

General Evidence

Citation	Design/Method Sample/Setting	Variables and Intervention	Outcome Measures	Results/Analysis	Limitations	Quality and Nursing Implications
<p>Miller, R.C., Petereit, D.G., Sloan, J.A., Liu, H., Martenson, J.A., Bearden, J.D., III, . . . Loprinzi, C.L. (2016). N08C9 (Alliance): A phase 3 randomized study of sulfasalazine versus placebo in the prevention of acute diarrhea in patients receiving pelvic radiation therapy. <i>International Journal of Radiation Oncology, Biology, Physics</i>, 95(4), 1168–1174. https://doi.org/10.1016/j.ijrobp.2016.01.063</p>	<p>Design/Method: Randomized double-blinded controlled trial of use of sulfasalazine versus placebo in patients receiving pelvic radiation</p> <p>Sample: Patients requiring definitive radiation therapy to posterior pelvis with or without use of 5-fluorouracil, oxaliplatin, or capecitabine concurrently with planned radiation therapy dosages of 45–53.5 Gy (N = 84)</p> <p>Setting: Multicenter, radiation oncology settings</p>	<p>Independent Variable: Sulfasalazine</p> <p>Dependent Variables: Diarrhea, constipation, abdominal pain, rectal bleeding, tenesmus, bowel function</p> <p>Intervention: Sulfasalazine 1,000 mg orally twice daily during radiation therapy and for 4 weeks after or placebo</p>	<p>Common Terminology Criteria for Adverse Events (CTCAE), version 4.0, measured:</p> <ul style="list-style-type: none"> • Diarrhea • Constipation • Abdominal pain • Rectal bleeding <p>Other criteria (not CTCAE graded): Tenesmus</p> <p>Patient-reported outcome bowel function: Bowel function questionnaire used (not well described)</p>	<p>Confidence intervals not reported</p> <p>Grade 3 or greater diarrhea treatment arm versus placebo (28.6% versus 11%, p = 0.04)</p> <p>No statistical differences in other symptoms except abdominal pain after treatment (p = 0.04), which was higher in treatment arm</p>	<p>Heterogeneity in type of cancer, type of chemotherapy received</p> <p>Dietary intake not monitored</p> <p>Patient-reported outcomes on bowel questionnaire incomplete and bowel questionnaire not available for review</p>	<p>Methodology was valid and results were reported with reliability. Sulfasalazine has been used as an off-label treatment for radiation-induced enteritis. Other single-institution studies have reported positive findings related to sulfasalazine for diarrhea symptom management. However, this multi-institution study found grade 3 or greater diarrhea in patients treated with sulfasalazine compared to the placebo arm at interim toxicity analysis, which was statistically significant p = 0.04. Findings resulted in futility analysis and early closure of the study. More research is needed to understand the safety and effectiveness of sulfasalazine over other standard interventions in the treatment of radiation-induced diarrhea.</p>