



## Measurement of CA15-3 level among women attending the surgery department at Brack General Hospital – South of Libya

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Breast cancer  
CA15-3  
Tumor marker  
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### ABSTRACT

CA15-3 is one of the most widely used tumor markers for diagnosing and monitoring therapy of breast cancer. However, scientific studies have differed significantly in the importance of measuring this antigen for early diagnosis of breast cancer. The study was conducted on 72 women who visited the surgery department of the Brack general hospital, The concentration of CA15-3 was measured using enzyme-linked immunosorbent assay (ELISA). The results showed that the level of CA15-3 was elevated in 2 samples (2.77%) with a mean level of  $38.5 \pm 1.7$  U/ mL, and 70 samples (97.23%) were normal with a mean level of  $13.77 \pm 6.17$  U/ml. The statistical analysis showed significant differences between the concentrations in the high and normal samples ( $P = 0.00$ ). We conclude that CA15-3 is not a reliable test to confirm breast cancer.

### قياس مستوى CA15-3 بين النساء المترددات على قسم الجراحة في مستشفى براك العام.

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### الكلمات المفتاحية:

اختبارات كيموحيوية  
استخلاص  
بكتيريا  
تضاد  
فطريات

### المخلص

CA15-3 هو أحد دلالات الأورام المستخدمة في تشخيص ومراقبة علاج سرطان الثدي. ومع ذلك ، فقد اختلفت الدراسات العلمية بشكل كبير في أهمية قياس هذا المستضد للتشخيص المبكر لسرطان الثدي ، أجريت الدراسة على 72 امرأة قمن بزيارة قسم الجراحة في مستشفى براك العام. تم قياس تركيز CA15-3 باستخدام التقنية المناعية الرابطة للانزيم . ELIAS أظهرت النتائج ارتفاع مستوى CA15-3 في عينتين فقط (2.77%) بمتوسط  $38.5 \pm 1.7$  وحدة / مل ، و 70 عينة (97.23%) كانت طبيعية بمتوسط  $13.77 \pm 6.17$  وحدة / مل. أظهر التحليل الإحصائي وجود فروق معنوية ذات دلالة إحصائية بين النساء اللاتي كان لديهن ارتفاع في مستوى المستضد والنساء اللاتي لديهن مستوى طبيعي لهذا المستضد. ( $P = 0.00$ ). خلصت هذه الدراسة الى أن هذا المستضد ليس اختبارا تشخيصيا موثوقا به لسرطان الثدي ويفضل استخدامه في حالات تتبع العلاج.

### Introduction

Early detection of cancer offers the best chance for a cure. The goal is to diagnosis cancer when a lesion is still small enough to be completely removed surgically. Unfortunately, most cancers do not produce symptoms until they are either too large to be removed surgically or have already spread to other tissues (metastasis) [1, 2]. Breast cancer markers include CA 15-3, CA 27.29, and mucin-like carcinoma-associated antigen (MCA): they are high-molecular-weight mucins expressed by mammary epithelium, known as

episialin [3]. None of these markers can be used to diagnose primary breast cancer because the incidence of elevated levels is low. However, each is useful in monitoring therapy and disease progression in patients with metastatic breast cancer. A change in CA 15-3 of at least 25% correlates with disease progression in 80% to 90% of patients and with disease stability in 60%. Owing to their sensitivity and specificity, these markers could replace use of CEA in metastatic breast cancer[4]. An ideal tumor marker should be

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specific for a given type of cancer and sensitive enough to detect small tumors for early diagnosis or during screening, number of studies on the diagnostic importance of CA15-3 and its role in the diagnosis of breast cancer indicate that this antigen lacks sensitivity and specialization[4]. Levels of this antigen are high in less than 10% of patients with early stage disease and about 70% of patients with advanced cancer. CA15-3 also reported to be elevated in benign liver and benign breast diseases (False positive results) and this increase is associated to advanced stages and recurrence[5,6]. Another study suggest that the CA15-3 assay reflect the clinical course of patients with advanced breast cancer and may be superior to CEA as a monitor of therapeutic efficacy [7]. CA15-3 will increase gradually and it can be used as a simple method that reflects the presence of bone metastases in association with bone scan and can use as a simple, reliable and inexpensive screening method for detecting bone metastases in the patients with breast carcinoma.[8]. CA 15-3 may also be used in the postoperative surveillance of asymptomatic women who have undergone surgery for invasive breast cancer [9]. The main limitation of CA 15-3 as a marker for breast cancer is that serum levels are rarely increased in patients with early or localized disease[10].

Low levels of CA15-3 usually indicate treatment success or failure[11]. However, CA15-3 levels may rise in the first few weeks after starting treatment because cancer cells die when their contents leak into the bloodstream[12].

The aim of this study was to estimate the CA15-3 level in women visiting the surgical department of Barak General Hospital who had breast problems ranging from pain and mild to severe secretions, but not yet diagnosed with breast cancer, to evaluate the sensitivity and specificity of this antigen in the diagnosis of breast cancer.

#### Martials and methods:

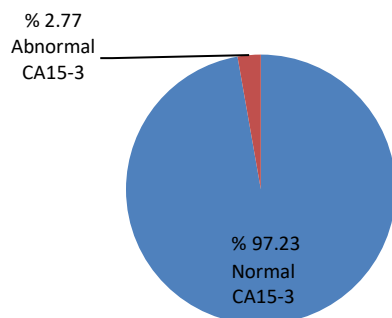
**Samples:** This study was conducted on 72 women aged between 20-60 years old. Visiting the surgery department and the women's department at Brack General Hospital based on symptoms and causes related to breast cancer. Blood samples were collected from all participants in a sterile tube. Blood samples were centrifuged for 15 minutes 3000 rpm, and then serum are separated and stored at -20 °C for analysis.

CA15-3 was measured using enzyme linked immune sorbent assay (ELISA) kits from Bio Check Inc.

**Statically Analysis:** the data are expressed as mean  $\pm$  SD. variance used to analyze the data, with the significant p-level set at 0.05 by using computer-based statistical software Minitab program (version 17).

#### Results:

The results of this study showed that 70 samples (97.23%) had a normal level of CA15-3 and two samples (2.77%) had a rise in the CA15-3 level Figure 1. The results showed that mean of CA15-3 in normal samples was  $13.77 \pm 6.17$  U/ml and mean of CA15-3 in abnormal samples was  $38.50 \pm 1.70$  U/ml, the statically analysis show a significant difference between the two groups ( $P < 0.05$ ). The mean age of two groups was  $34.2 \pm 10.74$ ,  $24 \pm 4.24$  year respectively and there is no significant difference between the two groups ( $p > 0.05$ ) Table 1.



**Figure1:** Percentage of normal and abnormal cases of CA15-3.

**Table 1:** Mean age and CA15-3 distribution

Parameters	Normal	abnormal	p-value
Age( years)	$34.2 \pm 10.74$	$24 \pm 4.24$	0.1

CA15-3 ( U/ml)	$13.77 \pm 6.17$	$38.50 \pm 1.70$	0.03*
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\*=significans

Samples of women were divided into age groups to determine the number of cases in each age group. The results showed that the two cases that showed an increase in the level of CA15-3 were in the age group (20-30) years with an average age of  $24.73 \pm 3.13$  years. The rest of the age groups showed no increase in the level of CA15-3 Table 2.

**Table 2: Distribution of cases in different age groups**

Age group	Mean $\pm$ SD	NO. Of cases
20 -30	$24.73 \pm 3.13$	2
31 - 40	$34.67 \pm 4.29$	0
41 - 50	$45.75 \pm 3.39$	0
51 - 60	$53.75 \pm 2.22$	0

#### Discussion:

CA 15-3 is most useful in the setting of breast cancer, being elevated in 69% of advanced cases. [13]. CA15-3 is not useful in screening because it is elevated in a number of benign conditions, including benign ovarian tumors, benign breast diseases[14]. Elevated CA15-3 is also found in other malignancies including pancreatic, lung, ovarian, colorectal, and liver cancer. In our study, which included women who were not diagnosed with breast cancer, the results showed that only two cases had an increase in the level of this antigen and that both cases did not show any symptoms of breast cancer. Both women suffered from breast cysts (a breast cyst is a noncancerous (benign), fluid-filled sac in the breast), both of them underwent surgery to remove breast cysts. This may be the reason for the high level of this antigen. It has been reported the published studies that the elevated levels of CA 15-3 can be detected in 1% of normal population, 3-20% of benign breast lesions[14-17]. But another study suggest that normal CA15-3 levels were found in females with benign breast lesions[18]. Breast cancer is sometimes found after symptoms appear, but many women with breast cancer have no symptoms, As for women who have a normal level of this antigen, it is also not possible to deny that they have breast cancer despite the presence of a normal level of this antigen (especially with the presence of some symptoms that these women suffer from that prompted them to visit a doctor) because some studies suggested that this antigen is not sensitive to the early stages of the disease[18]. Therefore, screening(a mammogram) remains the most accurate method for diagnosing and detecting breast cancer in its early stages.

Increasing age is one of the strongest risk factors for breast cancer. Although breast cancer can occur early in life, in general it is a disease of aging. For a woman in her 30s the risk is approximately 1 in 250, whereas for a woman in her 70s, it is approximately 1 in 30. Most breast cancers are diagnosed after the menopause; about 75% of breast cancer cases occur after 50 years of age. Age is considered to be a likely surrogate for DNA damage accumulated during life [18,19]. In our study, when women were divided into different age groups, the two cases with elevated CA15-3 level were in the <40-year age group, and this is consistent with some studies indicating that although breast cancer increases in the post-menopausal Menstruation, but it can occur in the pre-menopausal age. Some studies have indicated that breast cancer affects only 4-6% of women under the age of 40 and is rare in young women, but recently, a significant increase in incidence has been observed among pre-menopausal women [20,21].

#### Conclusion

the CA 15-3 test is valuable for monitoring breast cancer, it is less reliable when used for cancer screening. This is partly because the CA 15-3 is not a highly sensitive test and it's not specific to breast cancer.

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