<u>Title</u>: A study of the clinicopathological profile and prevalence of CDX2 biomarker expression in primary adenocarcinoma of colon in a tertiary care hospital among Indian population.

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Introduction: Colorectal cancer is one of the alarming health problems worldwide. It is the third most commonly diagnosed cancer in males and the second in females with an incidence rate of 9.4% and 10.1%, respectively, worldwide. In general, colorectal cancer is a disease of the elderly, but there is an increase in incidence among younger individuals due to many dietary and environmental changes. Prognostic biomarkers are key to the risk stratification of patients with colon cancer and the decision to recommend adjuvant chemotherapy, especially in early-stage colon cancer (stage II). It has been proved difficult to identify a single prognostic biomarker that aid in prognostication and prediction of benefit from adjuvant chemotherapy. Currently, tumor stage, tumor grade, and microsatellite instability remain the most important prognostic variables that aid in the treatment of patients with early-stage colon cancer. Few studies highlight that CDX2 immunohistochemistry negativity is an independent prognostic factor and indicates a worse survival rate. In Indian literature, very few studies have been done on CDX2 expression, its correlation with the clinicopathological features and its relevance in colon cancer prognosis.

<u>Aim</u>: To study the prevalence of CDX2 biomarker expression and its correlation with clinicopathological features in patients diagnosed as primary colonic adenocarcinoma.

Materials and methods: A cohort of 148 cases with endoscopic mucosal biopsies and corresponding resection specimens of colonic adenocarcinoma diagnosed from January 1, 2015, to June 30, 2018, were analyzed. Immunostaining for CDX 2 was performed on these cases and was graded for intensity and percentage of positive tumor cells which was correlated with clinicopathological features of colonic adenocarcinoma.

Results: The median age of colon cancer was 53 years with a male preponderance and right colon predominance. The prevalence of CDX2 expression in colon cancer was found to be 92%. CDX2 biomarker negativity was found to be higher in left-sided colon cancers, in poorly differentiated adenocarcinoma, mucinous carcinoma, and in higher TNM staging though these associations were not statistically significant.

<u>Conclusion</u>: CDX2-negative tumors are often associated with several adverse prognostic variables (e.g., advanced stage, poor differentiation, and metastasis). Hence, subclassification of colon cancer depending on CDX2 biomarker aids to separates them into prognostically relevant categories.

<u>Keywords</u>: Colon cancer, CDX2 biomarker, prognostic factors.