SWOG S1316 Randomization Recommendations

The purpose of these recommendations is to help with the accrual process, especially the concept of randomization in patients with advanced cancer. They have been developed by the team based on experience with the accrual process. This document is not to be shared with patients but used only for site-investigator team members who will discuss the trial with patients.

1. Focus initial conversation on diagnosis and work-up of malignant bowel obstruction (bowel obstruction in setting of advanced cancer).
    a. In situations of primary diagnosis of cancer, patients and/or family may have a difficult time accepting the diagnosis and may need time to process the new information.
    b. Often, multiple conversations regarding the work-up, treatment options, and natural history for patients with a MBO may be required.
2. Discuss Treatment Options: Operative or Non-operative treatments.
3. After initial discussion of the diagnosis and management of their MBO, ask about the patient's thoughts on proceeding with operative or a non-operative treatment approach.
4. *If the patient is leaning toward one option or the other*, introduce the information regarding the Malignant Bowel Obstruction Study (S1316):
    a. Be thoughtful not to use the word "trial" as patients often equate that to being on an experimental treatment rather than comparing two standards of care. Consider using the word "study" instead.
    b. Explain the purpose of the study is to help answer the difficult and increasingly common issue of managing a MBO in the setting of advanced cancer. There is no clear answer about the most appropriate treatment for MBO, and this study hopes to answer the question.
5. Discuss the S1316 study as a national collaboration among many well-known institutions (yours included) to try and answer this question – what treatment would be best for a particular patient with a malignant bowel obstruction?
    a. Explain the focus of the study is to gather information obtained from each patient and pool the data with other institutions. By combining the data, we hope to be able to give better guidance to future patients who present with a MBO about which option is most beneficial for a better quality of life for the time they have remaining.
    b. Stress that enrollment (involvement) in the S1316 study is completely voluntary. However, their involvement is very much appreciated, will provide valuable information, and will continue to help others in similar situations for a long time.
        i. Ensure they know there is no cost to them or their families to participate.
        ii. Make sure they realize there is no compensation for participation.
        iii. Importantly, emphasize **there is no experimental treatment offered**. Both treatment options (operative and non-operative) are standard of care recommendations for the diagnosis of MBO.
    c. Explain what their time commitment involves.
        i. As part of the study, a member from the research team will call **weekly** to check in on them. Study staff will ask questions about hospitalizations and quality of life. A different team member will call **monthly** from Arizona to see if you are eating.

d. Stress the benefit to participating in this study is potentially very helpful in providing information for future patients who experience a MBO.

e. Some patients will have clearly decided the treatment they prefer: operative or non-operative approach. If their mind is not completely 100% determined (most people), mention that we can allow the central site to choose the treatment path. It would be a random decision, and choosing this option is of the greatest benefit to future patients.
    i. Explain the advantage of randomization is that it offers an unbiased decision and provides very important information on the natural history and quality of life outcome information for their diagnosis.
    ii. Emphasize, again, that medical science really does not yet know if an operative or non-operative treatment is better for patients in your specific and difficult situation. This is why we randomize in studies like this one - together, with colleagues and patients like you across the country, we can learn which treatment is best. In other words, there is no risk of getting 'second best' treatment if you choose to be randomized.
    iii. Use this opportunity to discuss the treatment plan, based on either outcome after randomization:
        i. If you randomize to the surgical arm – We would anticipate surgery on X day. Our plan would be to perform a laparotomy and bypass or divert any obstruction. In some cases, a gastrostomy tube may be required if we are unable to bypass.
        ii. If you randomize to the non-surgical arm – We will optimize your condition with IVF support, nausea medication, and somatostatin analog (typically Octreotide) therapy to decrease secretions and improve abdominal symptoms. In some situations, a tube may be placed in the stomach to allow venting of the stomach or liquids for comfort.
    iv. For patients who are considering randomization, multiple discussions over several days may be required. This is why it is imperative to determine eligibility when you first see MBO patients since they must be registered within three (3) days if they are surgically eligible (or within 3 days of becoming surgically eligible). Patients in this situation may want to contribute to the purposes of the study but are also adjusting to the idea of giving up control of their treatment and outcome to someone other than you, their trusted physician. Making an extra effort to address their concerns and explaining the proposed potential treatment plan, depending on which arm they may randomize into is very important. ***Assure them you will continue to treat them and manage their MBO, irrespective of which treatment arm they may randomize into*** (i.e., if the patient is randomized to the non-surgical arm and then requires surgery, they will be able to receive surgery in the future).

6. It is very important to offer randomization to each eligible patient with MBO. While most surgeons will have biases about the most appropriate treatment option for patients with a MBO, randomization overcomes and negates these biases.

7. We also recognize, however, that randomization may not be for every patient. If the patient has a strong opinion regarding which treatment they prefer, participation in the surgical arm of the non-randomized study continues to provide important information and allows participation in the study. Reassure patients that their involvement in the study is valuable and appreciated.