Title

Baseline gut microbiota as a predictive marker for the efficacy of neoadjuvant chemotherapy in patients with early breast cancer: a multicenter prospective cohort study in the Setouchi Breast Project-14

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Abstract (238/250 words)

Purpose:

Various studies have demonstrated the causal relationship between gut microbiota and efficacy of chemotherapy, however, the impact of gut microbiota on breast cancer is not fully elucidated so far. This study aimed to evaluate the associations between the gut microbiota before neoadjuvant chemotherapy and its consequent efficacy in breast cancer.

Methods:

This prospective observational study included patients who received neoadjuvant chemotherapy for primary early breast cancer at eight institutions between October 1, 2019, and March 31, 2022. We performed 16S rRNA analysis of fecal samples and α and β diversity analyses of the gut microbiota. The primary endpoint was the association between the gut microbiota and pathological complete response (pCR) to neoadjuvant chemotherapy.

Results:

Among the 183 patients, the pCR rate after neoadjuvant chemotherapy was 36.1% in all patients and 12.9% (9/70), 69.5% (41/59), and 29.6% (16/54) in those with the luminal, human epidermal growth factor receptor 2, and triple negative types, respectively. The α

diversity of the gut microbiota did not significantly differ between patients with pCR and those without pCR. Among the gut microbiota, two species (*Victivallales*, p = 0.001 and *Anaerolineales*, p = 0.001) were associated with pCR, and one (*Gemellales*, p = 0.002) was associated with non-pCR.

Conclusions:

Three species in the gut microbiota had potential associations with neoadjuvant chemotherapy efficacy, but the diversity of the gut microbiota was not associated with response to chemotherapy. Further research is needed to validate our findings.

Keywords:

gut microbiota, predictive marker, neoadjuvant chemotherapy, early breast cancer