Aim: We performed a systematic review and meta-analysis of gastrointestinal adverse events associated with lapatinib.

Methods: Eligible studies included randomized phase II and III trials of patients with solid tumors on lapatinib; describing events of diarrhea, nausea, vomiting, stomatitis and abdominal pain.

Results: Our search strategy yielded 380 potentially relevant citations on lapatinib from Pubmed/Medline, CENTRAL Cochrane registry and ASCO meeting library. After exclusion of ineligible studies, a total of 19 clinical trials were considered eligible for the meta-analysis. The RR of all-grade diarrhea, nausea, vomiting, stomatitis and abdominal pain were 3.44 (95% CI 2.55-4.64; p < 0.00001), 1.27 (95% CI 1.08-1.49; p < 0.004), 1.29 (95% CI 1.11-1.51; p = 0.001), 1.45 (95% CI 0.98-2.16 p < 0.003), 0.90 [0.57, 1.41] (95% CI 0.57-1.41; p = 0.65); respectively. Exploratory subgroup analysis showed no effect of treatment regimen on the RR of the relevant adverse events.

Conclusions: Our meta-analysis has demonstrated that lapatinib is associated with a significantly increased risk of all-grade diarrhea, nausea and vomiting. Clinicians should be aware of these risks and perform regular clinical monitoring.

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