Results of trial will help guide treatment of malignant bowel obstruction in patients with advanced cancer

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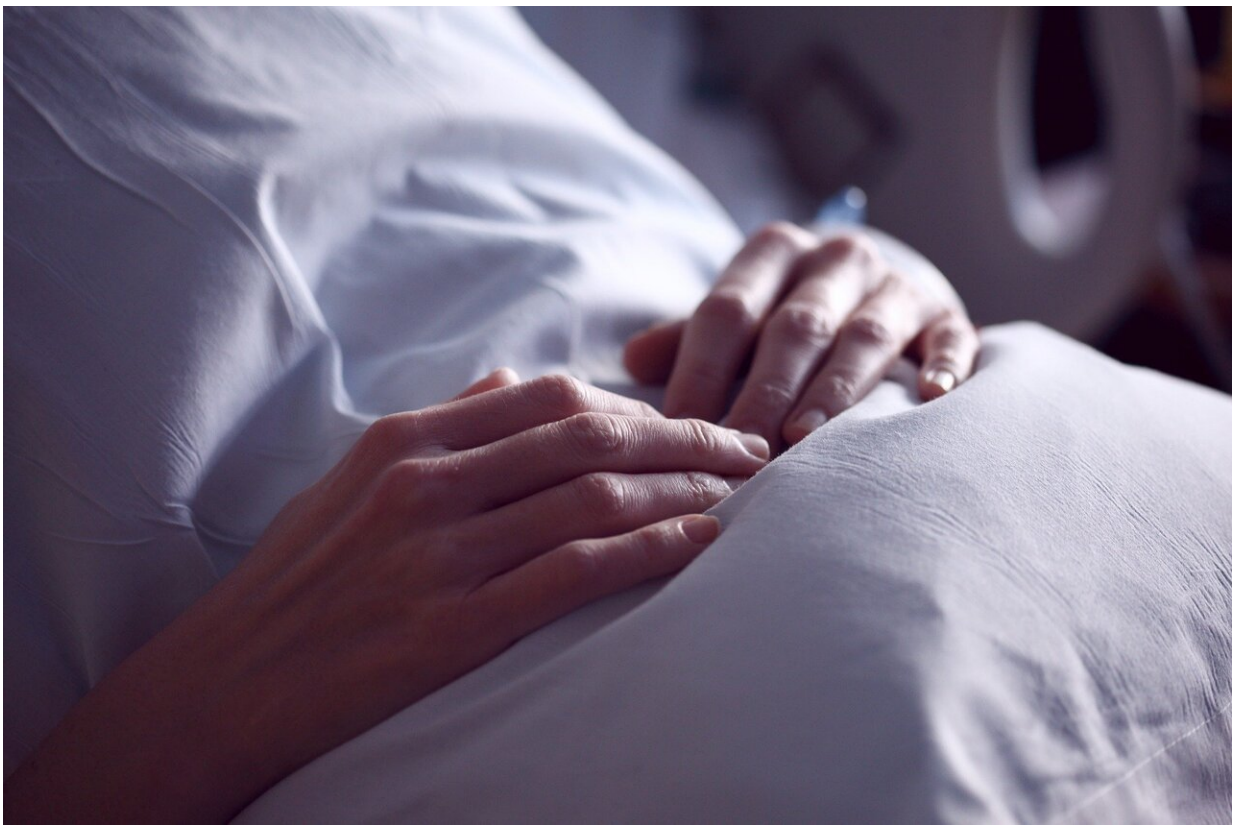

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Findings from the first-ever prospective trial including a randomized pathway comparing surgery to non-surgical treatment of malignant

bowel obstruction (MBO) provide important evidence to help inform clinical decision-making in managing this frequent complication in patients with advanced cancer.

Results include data on clinical outcomes and patient quality of life and are being reported in *The Lancet Gastroenterology & Hepatology.*

The S1316 study, a hybrid design trial that included a randomized component, was led by the SWOG Cancer Research Network, a clinical trials group. The principal investigator was Robert S. Krouse, MD, professor of surgery at the Perelman School of Medicine at the University of Pennsylvania and chief of surgery at the Corporal Michael J. Crescenz Veterans Affairs Medical Center in Philadelphia.

"We knew enrolling patients in the hospital with this acute issue and advanced cancer would be difficult, but the questions are of great importance to clinicians, patients, and families," Krouse said. "Based on the results, we believe surgically eligible patients with MBO should be offered an operation earlier in their hospital stay to improve their symptoms, even though these results suggest it will not increase their number of days alive and out of the hospital."

Partial or complete blockage of the bowel, most often the small intestine, is a common problem for patients with advanced abdominal tumors—particularly for those with ovarian or colorectal cancers. Bowel obstruction can be caused directly by tumors or by adhesions or other complications resulting from surgery or radiation treatment.

In addition to being potentially life-threatening, obstruction can cause considerable suffering, including vomiting, pain, and constipation, and can seriously reduce a patient's quality of life. Patients with MBO typically are facing end-stage cancer, and their care at this point is primarily palliative, intended to improve their quality of life and reduce

symptoms and pain.

Doctors treating MBO in these patients have two primary options—surgical management or non-surgical medical management. But evidence that can help them determine which approach should be preferred has been limited. The S1316 clinical trial was designed to generate such evidence.

Conducted at institutions across the United States within the NCI National Clinical Trials Network, including NCI Community Oncology Research Program (NCORP) sites, as well as at sites in Mexico, Peru, and Colombia, S1316 enrolled 221 patients with MBO, all of whom were considered candidates for surgery. Of these, 199 met the criteria for inclusion in the trial analysis.

At registration, patients were offered the opportunity to be assigned at random to surgery or non-surgical management. About one-quarter of patients selected randomization. Patients who chose not to be randomized instead decided with their physician whether to undergo surgery or to have their MBO treated non-surgically. About 40% in this patient-choice group opted for surgery.

The primary outcome assessed was a measure the researchers termed "good days," defined as days a patient was alive and out of the hospital. The team tracked the number of good days each patient had during their first three months (91 days) following registration to the trial. They found that the count of good days in those three months did not vary significantly between the two approaches to treating MBO. Additionally, patients' ability to eat at week five also did not differ between the two treatment approaches.

Other secondary measures, however, suggest that surgery resulted in improvements in MBO-related symptoms. Patients who underwent

surgery had, on average, better symptom severity scores for vomiting, constipation, nausea, and pain at week four than patients who were treated non-surgically. Overall, among patients hospitalized for their MBO, those who underwent surgery also reported fewer MBO-related symptoms after leaving the hospital.

"We are continuing to analyze the data to allow us to make recommendations to clinicians regarding the optimal operations and other quality of life factors that may be impacted by the type of treatment received," Krouse added. "Our network of institutions and investigators will allow us to examine other important question in this population of cancer survivors."

More information: Krouse RS, Surgical versus non-surgical management for patients with malignant bowel obstruction (S1316): a pragmatic comparative effectiveness trial, *The Lancet Gastroenterology & Hepatology* (2023). DOI: 10.1016/S2468-1253(23)00191-7

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