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RESEARCH ARTICLE

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## LEVELS OF CA 15-3 AND CEA IN NEWLY DIAGNOSE CARCINOMA BREAST PATIENTS

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### ABSTRACT

The term "breast cancer" refers to a malignant tumor that has developed from cells in the breast. This implies the incidence in both the sexes though more lethal in males. 85-90% of the cases show genetic abnormality. Only 5-10% is due to abnormally inherited from either of the parents. This occurs as a result of aging process that happens as a result of "aging process" and wear and tear of life in general. It more often begins in the cells of the lobules which are milk-producing glands or ducts or the ducts, the passages that drain milk from lobules to nipples. In addition to traditional prognostic factors, such as axillary lymph node status, tumor size, hormone receptor expression and HER-2 expression status, multigene assay and gene expression profiling have also been spotlighted. All these require tissue samples. Progressive reduction in size can make it difficult to obtain samples for them. On the other hand serum is easily accessible and soluble circulating tumor markers, if found to be accurate prognostic factor, would be ideal candidates for predicting outcome and monitoring treatment course. Markers like CA 15-3 and CEA have been the easily accessible, simple, objective, reproducible, cost effective and feasible. Due to low sensitivity and specificity, both CA 15-3 and CEA have no value for detecting primary Carcinoma Breast. They can be useful in predicting prognosis, monitoring treatment response and surveillance.

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## INTRODUCTION

Cancer cells in Breast continue to grow to form new and abnormal cells. These cells can sometimes grow to invade into other tissue, something that normal cells can't do. In most of cases breast cancer starts in cells that line the ducts, which are tubes that carry milk from gland to nipple. This type of cancer is called ductal carcinoma. Cancer can also start in the cells of lobules, which are group of glands that make milk. This type is called lobular carcinoma. Both the types can remain dormant in the tissue. They are sometimes invasive, which means they have gone into the surrounding tissues also. Rest types can be inflammatory breast cancer, Paget disease of the nipple and triple negative and basal-like breast cancers. Rare types are non-Hodgkin Lymphoma and sarcoma. Breast cancer is the most common of the cancers in females and the leading cause of death after lung disease. In Malwa region of Punjab which is a cotton growing area, high use of pesticides, presence of toxic metals in the subsoil water, leaching of uranium from rocks,

presence of thermal power plants based on coals are considered as possible causes for high incidence in this area. A panel of potential cancer markers selected for study is CA15-3 and CEA. So this study was conducted to compare the usefulness of combinations CA 15-3 and CEA in comparison with the utility of these individual markers for newly diagnosed carcinoma breast patients. CA 15-3 is a mucinous carbohydrate antigen product of MUC1 gene, originally identified by two monoclonal antibodies: DF3 rose against a membrane fraction of breast liver metastases. Recent data suggests that MUC1 gene plays a role in adhesions (Leading to decreased cell-cell and cell-extracellular interactions) immunity and metastases. An increased expression level of MUC1 in primary tumor suggests that it facilitates detachment of malignant cells, both from adjacent cells and extra-cellular matrix in primary cancer. Thus MUC1 may play a role in cancer invasion and metastatic invasion, but it is increased in only 3% of patients and 70% cases of metastatic dissemination. So it is not used for screening high risk population. However it can be used as prognostic marker of breast cancer patients. Duffy and co-workers reported that patients with increased preoperative concentration of CA 15-3 had a worse prognosis than those with low concentrations.

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Carcinoembryonic antigen (CEA) is a glycoprotein, which is present in the normal mucosal cells but increased amounts are associated with adenocarcinoma, especially colorectal cancer. So CEA has a role as a tumor marker. Sensitivity and specificity are low, however, so it is of more use for monitoring than for screening or diagnosis. CEA levels are useful in assessing prognosis (with other factors), detecting recurrence and monitoring treatment than for screening the diagnosis in cases of colorectal carcinoma. CEA is levels are useful in post-operative follow-up of patients with stage II and III colorectal cancer if further surgery or chemotherapy is an option. Malignant conditions which may have elevated CEA include: Colorectal cancer, Breast cancer, Lung cancer, cancer of stomach, esophagus, pancreas, mesothelioma, medullary thyroid carcinoma, skeletal metastases of tumors from primary bone and hematological malignancy. Normal ranges vary but CEA usually deemed to be normal at 0.20-3.3 ng/ml. Increasing levels of CEA suggestive of active disease. Levels exceeding 10ng/ml are rarely due to benign disease or the moderate elevation that may occur due to smoking. So it shouldn't be used as diagnostic criteria of carcinoma Breast. CEA levels should be done only after malignancy has been confirmed. In conjunction with other tumor markers of CA 27.29 and CA 15-3, the CEA test is of much more use in prognosis than diagnostic of carcinoma breast. So it shouldn't and shouldn't be used as screening breast cancer and shouldn't be used in isolation in advanced stages.

## MATERIALS AND METHODS

The present study was conducted in the department of Biochemistry and department of Surgery, GGS Medical College and Hospital, Faridkot. Study included 80 FNAC proven newly diagnosed patients of Ca Breast females and healthy control females, socioeconomic status matched controls, with the aim to estimate levels of CA 15-3 and CEA between carcinoma breast cases and similar healthy females without any history of carcinoma.

## AIMS AND OBJECTIVES

- To estimate serum levels of CA 15-3 and CEA in newly diagnosed female patients of Breast Carcinoma.
- To evaluate the association between tumor markers CA 15-3 and CEA in these patients, if any.
- To compare the serum levels of CA 15-3 and CEA between diseased and control group.

## EXCLUSION CRITERIA

The patients with suspected carcinoma in any other part of the body, taking anti metabolites, any other disease that can affect above parameters as pulmonary disease, renal disease, Hepatitis and thyroid disease were excluded from the study. Under all aseptic conditions 10 ml of blood by disposable syringe and needle were taken. Serum

**ROUTINE TESTS:** Levels were assessed for various investigations on Dimension Xp and plus and AU 480 based on spectrophotometric method. Routine parameters like Blood Sugar, Total serum protein, BUN/Blood Urea, Total serum Bilirubin, AST, ALT, and ALP were done as a routine exercise to rule out any underlying metabolic disease. Normal level: - 9.2-38 U/ml in Females and 9-51 U/ml in males.

**SPECIAL INVESTIGATIONS:** CA 15-3 and CEA were performed on chemiluminiscence. In this method there is emission of light when an electron returns from high energy level to lower energy level. Reading was taken at 425nm. CA 15-3 was done with two-side immunoenzymatic ("sandwich") assay.

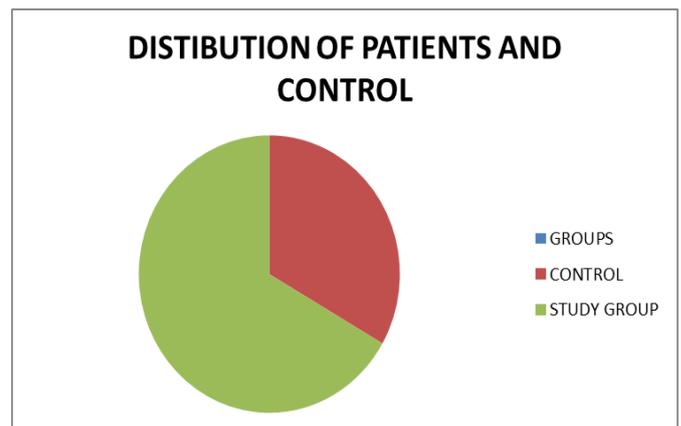
On the other hand CEA was assessed in a two-site immunoenzymatic "Sandwich" assay using two mouse monoclonic anti-CEA which reacts with different epitopes of CEA. Normal Value: - 0.4-6.3 ng/ml in smokers and 0.20-3.3 ng/ml. The amount of analyte in the sample is determined by means of a stored, multi-point calibrator curve.

## RESULT AND OBSERVATION

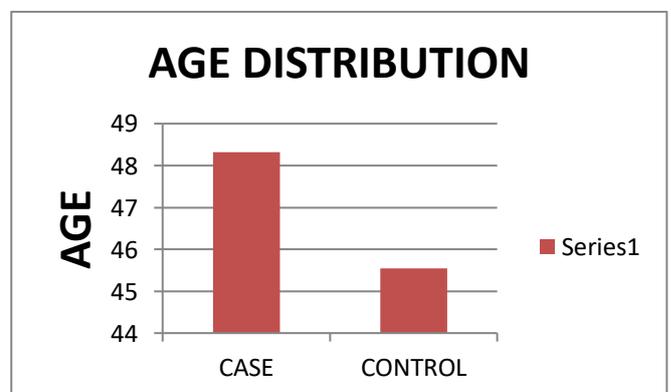
**Table 1. General Protocol of The Study**

Groups	No. of cases
Control Group	40
Study Group	80
Total	120

The study was conducted on 80 newly diagnosed cases of breast cancer. The control group of 40 was also processed with them.



As shown in tale-2, the mean  $\pm$  sd in control group was  $45 \pm 11.79$  and that of study group was  $48.32 \pm 13.08$  respectively. There was no significant difference seen between two groups = 0.245.



This shows significant relation of serum level of CA 15-3 in breast carcinoma cases and controls with  $p=0.000$ . This shows significant relation of serum level of CEA in breast carcinoma patients and control  $p=0.000$ .

**Table 2. Distribution according to age in both groups**

Parameter	group	No. of patients	Mean±SD	Range	T Value	P Value	Significance
age	case	80	48.32±13.08	26-70	1.171	0.245	NS
	control	40	45.55±11.79	37-69			

**Table 3. Relationship of Serum Level Of Ca 15-3 In Breast Carcinoma Subjects And Control**

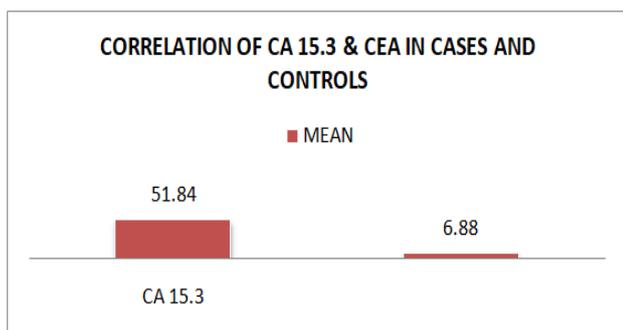
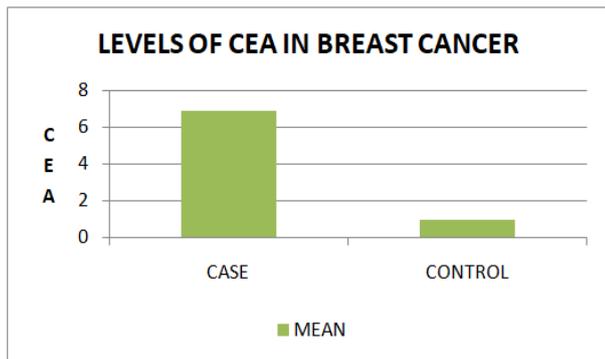
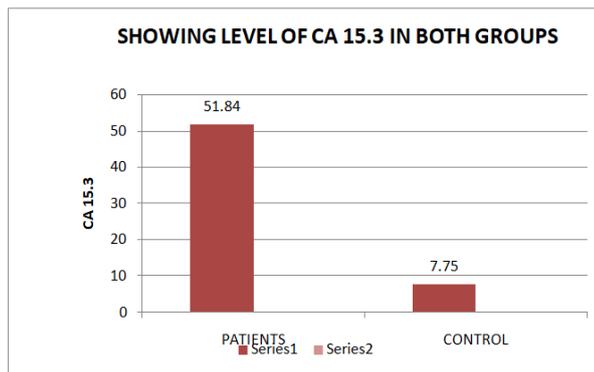
Parameter	group	No. of patients	Mean±SD	Range	T Value	P Value	Significance
CA 15.3 U/ml	Case	80	51.84±59.76	15-341	6.591	.000	Significant
	Control	40	7.75±2.11	4.1-11			

Table 4. Relationship of serum level of cea in breast carcinoma subjects and control

Parameter	Group	No. Of patients	Mean±sd	Range	T value	P value	Significance
Cea ng/dl	Case	80	6.88±13.76	0.87-6.5	3.866	0.000	Significant
	Control	40	0.93±0.460	0.21-2			

**Table 5. Correlation of ca 15-3 and cea in newly diagnosed carcinoma breast patients**

Parameter	No. of patients	Mean±SD	P value	Significant
CA 15-3	80	51.84±59.76	0.000	Significant
CEA		6.88±13.76		



## DISCUSSION

In addition to traditional prognostic factors, multigene assay and gene expression profiling have recently been spotlighted. All these require tissue samples. On the other hand serum is easily accessible and soluble circulating tumor markers. If found accurate and prognostic value, these tumor markers will be ideal candidates for predicting out outcome and monitoring of tumor course. The mean age of study group was  $48 \pm 11.130895$  and the  $t = 1.171$  as compared to control which was  $45.11.79 \pm 130895$  and  $p = 0.245$  which was just insignificant. CA 15-3 and CEA have been the most frequently investigated tumor markers in the breast carcinoma. Both have no role for early detection for early detection of carcinoma breast because of decreased sensitivity and specificity. They can be useful in predicting prognosis, treatment response and surveillance. Tondini C et al and Lamerz R et al found both CA 15-3 and CEA are the most sought after investigation. But it is generally agreed that both are not a primary tool for diagnosis because of low sensitivity and specificity. O'Hanlon et al tried to assess the prognostic role these in serum but most of them had low patient numbers or short follow-up periods and used for only univariate analysis. In the present study taken up shows that CA 15-3 were found to be elevated in 35% patients of newly diagnosed breast cancer cases with mean  $51.84 \pm 11.7952$  U/ml when compared with healthy controls. CEA levels were found to be when compared to control  $0.93 \pm 0.460$  ng/ml. On the other hand according to Moazzezy N et al serological level of CA ng/ml was there  $5.0033 \pm 0.49$   $\mu$ g/l and CEA level were  $178.1667 \pm 15.11$  U/L respectively in breast cancer patients and  $p = 0.000$  which was highly significant ( $p = 0.000$ ) as compared to serum level of healthy control which was  $1.1237 \pm 0.11$   $\mu$ L and  $21.13 \pm 3.058$  U/ml respectively. Our finding resemble study, it is conclude that between CA 15-3 & CEA in newly in newly diagnosed carcinoma there is parallel correlation. It was significant with p value = 0.000. So these markers in combination can be of used in diagnosing and monitoring the progress of carcinoma breast cases.

## SUMMARY AND CONCLUSION

In this study which included 80 patients and 40 healthy controls held at GGS Medical College, Faridkot concluded as such:-

- The mean age of study group is  $48.32 \pm 13.08$  as compared to control group is  $45.55 \pm 11.79$  where newly diagnosed cases were 80 and newly diagnosed cases and healthy controls only were considered. There was no significant relation statistically significant difference in two groups in two groups.
- Routine parameters like sugar, urea, LFT, TSP and liver are normal in both groups. No significant relation was found.
- Levels of CA 15.3 were significantly increased in cases when compared with controls. P value is 0.000
- The levels of CEA were significantly increased in cases when compared with controls and P value 0.000.
- So this is concluded that the assessment of both the CEA 15.3 and CEA in combination can be of immense help to
- Diagnose cancer breast cases. A wider study could bring the assumption correct.

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