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Evaluation of PD-L1 protein expression in primary breast carcinoma: An immunohistochemical study

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Abstract
Breast cancer is currently the leading cause of death among women in India with 25.8 per 100,000 women and mortality 12.7 per 100,000 women. In addition to surgery, conventional chemotherapy regimens, hormonal therapy and anti-HER 2 therapy (Herceptin) employed in some cases depending on biomarker results. In this aspect, the Programmed death (PD-1/PD-L1) pathway is of great interest. The activation of this pathway is found to be a poor prognostic factor in cancers of Lung, Gastrointestinal tract, Kidney. Therefore analysis of PD-L1 expression in breast cancer may help in clarifying the role of this pathway in tumor proliferation and may guide further research towards new treatment modalities. Currently anti-PD-L1 therapy useful in Non-small cell lung carcinoma, Urothelial malignancies, and Melanoma.Various papers published on this topic based on research in the western population. Molecular profile of breast cancer in the Indian scenario may be different from these results. Hence data from Indian patients is imperative to extrapolate the conclusions reached from studies in the western population.

Keywords: Breast carcinoma, programmed death ligand 1, tumor-infiltrating lymphocytes

Introduction
Breast cancer, leading cancer among Indian females with rate of 25.8 per 1 lakh women and a mortality of 12.7 per 1 lakh women [1]. Evidence shows that early detection of breast cancer helps in reducing the mortality and improving the prognosis of the disease [2]. Selective estrogen receptor modulators (SERM) such as tamoxifen was the first drug used to suppress tumor growth in estrogen-dependent breast cancers [3]. Targeted therapies are used in treating patients whose breast cancer cells overexpress certain surface proteins liable for abnormal growth pattern. Monoclonal antibodies are used, as they work in a similar way as the human immune system. For example, the recombinant antibody trastuzumab (Herceptin) targets HER2 positive breast cancers [4, 5]. The goal of immunotherapy is that of triggering the human immune response to recognize tumors as a foreign entity and ultimately kill the tumor cells. Blockade of the PD-1/PDL1 axis should enhance antibody function in cancer patients highlighting the importance of further investigation in this area of breast cancer research.

Materials and Methods
All tissue blocks of primary breast carcinoma are included in the study. PD-L1 immunohistochemistry performed in 107 primary breast carcinoma cases. Expression of PD-L1 IHC in tumor cells, tumor-infiltrating immune cells are evaluated and compare with ER, PR, HER-2, and Ki- 67 expression and also with various intrinsic molecular subtypes and histological subtypes of breast cancer.

Results
PD-L1 expression was observed in 39.3% of tumor cells and 52.3% of TILs. High PD-L1 expression was significantly associated with negative ER status and positive nodal status (p<0.05). Based on intrinsic subtypes, high PD-L1 expression and high TIL counts were found in HER2 and basal-like carcinomas.

Discussion & Conclusion

The study data suggest that PD-L1 expression is prevalent among high grade, hormone receptor-negative breast cancers with a range of histomorphology. Clinical trials are needed to determine the prognostic implications of PD-L1 expression. Also whether PD-1/PD-L1 axis can be targeted using novel drug molecules, remain to be established by further studies.

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