in places with limited resources [21]. Previous studies done in Iraq have revealed a variety of tumor subtypes and different levels of marker expression. This situation suggests that there is a need for an extensive correlation analysis via different demographic as well as clinicopathological factors [3, 5, 19]. Correlation studies are thus necessary not only for the development of guidelines and therapeutic strategies in accordance with the local population but also for the validation of the generalization from other populations.

AIM

The present investigation is designed as a correlation analysis aimed at the evaluation of relationships between the levels of serum markers and the factors of age, tumor grade, stage, and molecular subtypes. The understanding gained could streamline the monitoring, follow-up, and planning of treatment for breast cancer patients in Iraq.

MATERIALS AND METHODS

STUDY DESIGN AND POPULATION

A cross-sectional correlation study was held in oncological institutions across Iraq by involving 150 breast cancer patients. Histopathology-confirmed breast carcinoma with serum biomarker data was the foremost inclusion criterion. Patients with other malignancies were not included. Gender Distribution and Analysis: The study group included 148 females (98.5%) and only 2 males (1.5%). Male patients were totally eliminated from those statistical analyses of tumor markers and clinicopathological correlations due to not only the significant biological and clinical differences in breast cancer between genders but also the already small sample size of male patients which could not yield a meaningful subgroup analysis. Even so, all the results and comparisons, including statistical ones, still refers to the only female group (n=148) the results come from. Treatment Information: The subjects of the research were all partaking in the standard treatment procedures which were in accordance with the Iraqi federal oncology guidelines. The therapies were different based on the molecular subtype and the stage of disease:

- Luminal A/B: Endocrine therapy (Tamoxifen or Aromatase inhibitors) ± chemotherapy (regimens based on anthracycline or taxane)
- HER2-positive: Targeted therapy (Trastuzumab when available) + chemotherapy
- Triple-negative: Chemotherapy (regimens based on anthracycline and/or taxane)

Surgical options (mastectomy or lumpectomy) were directly determined by the tumor's stage and whether it was operable. Moreover, radiation therapy was granted post-surgically whenever it was clinically necessary.

DATA COLLECTION

Demographic and clinical data such as age, sex, marital status, education, and occupation, living area, and tumor stage, grade, and molecular type were extracted from medical records.

SERUM MARKER MEASUREMENT

Measurement of serum markers Serum levels of CEA (µg/L) and CA15-3 (U/mL) were determined through standard procedures following manufacturer's guidelines with the implementation of accurate quality control measures.

Timing of the measurement of markers: blood specimens for analysis of tumor markers were drawn at the following time intervals: pre-treatment baseline: 45% of patients (n=66) - markers assessed at the time of initial diagnosis before any therapeutic intervention; during active treatment: 38% of patients (n=56) - markers assessed during chemotherapy cycles (usually between cycles or during mid-treatment evaluations); post-treatment follow-up: 17% of patients (n=26) - markers assessed during monitoring after completion of primary treatment.

STATISTICAL ANALYSIS

This study used a test of independence to evaluate the association between serum tumor markers and

Table 1. Demographic and epidemiological features of breast cancer patients

Feature	Frequency or Mean ± SE [%]
Gender	Male: 1.5; Female: 98.5
Age (years)	51.35 ± 1.06
Age groups	<50: 47.1; >50: 52.9
Diagnosis period	<5 years: 88.3; >5 years: 14.7
Marital status	Married: 79.6; Single: 4.4; Widow: 11.8; Divorced: 4.4
Education	Illiterate: 41.3; Primary: 25.2; Intermediate: 8.8; Secondary: 10.3; Diploma: 5.9; Higher diploma: 2.9; Bachelor: 5.9
Occupation	Not employed: 93.6; Employee: 6.5; Retired: 1.5
Residence	Rural: 44.3; Urban: 54.9

Source: Compiled by the authors of this study

Table 2. Cancer stage distribution among molecular subtypes

Cancer Stage	Luminal A [%]	Luminal B [%]	Triple-negative [%]	HER2 [%]	p-value
T2	55.6	54.5	33.3	0.0	0.05
T3	33.3	36.4	66.7	0.0	
T4	11.1	9.1	0.0	100.0	
Total	100.0	100.0	100.0	100.0	

Source: Compiled by the authors of this study

Table 3. Tumor grade distribution among molecular subtypes

Cancer grade	Luminal A [%]	Luminal B [%]	Triple-negative [%]	HER2 [%]	p-value
G1	0.0	14.3	0.0	25.0	0.429
G2	54.5	71.4	50.0	50.0	
G3	27.3	14.3	50.0	25.0	
G4	18.2	0.0	0.0	0.0	
Total	100.0	100.0	100.0	100.0	

Source: Compiled by the authors of this study

clinicopathological features. Based on international oncology guidelines, the following reference (cut-off) values were used:

- CA15-3 > 25 U/mL = Elevated
- CEA > 5 µg/L = Elevated

These cut-offs were incorporated into all statistical comparisons.

- Continuous variables (CEA and CA15-3) were analyzed using:
- ANOVA (comparison across ≥3 groups)
- Independent t-test (comparison across 2 groups)
- Categorical variables (elevated vs. non-elevated markers) were analyzed using:
- Chi-square test of independence
- Fisher's exact test when expected frequencies were <5
- Significance threshold: $p < 0.05$

Table 1 shows demographic and epidemiological features in the studied group of breast cancer patients. Most patients were female, married, and from urban areas.

Most patients were female, married, and from urban areas.

Table 2 shows cancer stage distribution among molecular subtypes. The result of the p-value (0.05) was from a Chi-square independence test, which showed that there was a significant statistical association between the different molecular subtypes and the TNM tumor stage at diagnosis.

HER2-positive tumors predominantly present at T4 stage, whereas triple-negative tumors were mainly at T3.

There was a significant difference in the distribution of cancer stages according to molecular subtypes ($p = 0.05$). The majority of HER2-positive tumors were diagnosed at T4 stage (100%), while the triple-negative were mainly at T3 (66.7%), and the Luminal subtypes had the highest frequency at T2 stage (Table3).

Table 3: Luminal subtypes mostly exhibited G2 grade, while triple-negative showed higher G3 frequency.

Luminal subtypes predominantly exhibited G2 grade, with Luminal B showing the highest proportion (72.2%), followed by Luminal A (55.2%). Triple-negative tumors

Table 4. Serum CEA and CA15-3 levels by cancer stage

Cancer stage	CEA [µg/L] Mean ± SE	CA15-3 [U/mL] Mean ± SE	p-value (CEA)	p-value (CA15-3)
T2	0.83 ± 0.33	16.26 ± 4.06	0.041	0.032
T3	2.05 ± 1.55	203.34 ± 171.09		
T4	3.50 ± 1.10	56.69 ± 35.55		

Source: Compiled by the authors of this study

Table 5. Serum CEA and CA15-3 levels by tumor grade

Tumor grade	CEA [µg/L] Mean ± SE	CA15-3 [U/mL] Mean ± SE	p-value (CEA)	p-value (CA15-3)
G1	0.50 ± 0.10	18.70 ± 5.12	0.021	0.044
G2	13.09 ± 11.27	99.39 ± 48.81		
G3	47.15 ± 44.32	51.32 ± 27.83		
G4	28.00 ± 14.50	45.00 ± 20.30		

Source: Compiled by the authors of this study

Table 6. Serum CEA and CA15-3 levels by molecular subtype

Subtype	CEA [µg/L] Mean ± SE	CA15-3 [U/mL] Mean ± SE	p-value (CEA)	p-value (CA15-3)
Luminal A	74.59 ± 6.43	78.51 ± 7.61	0.008	0.011
Luminal B	13.41 ± 11.20	131.85 ± 8.22		
Triple-negative	0.50	25.69		
HER2	2.05	21.84 ± 3.52		

Source: Compiled by the authors of this study

Table 7. Relationship of age with serum markers

Age group [years]	CEA [µg/L] mean ± SE	CA15-3 [U/mL] mean ± SE	p-value
<50	55.08 ± 43.69	144.56 ± 53.94	0.160
>50	6.41 ± 4.30	27.01 ± 5.25	0.010

*$p < 0.05$ considered statistically significant
Source: Compiled by the authors of this study

Table 8. Relationship of diagnosis period with serum markers

Diagnosis Period [years]	CEA [µg/L] Mean ± SE	CA15-3 [U/mL] Mean ± SE	p-value (CEA)	p-value (CA15-3)
<5	25.63 ± 17.39	78.40 ± 24.76	0.327	0.292
>5	1.16	10.37 ± 3.67		

Source: Compiled by the authors of this study

demonstrated a higher frequency of G3 grade (46.7%) compared to other subtypes. Grade 4 tumors were observed exclusively in the Luminal A subtype (17.9%). No statistically significant difference was found in grade distribution across molecular subtypes ($p = 0.429$) (Table 4).

Table 4: A statistically significant difference was found between cancer stages for both CEA and CA15-3, indicating that tumor markers increase proportionally with tumor advancement ($p < 0.05$ for both markers).

A statistically significant difference was found between cancer stages for both CEA and CA15-3, indicating that tumor markers increase proportionally with tumor advancement ($p < 0.05$ for both markers) (Table5).

Table 5: CEA levels showed statistically significant elevation with increasing tumor grade ($p = 0.021$). CA15-3 values differed significantly across grades ($p = 0.044$), with the highest levels in G2 tumors.

CEA levels showed statistically significant elevation with increasing tumor grade ($p = 0.021$). CA15-3 values differed significantly across grades ($p = 0.044$), with the highest levels in G2 tumors. Significant differences were detected between molecular subtypes for both CEA ($p = 0.008$) and CA15-3 ($p = 0.011$). Luminal A subtype had the highest CEA, while Luminal B subtype had the highest CA15-3 (Table 6).

Table 6: Significant differences were detected between molecular subtypes for both CEA ($p = 0.008$) and

CA15-3 (p = 0.011). Luminal A subtype had the highest CEA, while Luminal B subtype had the highest CA15-3.

At a statistically significant level (p=0.010), patients who were less than 50 years of age (<50 years) had very high CA15-3 levels as compared to the older patients (>50 years), on the other hand, the CEA levels did not show any age-related differences as such (p=0.160). This could imply different patterns of CA15-3 secretion or different tumor biology with respect to age (Table 7).

Table 7: Younger patients exhibited higher CA15-3 levels, with significant differences.

No statistically significant differences were found for either marker according to diagnosis duration (p > 0.05), although levels were higher among recently diagnosed patients (Table 8).

Table 8: No statistically significant differences were found for either marker according to diagnosis duration (p > 0.05), although levels were higher among recently diagnosed patients.

DISCUSSION

In this report, it is shown that the serum tumor markers CEA and CA 15-3 are closely related to the clinical and pathological characteristics of breast cancer patients. The demographic study indicated that the majority of the participants were women older than 50 which conforms to the worldwide epidemiological trends [1-3]. The analysis of tumor markers revealed the presence of higher levels of CEA and CA15-3 in patients with advanced tumor stages and grades thus corroborating with the previous studies that these markers indicate the burden and aggressiveness of the tumor [9, 6, 4, 2]. CA15-3 levels were particularly high among younger patients probably indicating age-related differences in tumor biology or immune response [5, 8, 13, 15]. The molecular subtypes distribution revealed Luminal A as the most prevalent one and the other subtypes as Luminal B, triple-negative, and HER2-enriched. The levels of the markers varied according to the subtype, with Luminal A being the highest CEA producer and Luminal B being the biggest CA15-3 producer, which agrees with earlier studies [12-14, 21-22]. Correlation analysis showed that CEA and CA15-3 could be used as non-invasive markers for the evaluation of tumor characteristics and the prediction of prognosis. Yet, the marker levels were not consistently high in all stages and subtypes, making it even more necessary to take both biomarkers and imaging into account [7, 15, 17, 20]. The current investigation points to the clinical value of serum tumor markers monitoring in parallel with molecular subtyping for the purpose of tailoring treatment strategies more precisely. The combination of CEA and CA15-3 might be a good tool for revealing aggressive tumor cases earlier, monitoring their recurrence, and being a decisive factor in therapy [10-11, 18-19]. This study demonstrated significant associations between serum tumor markers (CEA and CA15-3) and several clinicopathological characteristics of breast cancer patients. The incorporation of reference cut-off values (CEA >5 µg/L, CA15-3 >25 U/mL) allowed for the application of tests of independence, strengthening the statistical interpretation of disease correlations. The significant differences observed across tumor stages indicate that both markers increase proportionally with disease progression, consistent with global findings [6, 9, 12]. Tumor grade also showed statistically significant elevation of markers, particularly CEA (p=0.021) and CA15-3 (p=0.044), suggesting aggressive histopathological behavior reflected through serum biomarkers. Molecular subtypes displayed robust marker variability. Luminal A showed the highest CEA levels, while Luminal B had highest CA15-3, with both relationships being statistically significant (p < 0.05). These findings align with previous molecular biology studies identifying subtype-specific secretory behavior [12, 14, 22]. Such results bring the attention to the necessity of community-based studies since the Iraqi patients had different marker profiles according to their age, stage, and molecular subtype [3, 5, 16, 21].

CONCLUSIONS

The serum tumor marker CEA and CA15-3 are significant indicators for keeping track of the breast cancer process and they are associated with the tumor stage, grade, and molecular subtype. Serum tumor markers CEA and CA15-3 demonstrate significant associations with tumor stage, grade, and molecular subtype in breast cancer patients, serving as valuable indicators for disease monitoring and prognostication. However, routine and systematic measurement of these markers is not currently implemented in standard clinical practice in Iraq due to limited resources, lack of standardized protocols, and inconsistent laboratory availability. The integration of regular CEA and CA15-3 monitoring into routine clinical assessments is strongly recommended, as it could substantially improve early detection of disease progression, optimize treatment planning, and enhance prognostic accuracy for breast cancer patients in Iraq. Establishing evidence-based guidelines for the systematic use of these cost-effective biomarkers should be a priority for improving breast cancer care in resource-limited settings.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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