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RESEARCH ARTICLE

Prognostic utility of Atherogenic Index of Plasma (AIP) in Breast cancer cases in correlation with different immunological markers across India

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Abstract:
Background: *The present study is a prospective interventional study; the study will be carried out in the Dept. of Biochemistry at Jawaharlal Nehru Medical College, Acharya Vinoba Bhave Rural Hospital, Datta Meghe Institute of Higher Education and Research Sawangi (Meghe), Wardha. Participants will be outpatients of this institution. Any participant fulfilling the eligibility criteria will be included in the study. Protocol amendments are not expected. However, if necessary, any modification to the protocol will be reported to the entire investigational team through a conference. All changes will be included in the final manuscript prior to submission.*
Aim and Objectives: *Present study is targeted to correlate atherogenic index of plasma with different stages of breast cancer. Implications: Present study will be helpful to detect the different stages of breast cancer with help of different biomarkers.*

Keywords: Atherogenic index of Plasma, LDL, HDL, Breast cancer.

INTRODUCTION

Breast cancer is a major threat worldwide and a responsible cause of death especially in post-menopausal women. By the year 2020, the estimated number of cases was found to be 2.3 million which is about 11.7 % of all the cancer cases. [Sung et al.,2020] whereas in India the number of breast cancer cases reported in 2016 was up to 118000, out of which 98 % of cases were reported in women and this number has been significantly increasing over the years [Saxena et al., 2002]. According to the Globocan data 2020, breast cancer cases in India were found to be around 13.5% of all the cases wherein 10.6% deaths were reported [Globocan 2020]. According to 2022 statistical analysis, 216,108 reported breast cancer cases, 28.2% were female cancer patients [Sathishkumar et al., 2023]. The risk increases in females due to unhealthy eating habits leading to obesity, heart, related disorders, atherosclerosis and even cancer [Munsel et al., 2017].

The majority of women are found to suffer from breast cancer and the risk of development especially in premenopausal women is related to poor prognosis. The prominent cause of breast cancer is not reported, but various factors have been found responsible including age, gender, unhealthy lifestyle, gene mutations, hormonal imbalance, obesity, hypertension, etc [Sun et al., 2017]. Hormonal imbalance and certain receptors such as Progesterone receptor (PR), Estrogen Receptor (ER), Human epidermal growth factor receptor 2 (HER2), Prolactin (PRLR), and certain genetic mutations such as BRCA 1/2 have been found associated with the development of breast cancer [Silverstein et al., 2016].

The changing lifestyle patterns have a great impact on the health of an individual and lead to many health-related issues. Several studies suggest that women with healthy dietary intake including fruits, vegetables, whole grains, poultry, and dairy products having less fats are less prone to breast cancers [Brennan et al., 2010]. However, unhealthy eating patterns pose a great threat to health. One such problem is obesity which has become a life-threatening problem leading to diabetes, heart-related disorders, atherosclerosis, and even cancer. Obesity has been found to be the sole responsible factor for the occurrence of breast cancer especially in post-menopausal women [Munsell et al., 2014]. Examination of breast cancer patients showed a correlation between obesity and dyslipidemia. Obesity is also related to high body mass index (BMI). When examined, breast cancer patients were found to be affected with dyslipidemia and obesity. Other studies reveal the fact that premenopausal women with high body mass index showed an inverse ratio with breast cancer chances whereas postmenopausal women having high body mass index showed a positive correlation with the risk of breast cancer. The atherogenic index of plasma (AIP) is a logarithmic ratio of the molar concentrations of triglycerides to High-density lipid (HDL) cholesterol. The increased level of the atherogenic index of plasma

favors the occurrence of dyslipidemia which may further lead to the increased risk of cardiovascular diseases. Studies suggest the relation between AIP values and risk of cardiovascular diseases as AIP values of 0.3 to 0.1 have low risk, values between 0.1 to 0.24 are at medium risk while values 0.24 and above are at high risk for occurrence of cardiovascular diseases [Dobiásová 2006]. Cardiovascular diseases are a cause of death for nearly one-third of people worldwide. The atherogenic index of plasma (AIP) serves as a suitable biomarker for the prediction of cardiovascular diseases. This study is performed to determine the correlation between a high atherogenic index of plasma (AIP) and breast cancer.

The purpose of this study is to investigate role of Atherogenic Index of Plasma (AIP) in Breast cancer in correlation with different immunological markers individuals. It is focused to assess the role of AIP as predictive markers and important flag signs for assessment for breast cancer in individuals.

1.1 Hypotheses

1.1.1 Null hypothesis

There is no statistically significant role of AIP as predictive biomarkers in breast cancer cases.

1.1.2. Alternative hypothesis

There is statistically significant role of AIP as predictive biomarkers in breast cancer cases.

1.1.3. Research gap

Several studies have been conducted to evaluate the role of AIP in serving as a suitable biomarker for breast cancer especially in post-menopausal women, however, their role further needs to be evaluated in establishing its correlation with different biomarkers across India. There is inconclusive evidence regarding role of lipid biomarkers in breast cancer risk. Moreover, the relationship between Lipid parameters, Oxidative Stress, Immuno-biomarkers and Body mass Index and carcinoma breast molecular subtypes remains unclear.

1.2. Research question

Is there any predictive utility of Atherogenic Index of Plasma in breast cancer cases in correlation with different immunological biomarkers across India?

MATERIALS AND METHODS

The present study is a Prospective Interventional Study. The current study is set to take place in Department of Biochemistry, Jawaharlal Nehru Medical College Wardha, and Histopathology and Radiology division of Department of Pathology, JNMC, in collaboration with Department of Surgery, JNMC, and Acharya Vinoba Bhave Rural Hospital, Datta Meghe Institute of Higher Education and Research Sawangi (Meghe), Wardha.Participants will be outpatients of this institution. Any participant fulfilling the eligibility criteria will be included in the study. Protocol amendments are not expected. However, if necessary, any modification to the protocol will be reported to the entire investigational team through a conference. All changes will be included in the final manuscript prior to journal submission.

2.1 Aim and Objectives

2.1.1 Aim

To determine Prognostic utility of Atherogenic Index of Plasma in correlation with different immunohistochemical biomarkers and Histopathological examination for breast cancer.

Objectives

1. To evaluate immunohistochemistry phenotype status of diagnosed carcinoma breast patients.
2. To classify breast carcinoma patients into subtypes based on grading and staging as determined by histopathological examination.
3. To calculate Atherogenic Index of Plasma in all diagnosed carcinoma breast patients.
4. To correlate immunohistochemistry phenotype status of diagnosed carcinoma breast patients with Atherogenic Index of Plasma.
5. To correlate histopathological status of diagnosed carcinoma breast patients with Atherogenic Index of Plasma.

2.2 Sample Size

Sample size for study is calculated on the basis of inclusion criteria to find out the correlation.

where formula **N = 4pq/L2 will be used, and** P will be Prevalence (28.2%), q - (100-p), L- Allowable error =10%, N = $4x28.2x71.8/10^2$, = 8099.04/100, = 80.99, sample size= ~ 81. Classifications of age group will be done as 0–14 years old (paediatric group), 15– 47 years old (youth group), 48–63 years old (middle-aged group), and ≥ 64 years old (elderly group).

2.2.1 Inclusion criteria

All women diagnosed with breast cancer and confirmed by histological and radiological examination, patients with denovo diagnosis of breast cancer, and resection specimens from modified radical mastectomy will be included in the study.

2.2.2 Exclusion criteria

All known individuals with prior breast cancer receiving therapy, breast cancer patients with metastatic deposits, patients undergoing neoadjuvant therapy for breast cancer and patients with recurrent carcinoma of the breast will be excluded from the study.

EXPECTED OUTCOMES

3.1 Statistical analysis

The statistical data will be recorded by calculating the mean and standard deviation. Their mean values will be assessed for significance by determining unpaired student –t test. Chi Square test and Fisher exact test will be performed to determine the differences between categorical variables within the same population while Kruskal–Wallis will be performed for nonparametric

tests for continuous variables. Moreover, through multiple regression analysis (MRA) values of more than one variable will be predicted. Probability values $p < 0.05$ will be considered significant.

3.2. Descriptive analysis

Descriptive characterization of the samples will be made and the results will be analysed through frequencies and proportions for categorical variables and medians. The correlation between each lipid biomarker including total cholesterol, HDL, LDL, and triglycerides and odds of breast cancer using logistic regression models will be calculated. Each model analysis will comprise of different variables including high and low cholesterol, LDL and triglycerides based on one unit SD increase or decrease. The final study will comprise of analysis of all lipid measures in correlation with different variates, their exposure and outcomes. The study will further include analysis of subset of breast cancer cases through multinomial logistic regression models. Thereafter the odds will be predicted through luminal A, Luminal B, TN, HER2 cancer subtypes.

CONCLUSION

The correlation between lipid profile biomarkers and odds of breast cancer disproportionately affected by aggressive TNBC was evaluated. The former studies conducted have various conflicts while very few studies have evaluated associations by specific breast cancer molecular subtypes. The studies reveal a strong correlation between triglycerides, low HDL with TNBC, and high LDL with Luminal B and odds of breast cancer. Lipids can easily be diagnosed hinting towards its effective potential in targeting for cancer prevention strategies.

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AUTHOR CONTRIBUTION

This manuscript was written by Abhishek Pant and its supervision was performed by Ashish Anjankar.

CONSENT AND ETHICAL APPROVAL

Ethical approval and consent to participate was taken well in advance. All the procedures performed in studies with the human participants were abiding by the rules as laid down by the ethical standards of the institutional and/or national research committee. The proposed study will be carried out in accordance with the ethical guidelines prescribed by Central Ethics Committee on Human Research (C.E.C.H.R.). The current study has received the approval of the Institutional Ethics Committee, committee has approved the research work proposed to be carried out at Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha. Written informed consent will be obtained prior to the study by the investigator. The confidentiality of the patient's personal details will be maintained. Each patient will be allotted an identification number during enrolment and all records will be securely maintained in a locked cabinet or password-protected computer files during and after the completion of the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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