

Original Research Article

The role of cancer antigen 15-3 and carcinoembryonic antigen in assessing treatment response in patients with metastatic breast cancer

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ABSTRACT

Background: In breast cancer, the most widely used tumor markers are cancer antigen 15-3 (CA 15-3) and carcinoembryonic antigen (CEA). These markers are primarily used for surveillance purposes and monitoring of treatment responses in clinical practice. This study aims to examine the role of CA 15-3 and CEA in assessing treatment response in patients with metastatic breast cancer (MBC).

Methods: This study investigated 45 MBC patients who met the eligibility criteria. We evaluated the levels of CA 15-3 and CEA before chemotherapy, after 3 months, and after 6 months. The response to therapy was assessed by imaging.

Results: There were statistically significant differences between changes in CA 15-3 and CEA after 6 months of chemotherapy and treatment response as assessed by imaging ($p < 0.001$ and $p = 0.002$, respectively). The CA 15-3 level of good responders at 6 months after chemotherapy decreased by 32.3% from the baseline level, while that of poor responders increased by 141.6% from the baseline level, which was statistically significant ($p < 0.001$). The CEA level of good responders at 6 months after chemotherapy decreased by 0.03% from the baseline level, while that of poor responders increased by 182.38% from the baseline level, which was statistically significant ($p = 0.012$).

Conclusions: Our results showed a clear correlation between tumor markers and treatment response as assessed by radiological methods. The use of tumor markers for assessing treatment response has several advantages, including availability, cost savings, and no radiation exposure. Tumor markers can potentially reduce the need for frequent radiological assessments.

Keywords: Metastatic breast cancer chemotherapy, Cancer antigen 15-3, Carcinoembryonic antigen

INTRODUCTION

Cancer is a leading cause of disease worldwide. According to the American Cancer Society, breast cancer is the most common cancer among women in the United States, accounting for about 30% of all new female cancers each year. In 2023, the estimated number of new breast cancer cases in the United States was 297,790, with an estimated 44,170 deaths. Breast cancer is also the second most common cause of cancer-related death

among women, following lung cancer.¹ In 2022, 524 new breast cancer patients visited the Medical Oncology Department at Yangon General Hospital, of which 11.8% were in the metastatic stage.

Systemic therapy is the standard of care for metastatic breast cancer (MBC) patients, often supplemented with locoregional treatments based on the individual patient's disease status.² Despite advancements in therapy reducing the mortality rate of breast cancer patients, regional and

distant metastasis remains a major threat, as metastasis is the primary cause of mortality in breast cancer.³⁻⁵

A tumor marker is a biomarker found in blood, urine, or body tissues that can be elevated by the presence of one or more types of cancer. These markers are produced either by the tumor itself or by the host in response to the tumor.⁶ The cancer antigen 15-3 (CA 15-3) and carcinoembryonic antigen (CEA) are the most commonly used tumor markers for breast cancer. The American Society of Clinical Oncology 2007 recommended the monitoring of MBC patients during active therapy with CA 15-3 and CEA, in conjunction with diagnostic imaging, history, and physical examination. These tumor markers are primarily used for surveillance and monitoring treatment response in clinical practice.⁷

Human mammary cells express polymorphic epithelial mucins (PEM) that are developmentally regulated and aberrantly expressed in tumors.⁸ These molecules have been identified as target antigens for various monoclonal antibodies raised against materials such as human milk and breast tumor cell extracts.⁹ CA 15-3 is an examination to detect Mucin 1 (MUC1), one of these mucins. CA 15-3 can be elevated in benign conditions like liver and breast disease and other cancers such as pancreatic, lung, ovarian, colorectal, and liver cancer. Therefore, it cannot be used as a screening tool for breast cancer. However, the US FDA approved CA 15-3 for the early detection of recurrence and monitoring of the response to therapy in MBC patients.¹⁰

In MBC, elevated tumor markers can be found in the serum of patients, on average, 2-18 months before clinically detected metastasis.¹¹ The major applications of CA 15-3 include preclinical detection of disease recurrence, assessment of prognosis, and disease monitoring during antineoplastic treatment.¹²

The carcinoembryonic antigen (CEA) is a glycoprotein (oncofetal antigen) involved in cell adhesion that is normally produced during fetal development, with production ceasing before birth.¹¹ CEA is elevated in several primary cancers, including colorectal, breast, pancreatic, liver, lung, gastric, ovarian, and uterine cancers, and is elevated in the majority of metastatic liver disease cases. It can also be elevated in benign diseases such as cirrhosis, emphysema, rectal polyps, ulcerative colitis, and benign breast disease. Due to this elevation, CEA is not useful for screening.¹⁰ However, 36%-70% of breast cancers have elevated serum CEA levels, which can be used to monitor treatment response, especially with bone metastasis.¹³

A study conducted by Stieber et al showed a specificity of >98% for both biomarkers and a sensitivity of 40.6% for CEA alone, 55.6% for CA 15-3 alone, and 66.3% for the combination of both markers.¹⁴ Using fixed cut-off values (CEA: 4 ng/ml, CA 15-3: 30 U/ml), specificity was 86.3%, and sensitivity was 70.6% for the combination of

CEA and CA 15-3. Meta-analysis revealed that elevation of tumor markers was greatly associated with tumor stage, increasing as the stage worsened.¹⁵

Although tumor markers alone are insufficient to evaluate therapeutic response, several studies suggest that tumor marker levels correlate with treatment response.¹⁶⁻¹⁸ For example, Robertson et al. reported that changes in tumor marker levels correlated with patients' therapeutic response, as assessed by imaging methods.¹⁶ Furthermore, a reduction in CEA and CA 15-3 levels predicted a positive response to systemic therapy in MBC patients. To assess the predictive efficacy of CEA and CA 15-3 in MBC, these levels were compared with the radiological response by RECIST 1.1.¹⁹

Although multiple studies have explored the correlation between tumor markers and the site of distant metastasis, the results have been contradictory. Elevated CA 15-3 levels were consistent with bone metastasis⁷ and liver metastasis,¹² while elevation of CEA was associated with liver and brain metastasis.¹¹ In Myanmar, there is a limited number of studies on treatment responses using tumor markers, especially CA 15-3 and CEA, for breast cancer. Hence, we conducted this study to assess the usefulness of these tumor markers for evaluating chemotherapy response among MBC patients.

METHODS

This prospective clinical study was conducted at the Medical Oncology Department, Yangon General Hospital, from December 2022 to May 2024. A total of 45 MBC patients who met the inclusion criteria were consecutively selected for the study. Patients with conditions that could elevate CA 15-3 (such as benign conditions of the liver and breast) or CEA (such as cirrhosis, emphysema, rectal polyps, ulcerative colitis, and locoregional recurrence) were excluded.

A comprehensive history and physical examination were conducted for each patient. CA 15-3 and CEA levels were monitored before the start of chemotherapy, at the 3rd month, and at the 6th month of chemotherapy. A high CA 15-3 level was defined as ≥ 35 U/ml, and a high CEA level was defined as ≥ 5 ng/ml for non-smokers and ≥ 6.5 ng/ml for smokers. Tumor marker measurements were performed at the National Health Laboratory using an electrochemiluminescence immunoassay (ECLIA) on a Cobas 6000 series automated analyzer, Roche Diagnostic, Switzerland. "Decreased" in tumor markers level was taken as more than or equal 25% reduction from baseline, and "increased" in tumor markers level was taken as more than or equal 25% elevation from baseline. Levels of tumor markers not categorized as "increased" or "decreased" will be concluded as "stable" in condition ($\pm 25\%$ from baseline).

Chemotherapy response was assessed through imaging, and the proportion of change in CA 15-3 and CEA levels

among the study population was evaluated. Good responders included patients with decreased or stable in size of metastasis and poor responders included patients with increased in size of metastasis or appearance of new lesions or expired.

Statistical analysis

Collected data were cleaned and entered into Excel using a double-entry method. Numerical data were summarized using mean and standard deviation, while categorical data were described using frequency distribution tables. Bivariate statistics, including independent t-tests and chi-square tests, were applied to assess the association between variables. A p-value of 0.05 was considered statistically significant. We used SPSS version 16 for all data analyses.

RESULTS

About three-quarters (73.3%) of the study population were middle-aged (41-60 years), and the mean age was 51 years. The most common clinical presentation was dyspnea, and 82.2% of patients had a single site of metastasis. The lungs and bones were the most common sites of metastasis. Approximately 91% of the patients had ductal carcinoma. Half of the patients (46.7%) had HR+, HER2- receptor status. Patients whose tumors decreased in size (14 patients) or remained stable (8 patients) were categorized as having a good response (22 patients, 48.9%). Patients with increased tumor size (11 patients), new lesions (7 patients), or who had expired (5 patients) were categorized as having a poor response (23 patients, 51.1%) (Table 1).

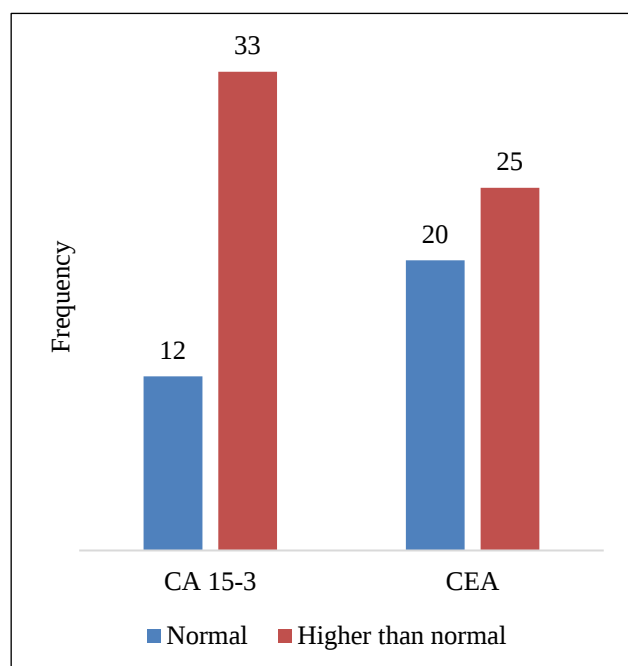


Figure 1: Distribution of CA 15-3 and CEA level at the start of systemic chemotherapy.

Table 1: Background and clinical characteristics of the study population.

Background and clinical characteristics	Frequency	Percentage
Age		
≤40	6	13.3
41-60	33	73.3
>60	6	13.3
Clinical features*		
Back pain	12	26.7
Dyspnoea	22	48.9
Cough	3	6.7
Jaundice	1	2.2
Limb weakness	3	6.7
Headache	3	8.9
Abdominal pain	4	4.4
Others	2	-
Site of metastasis		
Single site	37	82.2
Multiple sites	8	17.8
Distribution of site of metastasis*		
Bone	16	35.6
Lungs only	16	35.6
Lungs and pleura	6	13.3
Liver	14	31.1
Brain	4	8.9
Histological distribution		
Ductal	41	91.1
Lobular	4	8.8
Distribution of receptor status		
Hr+, her2-	21	46.7
Hr+, her2+	8	17.8
Hr-, her2-	5	11.1
Hr-, her2+	6	13.3
Unknown	5	11.1
Distribution of different types of chemotherapy regimen		
Single agent therapies	15	33.3
Anthracycline-based combination	13	28.9
Taxane-based combination	6	13.3
Gemcitabine-based combination	4	8.9
CMF	7	15.6
Outcome of chemotherapy		
Good responder	22	48.9
Poor responder	23	51.1

*Multiple responses

Table 2: Comparison of changes in CA 15-3 level at the start by after 3rd month and 6th month of chemotherapy.

CA 15-3 level	CA 15-3 at the start of chemotherapy		P value
	Higher than normal	Normal	
After 3 rd month			
Increased	9 (31.0)	7 (58.3)	0.280*
Stable	5 (17.2)	2 (16.7)	
Decreased	15 (51.8)	3 (25.0)	
After 6 th month			
Increased	11 (37.9)	7 (63.6)	0.346*
Stable	6 (20.7)	2 (18.2)	
Decreased	12 (41.4)	2 (18.2)	

*Fisher's Exact Test p value = 0.280, N (%)

Table 3: Comparison of changes in CEA level at the start by after 3rd month and 6th month of chemotherapy.

CEA level	CEA at the start of chemotherapy		P value
	Higher than normal	Normal	
After 3 rd month			
Increased	10 (47.6)	9 (45.0)	0.439*
Stable	5 (23.8)	8 (40.0)	
Decreased	6 (28.6)	3 (15.0)	
After 6 th month			
Increased	10 (47.6)	11 (57.9)	0.831*
Stable	3 (14.3)	3 (15.8)	
Decreased	8 (38.1)	5 (26.3)	

*Fisher's Exact Test p value = 0.280, N (%)

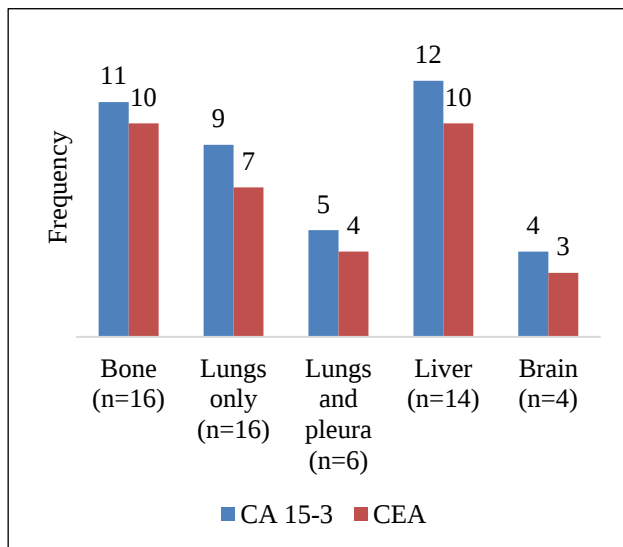
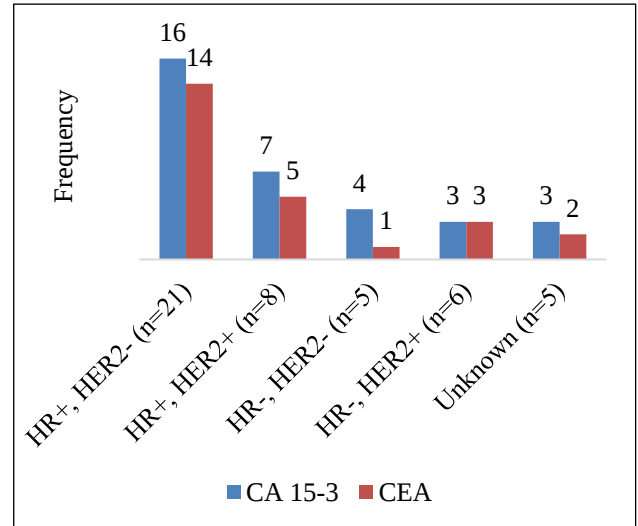
**Figure 2: Frequency distribution of higher-than-normal level of CA 15-3 at the start of systemic chemotherapy and CEA by organs of metastasis.**

Figure 1 shows CA 15-3 and CEA levels at the start of systemic chemotherapy. It was found that 33 (73.3%) patients had elevated CA 15-3 levels, and 25 (55.6%) had elevated CEA levels (Figure 1). Figures 2 and 3 show the distribution of elevated CA 15-3 and CEA levels by metastatic organs and receptor statuses (Figure 2 and 3).

**Figure 3: Frequency distribution of higher-than-normal level of CA 15-3 at the start of systemic chemotherapy and CEA by receptor status.**

We also assessed the effect of changes in tumor marker levels on chemotherapy responses, as presented in Table 4. As tumor markers decreased, the percentage of good response rates increased: 16.7% of good responses among patients with increased CA 15-3 levels versus 92.9% of good responses among patients with decreased CA 15-3 levels, which was statistically significant ($p < 0.001$). Similar results were found for CEA levels: 38.1% of good responses among patients with increased CEA levels versus 76.9% of good responses among patients with decreased CEA levels; however, this was not statistically significant ($p = 0.085$) (Table 4).

Table 4: Association between response of chemotherapy and changes of CA 15-3 and CEA after 6th month of chemotherapy.

Variable	Response of chemotherapy		P value
	Good response	Poor response	
CA 15-3 level after 6th month			
Increased	3 (16.7)	15 (83.3)	<0.001*
Stable	6 (75.0)	2 (25.0)	
Decreased	13 (92.9)	1 (7.1)	
CEA level after 6th month			
Increased	8 (38.1)	13 (61.9)	0.085*
Stable	4 (66.7)	2 (33.3)	
Decreased	10 (76.9)	3 (23.1)	

*Fisher's Exact Test P-value, n (%), row %

Table 5: Comparison of CA 15-3 and CEA percent changes by treatment response status.

Variable	Good responders (mean ± SD)	Poor responders (mean ± SD)	Mann-Whitney U test (Z)	P value
CA 15-3 percent changes at 6th month	-32.3±46.9	141.6±146.1	-4.622	<0.001
CEA percent changes at 6th month	0.03±75.06	182.38±272.14	-3.126	0.002

Percent change = (After-Before)/Before × 100

Table 2 and 3 assess the effect of chemotherapy on CA 15-3 and CEA levels through cross-tabulation of these tumor marker levels at the start of chemotherapy and at different follow-up periods. No significant differences were found in these comparisons (Table 2 and 3).

The effect of chemotherapy was also assessed by comparing the mean percentage changes in CA 15-3 and CEA levels at the 6th month of chemotherapy between good and poor responders (Table 5). It was found that CA 15-3 levels were reduced by 32.3% from the start of chemotherapy among good responders, while this tumor marker increased by 141.6% among poor responders ($p < 0.001$). A similar finding was observed for the CEA tumor marker ($p = 0.002$).

DISCUSSION

This hospital-based prospective clinical study investigates the clinical presentations of metastatic breast cancer (MBC) and evaluates the role of CA 15-3 and CEA as biomarkers for therapeutic monitoring in patients undergoing chemotherapy. The study provides a comprehensive analysis of patient demographics, clinical presentations, metastatic sites, histological types, receptor statuses, chemotherapy regimens, and biomarker levels before and after treatment.

About half of the participants had stable or decreased sizes of metastatic lesions after chemotherapy (good responders). The six-month chemotherapy treatment significantly reduced the CA 15-3 level by 33% from the baseline level among good responders while it increased by about 150% among poor responders. For CEA, it significantly reduced by less than 1% from baseline among good responders while it increased by nearly 200% among poor responders.

In this study, the age of the study population ranged from 35 to 76 years, with a mean age of 51 years. The majority (73.3%) were between 41 to 60 years old, consistent with other studies that report similar average ages for breast cancer onset.^{20,21} This suggests that MBC predominantly affects middle-aged women, aligning with broader epidemiological data on breast cancer.

Dyspnea was the most common symptom, affecting 50% of patients, followed by back pain (26.7%). Other symptoms included abdominal pain (8.9%), cough, limb weakness, and headache (6.7% each), with jaundice being

the least common presentation. This symptom distribution highlights the varied and often severe clinical manifestations of MBC, necessitating comprehensive symptomatic management alongside oncological treatment.

In this cohort, about 80% had a single site of metastasis, and less than 20% had multiple metastatic sites. Bone and lung metastases were equally common (35.6% each), followed by liver (31.1%), lungs and pleura (13.3%), and brain (8.9%). These findings are comparable to another study, where bone and lung metastases were also prevalent.¹¹ The distribution of metastatic sites underscores the importance of monitoring these common areas for metastasis in MBC patients.

Ductal carcinoma was the predominant histological type (91%), followed by lobular carcinoma (8.8%). The receptor status analysis revealed that half of the patients were HR+ HER2-, 17.8% were HR+ HER2+, and 13.3% were HR- HER2+. Overall, about two-thirds were HR+, similar to the Laessig et al. study.²⁰ This high prevalence of HR+ tumors is consistent with other studies and has significant implications for treatment strategies, as HR+ tumors often respond well to hormone therapies.

Single-agent therapies were the most frequently used (33.3%), followed by anthracycline-based combinations (28.9%). This pattern is in line with the trial in Germany and a local study conducted by Htet-Myat-Han.^{21,22} The choice of chemotherapy regimen depends on various factors, including the patient's overall health, the cancer's characteristics, and previous treatments.

Before chemotherapy, about three-fourths of patients had elevated CA 15-3 levels, and half had elevated CEA levels. These elevations were consistent with other studies.^{20,23} CA 15-3 was notably elevated in lung, pleura, and liver metastases, while CEA was elevated in bone, lung, pleura, liver, and brain metastases. However, no significant association was found between tumor markers and receptor status. This suggests that although these biomarkers are useful for monitoring disease progression, their levels cannot be used to predict metastatic sites or receptor statuses.

After six months of chemotherapy, there was a significant difference in biomarker levels between good and poor responders. Good responders significantly decreased, while poor responders significantly increased the CA 15-3 level from the baseline. The study found similar

findings for CEA. The strong correlation between decreasing CA 15-3 and CEA levels and positive treatment response supports their utility in monitoring therapeutic efficacy. These findings are consistent with other studies, which also observed significant correlations between biomarker levels and radiological assessments of treatment response.^{18,21}

Strengths

The study's strengths include its prospective design and comprehensive clinical, radiological, and biomarker data evaluation.

Limitations

However, limitations include the small sample size and heterogeneity in treatment and assessment methods. Other potential biomarkers like CA 27.29, HER-2, and uPA were not analyzed, which could provide a more comprehensive understanding of tumor biology and treatment response.

CONCLUSION

This study highlights the importance of CA 15-3 and CEA as valuable biomarkers for monitoring treatment response in MBC patients undergoing chemotherapy. The significant correlations between these markers and radiological assessments suggest that they can be effectively used to gauge therapeutic efficacy, potentially reducing the need for frequent imaging. However, larger studies with more homogeneous patient populations and the inclusion of additional biomarkers are needed to validate these findings and refine the use of tumor markers in clinical practice.

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