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Serum Tumor Markers CA15-3 and CEA for Early Breast Cancer Detection in a Low-Resource Population: A Cross-Sectional Study from Al-Jufra, Libya

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ABSTRACT

This study aimed to evaluate the role of the tumor markers CA15-3 and carcinoembryonic antigen (CEA) in contributing to the early detection of breast cancer among women in Al-Jufra Municipality. The data of this study were extracted from 92 women diagnosed with breast cancer and control group of 10 healthy women. Demographic and clinical data were collected, serum levels of CA15-3 and CEA were measured using the Cobas e 411 Analyzer. Data were analyzed using the Independent Samples t-test. The results demonstrated a significant increase in both CA15-3 and CEA levels in the patients compared with the control group. The mean CA15-3 level was 43.02 U/mL versus 6.19 U/mL in control group ($p< 0.001$), while the mean CEA level was 6.88 ng/mL in the patient compared with 1.78 ng/mL in controls ($p< 0.001$). Following treatment, CA15-3 levels showed a significant reduction, with a mean value of 19.33 U/mL ($p< 0.001$). Nevertheless, CA15-3 levels remained significantly higher than those observed in the control group ($p < 0.01$). In contrast, CEA levels did not exhibit a significant decrease after treatment ($p = 0.965$), compared with the control group after treatment ($p = 0.096$). The study concludes that CA15-3 was a potential marker for the presence of breast cancer and for evaluating treatment effectiveness compared to CEA marker. These findings highlight the potential role of CA15-3 serum tumor markers as supportive tools in breast cancer management in low-resource settings. Further studies using large sample sizes are needed.

المؤشرات الورمية المصلية CA15-3 وCEA للكشف المبكر عن سرطان الثدي في مجتمع محدود الموارد: دراسة مقطعية من الجفرة، ليبيا

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الكلمات المفتاحية

المؤشرات الورمية المصلية
CA15-3
CEA
سرطان الثدي
علم الأورام
ليبيا

الملخص

هدفت هذه الدراسة إلى تقييم دور المؤشر الورمي CA15-3 والمستضد السرطاني (CEA) في المساهمة في الكشف المبكر عن سرطان الثدي بين النساء في بلدية الجفرة. استُخلصت بيانات الدراسة من 92 امرأة تم تشخيصهن بسرطان الثدي، بالإضافة إلى مجموعة ضابطة مكونة من 10 نساء سليمة. تم جمع البيانات الديموغرافية والسريرية، وكذلك قياس مستويات CA15-3 وCEA في المصل باستخدام جهاز التحليل Cobas e 411 Analyzer. تم تحليل البيانات باستخدام اختبار (t) لعينتين مستقلتين. أظهرت النتائج ارتفاعًا معنويًا في مستويات كل من CA15-3 وCEA لدى المريضات مقارنة بالمجموعة الضابطة. بلغ متوسط مستوى CA15-3 (43.02 وحدة/مل) مقابل (6.19 وحدة/مل) في المجموعة الضابطة ($p < 0.001$)، بينما بلغ متوسط مستوى CEA (6.88 نانوغرام/مل) لدى المريضات مقابل (1.78 نانوغرام/مل) لدى الضوابط ($p < 0.001$). بعد تلقي العلاج، أظهرت مستويات CA15-3 انخفاضًا معنويًا، حيث بلغ المتوسط (19.33 وحدة/مل) ($p < 0.001$)، إلا أنها بقيت أعلى بشكل ملحوظ مقارنة بالمجموعة الضابطة ($p < 0.01$). في المقابل، لم تُظهر مستويات CEA انخفاضًا ذا دلالة إحصائية بعد العلاج ($p = 0.965$)، كما لم تختلف بشكل معنوي مقارنة بالمجموعة الضابطة بعد العلاج ($p = 0.096$). خلصت الدراسة إلى أن CA15-3 يُعد مؤشرًا مهماً للإصابة بسرطان الثدي وكذلك لتقييم فعالية العلاج مقارنةً بمؤشر CEA وتبرز هذه النتائج الدور المحتمل للمؤشر الورمي المصلي CA15-3 كأداة داعمة في إدارة سرطان الثدي في البيئات محدودة الموارد. كما توصي الدراسة بإجراء مزيد من الأبحاث باستخدام عينات أكبر حجمًا

Introduction

Breast cancer remains the most prevalent malignancy among women worldwide, accounting for higher incidence and mortality rates than any other cancer type [1]. World Health Organization estimates that more than 2.3 million new breast cancer cases occur each year while global deaths from the disease exceed 685,000 fatalities [2,3]. It has been reported that early breast cancer detection remains a significant goal to improve treatment success and survival outcomes

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compared to advanced stages [4]. The results confirm that early cancer detection functions as essential method to decrease breast cancer deaths while enhancing patient treatment results. The field of digital health technology and medical imaging has made significant progress yet there remains a critical need for affordable and practical and groundbreaking diagnostic solutions that will improve breast cancer detection and treatment results [5]. Healthcare professionals use conventional diagnostic imaging techniques which include chest radiography and hepatic ultrasonography and skeletal X-ray imaging and computed tomography (CT) to detect cancer and determine its stage. The imaging techniques require specialized equipment and technical know-how which lead to expensive costs that most institutions cannot meet. The need for these specialized resources makes it impossible to deliver services in remote areas which causes delays in diagnosing patients and starting their essential medical care [6,7].The use of serum tumor markers as non-invasive biomarkers has proven to be effective for supporting cancer diagnosis and treatment assessment. The tests serve as effective tools for tracking cancer progression because they can be repeated and produce consistent results at an affordable cost [8,9]. The medical field uses carcinoembryonic antigen (CEA) and cancer antigen 125 (CA-125) and cancer antigen 15-3 (CA15-3) as standard tumor markers to track disease development and evaluate treatment success. The clinical value of these biomarkers in breast cancer patient monitoring and treatment evaluation has been studied in recent research studies [10]. The medical community has recognized CA15-3 and CEA tumor markers as effective tools for identifying breast cancer in its early stages because of their vital role in decreasing death rates while improving patient outcomes through timely detection. The systematic review published in 2025 in a Scopus-indexed journal showed that multi-biomarker panels increase both sensitivity and specificity for detecting early-stage cancer compared to single biomarkers. The medical field currently uses CA15-3 and CEA for monitoring diseases and detecting relapses but new research indicates that both tests may help identify early-stage breast cancer when used with imaging tests and other diagnostic methods [11].

The studies conducted in Libya at both national and regional levels prove that breast cancer detection rates improve when diagnostic methods combine tumor markers with standard screening techniques. The panels still need more research to prove their usefulness for early detection because their diagnostic capabilities change depending on the biological characteristics of tumors and the stage of diseases and the methods used for implementation [11,12]. The study intends to assess the importance of the serum tumor markers as early breast cancer detection tools since the region lacks sufficient advanced diagnostic and screening facilities.

Methodology

Study Design

A descriptive cross-sectional study was designed to determine whether specific serum tumor markers could serve as additional methods for early detecting of breast cancer at its initial stages. The research site was Al-Jufra Municipality which exists in central of Libya and contains five principal urban centers. An oncology unit opened in Al-Jufra during 2022 to provide treatment and monitoring services for breast cancer patients in Aljufra Municipality.

Study Population

The required information were collected from 92 breast cancer patient, in addition to a control group which consisted of 10 women who had no breast cancer symptoms and no history of the disease. The confirmation of the diagnosis of breast cancer cases was done by, including the radiological findings from computed tomography, mammography, and magnetic resonance imaging. Furthermore, the serum levels of the tumor markers cancer antigen 15-3 (CA15-3) and carcinoembryonic antigen (CEA) were evaluated. The analysis of all the tumor markers was done using the Cobas e 411 immunoassay analyzer (disk system).

Ethical Considerations

The research followed the Declaration of Helsinki (2013 revision) principles which govern studies involving human subjects. All control group participants provided written permission after receiving detailed information about the study aim and methods. a retrospective study was conducted on breast cancer patient data which they obtained from medical records while maintained full confidentiality

Statistical Analysis

The independent samples t-test was used to examine differences in mean values between two groups. The study conducted to compare mean tumor marker levels from two different patient groups as following: firstly, compared mean tumor marker levels which patients showed before their treatment started against the control group. Secondly, compared mean tumor marker levels which patients showed after their treatment ended against the control group. The third compared mean tumor marker levels which patients showed before their treatment started against their levels after treatment. Statistical differences between groups were evaluated using independent samples t-tests, with a p-value < 0.05 considered as statistical significance.

Results

Analysis of Tumor Markers Before Treatment

Table 1 shows the descriptive statistics of the tumor markers CA15-3 and CEA. The data showed that the mean serum level of CA15-3 in women with newly diagnosed breast cancer was 43.02 U/mL, which was significantly higher than the cutoff value of the assay. The standard deviation was 19.98, showing moderate variability in the levels of CA15-3. The range was 10.5 to 85.75 U/mL, showing a large difference between the highest and lowest levels. For CEA, the mean in women with breast cancer was 6.88 ng/mL, with a standard deviation of 6.75, showing a wider range of variability in the levels of CEA compared to CA15-3. The range of CEA levels was 29.87 ng/mL, showing a large variability in the serum levels of CEA among the patient.

Table 1: Descriptive statistics (mean, standard deviation, and range) of serum CA15-3 and CEA levels prior to initiation of the treatment protocol

Variable	Mean	Standard deviation	Range
CA15-3	43.02 U/mL	19.98	75.25
CEA	6.88 ng/mL	6.75	29.87

Tumor Marker Analysis in the Control Group

Table 2 shows the descriptive statistics of serum tumor marker concentrations in healthy women with no past history of breast cancer. The average serum concentration of CA15-3 and CEA was 6.19 U/mL and 0.52 ng/mL, respectively, which was lower than the respective cutoff values. The table also lists the standard deviations and ranges of the tumor markers, which indicate the small variability of the tumor markers in healthy individuals.

Tumor Marker Analysis Post-Treatment

Table 3 shows the descriptive statistics of serum tumor markers CA15-3 and CEA in breast cancer patients after treatment. The data showed a substantial reduction in the mean values of both CA15-3 and CEA compared to their pre-

Table 2: Descriptive statistics (mean, standard deviation, and range) of serum CA15-3 and CEA levels in healthy control women.

Variable	mean	standard deviation	Range
CA-15.3	6.19 U/mL	1.84	5.6
CEA	1.78 ng/mL	0.52	1.3

treatment levels, indicating a positive response to the treatment administered. In the case of CA15-3, the mean value of serum levels was 19.33 U/mL with a standard deviation of 12.06, indicating that most patients had returned to the normal range (<23 U/mL). The range observed was 38.0 U/mL, indicating variability in the response to treatment, where some patients showed a significant reduction in levels, while others showed relatively high levels. For CEA, the mean level was 6.74 ng/mL with a standard deviation of 9.07, indicating a general reduction in the mean levels. However, the relatively high standard deviation and range (30.74 ng/mL) indicated that some patients still showed high levels of CEA, which requires continuous monitoring.

Table 3. Descriptive statistics (mean, standard deviation, and range) of serum CA15-3 and CEA levels in breast cancer patients after treatment

Variable	Mean	Standard deviation	Range
CA15-3	19.33 U/mL	12.06	38.0
CEA	6.74 ng/mL	9.07	30.74

Statistical Comparisons of CA15-3 Levels between Groups

An independent samples t-test was used to compare the mean CA15-3 levels in different groups (pre-treated patients, post-treated patients, and healthy controls). The level of significance was set at $p < 0.05$. The results, as shown in Table 4, revealed a highly significant difference between pre-treated and post-treated CA15-3 levels ($p < 0.001$), thus confirming that the treatment given had a significant and effective effect on lowering tumor marker levels in patients. Comparison between pre-treated patients and healthy controls showed a highly significant difference ($p < 0.001$), thus suggesting that CA15-3 levels were significantly higher in breast cancer patients than in healthy individuals. However, a comparison between post-treated patients and healthy controls also showed a statistically significant difference ($p < 0.01$). Although there was a significant reduction in CA15-3 levels in patients after treatment, these levels were not completely within the normal range for all patients, thus emphasizing the need for continuous monitoring for the possibility of disease reappearance.

Statistical Comparisons of CEA Levels Between Groups

Statistical differences in serum CEA concentrations between groups (pre-treated patients, post-treated patients, and healthy controls) were evaluated using independent samples t-tests. A p-value of < 0.05 was deemed statistically significant.

As shown in Table 5, there was no significant difference between pre-treated and post-treated CEA concentrations ($p = 0.965$), suggesting that the applied treatment did not lead to a statistically significant reduction in CEA concentrations. This is in contrast to the CA15-3 results. However, comparisons between pre-treated patients and healthy controls showed a highly significant difference ($p< 0.001$), indicating that CEA concentrations were significantly higher in breast cancer patients compared to healthy individuals. .Comparisons between post-treated patients and healthy controls showed no statistically significant difference ($p = 0.096$). Although the average CEA concentration in the post-treated group was higher than that in healthy controls. This could be due to individual differences in patient responses or may indicate that CEA is not the best marker for post-treated monitoring in all cases.

Discussion

The statistical analysis of this study showed that the tumor markers CA15-3 and CEA were at intermediate levels, which aligns with their use as supplementary markers for early diagnosing and monitoring breast cancer. The mean serum levels in breast cancer patients were 43.02 U/mL for CA15-3 and 6.88 ng/mL for CEA, both significantly above the assay's reference values. The mean CA15-3 level in this study (43.02 U/mL) is consistent with ranges reported in previous studies for breast cancer patients, particularly those not in very early stages. For example, prior research has reported pre-treatment CA15-3 levels around 50.59 U/mL, which is comparable to the current findings [13,14]. Elevated CA15-3 levels are strongly linked to disease progression, tumor size, and lymph node involvement, highlighting its usefulness not only for early detection but also for monitoring treatment outcomes [15]. Moreover, there is sufficient evidence that even when CA15-3 values lie within the normal range, their increase has a great prognostic significance in cases of early breast cancer, especially in terms of recurrence. According to a study involving a massive number of participants, individuals who exhibited elevated levels of CA15-3 had a considerably higher chance of recurrence, even when the initial values of the marker were found to be normal [16].

In the control group, the average CA15-3 level was 6.19 U/mL, which aligns well with previous findings. For example, a study of 1,050 healthy individuals reported a mean CA15-3 level of 13.3 U/mL, while other research has set the normal reference range at <30 U/mL [17]. The low standard deviation (1.84) in the control group indicates minimal variation, supporting the homogeneity of the healthy sample and confirming the absence of abnormal elevations that might be associated with benign or malignant conditions [18]. The mean CEA level in the patient group (6.88 ng/mL)

Table 4. Statistical comparisons of mean CA15-3 levels among pre-treatment patients, post-treatment patients, and healthy control women.

Comparison	Mean (Pre-treatment)	Mean (Post-treatment)	Mean (Control)	P-value	Statistical Significance
Pre-treatment vs. Post-treatment	43.02 U/mL	19.33	-	< 0.001	Highly significant
Pre-treatment vs. Control	43.02 U/mL	-	6.19	< 0.001	Highly significant
Post-treatment vs. Control	-	19.33	6.19	< 0.01	Significant

Table 5. Statistical comparisons of mean CEA levels among pre-treatment patients, post-treatment patients, and healthy control women

Comparison	Mean (Pre-treatment)	Mean (Post-treatment)	Mean (Control)	P-value	Statistical Significance
Pre-treatment vs. Post-treatment	6.88 ng/mL	6.74	-	0.965	Not significant
Pre-treatment vs. Control	6.88 ng/mL	-	1.78	< 0.001	Highly significant
Post-treatment vs. Control	-	6.74	1.78	0.096	Not significant

exceeded the reference range in healthy individuals which have been reported below 5 ng/mL, with more specific population-based intervals reported a (0.35–3.45 ng/mL in females and 0.51–4.86 ng/mL in males), [19,20].

Since the study population consisted of non-smokers, this increase is consistent with prior research showing that CEA levels rise in various malignancies, including breast cancer. However, some research has shown that CEA may not always correlate with tumor size or stage before treatment, which could explain the large standard deviation and range observed in this sample [21]. In the control group, the average CEA level was 1.78 ng/mL, well within the normal range for non-smoking adults (<2.5 ng/mL, potentially up to 5.0 ng/mL for smokers) [22. This alignment with international reference values supports the reliability of the data and the representativeness of the collected sample. The low standard deviation (0.52) further confirms the stability of CEA levels in the healthy group, with no notable outliers.

The analysis of tumor marker levels after treatment provided important insights into treatment effectiveness and patient response. Since the average of CA15-3 level dropped significantly from 43.02 U/mL before treatment to 19.33 U/mL afterward. This substantial decrease strongly suggests a positive therapeutic response, aligning with multiple studies showing that CA15-3 levels typically fall following successful chemotherapy or surgery [23,24]. In contrast, the average CEA level showed only a slight reduction after treatment (from 6.88 to 6.74 ng/mL), with a high standard deviation (9.07) and a wide range (30.74), reflecting considerable variability in patient responses. This aligns with existing evidence showing that CEA levels may not always decrease substantially after treatment, particularly in early-stage disease or certain tumor types [25,26]. Although CEA may be less sensitive for short-term post-treatment monitoring, it remains valuable for long-term follow-up, as persistent or rising levels can indicate disease recurrence even before symptoms or imaging findings appear. Statistical analysis revealed highly significant differences in average CA15-3 levels across all groups. Pre-treatment patients had much higher CA15-3 levels (43.02 U/mL) compared to healthy controls (6.19 U/mL, $p < 0.001$), supporting previous findings that CA15-3 is elevated in breast cancer patients [27,28]. After treatment, CA15-3 levels dropped significantly to 19.33 U/mL ($p < 0.001$ versus pre-treatment), confirming that monitoring CA15-3 is an effective way to evaluate treatment response and reductions in tumor burden [29,30]. CEA was also shown to be a useful biomarker for assessing and managing breast cancer patients. Elevated CEA levels before treatment were linked to more advanced disease, while decreases after treatment indicated a positive response and reduced tumor burden, consistent with previous studies [31]. However, recent research suggests that CEA may be less sensitive for early detection and short-term monitoring, highlighting the importance of interpreting its levels alongside other biomarkers and imaging results [32]..The latest developments in artificial intelligence technology have shown that early diagnosis is key, with CNN methods having been shown to have accuracy levels in excess of 95% in skin cancer patients. This method minimizes any variation in diagnosis and increases early detection, making it ideal to combine with traditional biomarkers like CA15-3 and CEA [33].

Conclusion

This study highlights that the serum tumor markers CA15-3 and CEA are valuable tools for diagnosing and monitoring breast cancer. CA15-3 levels were significantly higher in patients compared to healthy controls and dropped substantially after treatment, making it a reliable marker for assessing therapeutic response and tracking disease progression. Although CEA levels were elevated before treatment, they showed less change afterward, indicating it is less sensitivity for short-term monitoring. Overall, these findings support using CA15-3 in clinical practice for early detection, treatment evaluation, and ongoing follow-up of breast cancer patients, particularly in settings with limited resources.

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