Chemotherapy-Induced Diarrhea Evaluation Table 2023: Crofelemer

General Evidence

Citation	Design/Method Sample/Setting	Variables and Intervention	Outcome Measures	Results/Analysis	Limitations	Quality and Nursing Implications
Pohlmann, P.R., Graham, D., Wu, T., Ottaviano, Y., Mohebtash, M., Kurian, S., . . . Swain, S. M. (2022). HALT-D: a randomized open-label phase II study of crofelemer for the prevention of chemotherapy-induced diarrhea in patients with HER2-positive breast cancer receiving trastuzumab, pertuzumab, and a taxane. *Breast Cancer Research and Treatment, 196*(3), 571–581. https://doi.org/10.1007/s10549-022-06743-9	**Design:** Randomized double-blind controlled trial **Method:** Crofelemer 125 mg delayed-release tablets orally twice daily during cycles 1 and 2 of chemotherapy **Sample**: 51 patients with HER-2 positive breast cancer receiving taxane therapy with or without carboplatin and trastuzumab and pertuzumab or taxane therapy with trastuzumab and pertuzumab (TCHP/ THP chemotherapy regimen (docetaxel or paclitaxel); 26 in the intervention group and 25 in the control group. **Setting:** Not specified	**Independent Variable(s):** Crofelemer **Dependent Variable(s):** Diarrhea, rescue medication use for diarrhea, QoL **Intervention:** Patients who received chemotherapy/HER2-targeted therapy were randomized to crofelemer 125 mg orally twice daily during the first 2 cycles. For the 3rd cycle and subsequent cycles, standard treatment was administered for both groups.	Grade of diarrhea using Common Terminology Criteria for Adverse Events, version 4.0 Rescue medication diary used to measure use of standard-of-care breakthrough antidiarrheals Bowel movement diary: used to measure consistency of stool using the Bristol Stool Form Scale, Time to onset and length of diarrhea episodes Functional Assessment of Chronic Illness Therapy for Patients with Diarrhea (FACIT-D) was used to measure patient quality-of-life.	During cycle 1, 68% of patients in the crofelemer arm and 69.6 % of patients in the control arm had diarrhea. During Cycle 2, 65.2% of patients in the crofelemer arm and 72.2% of patients in the control arm had diarrhea. Results were not statistically different, p = 0.074. During cycle 2, no patients receiving crofelemer reported grade 3-4 diarrhea compared to 17.3% in control arm, (p=0.0196). Patients receiving crofelemer also experienced less watery diarrhea in cycle 1 (odds ratio [OR] = 0.77, 95% CI, [0.6129, 0.9774]; p = 0.03) and were 1.8 times as likely to have their diarrhea resolve in cycle 2 (OR = 1.804, 95% CI [1.02, 3.189]; p = 0.0425]). Adverse events were similar in both the crofelemer and control groups and included fatigue, nausea, anorexia, mucositis, and constipation. One serious AE in the crofelemer arm (grade 4 neutropenia) was attributed to chemotherapy.	Small sample size Possible variability in patient-reported outcomes Narrow population may limit generalizability of findings.	Crofelemer may be a useful prophylactic intervention to reduce grade 2 or greater chemotherapy-induced diarrhea in patients with HER-2 positive breast cancer receiving TCHP or THP (docetaxel or paclitaxel). This study was limited by a small sample size, and only some of the secondary endpoints were met. Further larger studies are needed to validate these findings.