French Editorial Commentary from the ACHBPT

Comparable results of surgical versus non-surgical management for patients with malignant bowel obstruction—a lesson from S1316 study

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We had the pleasure to read the paper published online by Krouse *et al.* in August 2023 in the *Lancet Gastroenterology and Hepatology* (1). The study labeled as S1316 was a prospective pragmatic comparative effectiveness trial evaluating the surgical versus non-surgical management for patients with malignant small intestinal bowel obstruction (MIO) and having an intra-abdominal or retroperitoneal primary cancer and were aged 18 years or older with a Zubrod performance status 0–2 within 1 week before admission; had a surgical indication; and treatment equipoise. The patients were divided in two pathways. Those who accepted the randomization were randomly assigned to surgical and non-surgical treatment groups. Those who declined consent for random assignment were offered a prospective observational patient choice pathway where the patients with their caring team decide upon the treatment option. The study primary endpoint was the number of good days (days alive and out of the hospital) at 91 days since registration. Two hundred and twenty-one patients were included over the period from May 2015 till April 2020. Out of this number, 199 met the criteria for evaluation (49 in the randomized pathway and 150 in the patient choice pathway). There was no difference in the primary endpoint between different groups {mean 42.6 days [standard deviation (SD): 32.2] in the randomized surgery group, 43.9 days (SD: 29.5) in the randomized non-surgery group, 54.8 days (SD: 27.0) in the patient choice surgery group, and 52.7 days (SD: 30.7) in the patient choice non-surgery group}.

Although the number of patients included which is 221 patients (49 in the randomized pathway and 150 in the patient choice pathway) looks small taking in account the study inclusion period of 5 years and number of participating centers which is 30, however, this is the first successful prospective trial using randomization to compare surgery versus non-surgery in patient with one of the commonest presentation in case of advanced malignancy which is MIO (2). In addition, it is not easy to enroll patients with acute event in a treatment based study. Moreover, the sample size calculated initially of 180 would have provided 90% power to detect a mean difference of 14 good days; however, this sample size was set to 220 to overcome anticipated loss of statistical power from probable imbalance in treatment selection in the patient choice pathway, missing data and ineligible patients.

Interestingly, the hybrid study design of the two pathways; randomization and patient choice pathway, could have probably overcome the limited number of patients

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(n=49) in the randomization pathway.

The chosen study primary endpoint looks realistic and more representative of any treatment superiority—if any—in such advanced cancer stage. Despite the fact that most surgical consultations for MIO ends up with non-surgical treatment (3,4), but offering—through randomization—a non-surgical treatment for surgically eligible patients is challenging and explains the 67% of patients being non-randomized. Before patient registration, the patient has to be seen by the surgical team to confirm that there was a surgical indication, the patient could tolerate an operation and there was equipoise (no evidence to prefer one treatment approach over the other). This surgical review is subjective and could vary from one center to another in such a multicentric study. In addition, the mentioned surgical indication is not well-defined in this article.

When it comes to treatment, the non-surgical groups were offered somatostatin; however, due to supply issues, it was not used subsequently. Even the post-hoc analysis did not show any differences in the primary endpoint with the use of somatostatin analogue, but its effect on other endpoints especially the nasogastric tube use and the presence of symptoms including nausea, vomiting and pain was not analyzed. Concomitantly, the types of operations performed were according to the intraoperative findings however their complexity is not elaborated here. This elaboration would not make a difference in the study endpoints however it may help the surgeons or the caring team while discussing the surgical option with the patient as an additional message from the study.

One of the good points in data analysis is to include those patients who did not complete their initial treatment plan due to symptom improvement in the surgical treatment groups or due to failure of improvements in the non-surgical treatment groups as logically the outcomes of these patients are influenced by the initial decision of treatment type. The study showed that less than half (42%) of the patients in the non-surgical treatment groups received the somatostatin analogues and 10% of the patients in the surgical treatment group who received it. It would have been interesting if the authors pointed out any correlation—if any—between the somatostatin analogues use and the non completion of the initial treatment plan. *Tab. 2* of the paper showed that 29% of the surgical treatment groups patients received steroids and again the correlation—if any—of that with the patients who improved without surgery is not elaborated here.

The same table revealed that 11 (22%) patients in the randomized pathway and 13 (8.6%) patients in the patient choice pathway did not go through their initial treatment type which means that it is less risky to deviate from the initial treatment plan in the patient choice pathway. Although the significance of this difference is not calculated in the paper, but this will raise the discussion of how really good are the decisions taken in the patient choice pathway especially when we know that the full regression model analysis revealed significantly a shorter length of stay for patients in the patient choice pathway {adjusted mean difference: −6.8 days [95% confidence interval (CI): −10.5 to −3.0] in the patient choice pathway *vs* in the randomized pathway}.

It is clinically practical to see that the authors have explored the effect of factors like baseline albumin levels, large quantities of ascites, and presence of carcinomatosis. No evidence of effect modification was found with any of these factors for either good days or overall survival.

In conclusion, we admire the novelty in designing such study for the treatment of acute medical events and the quality of work and analysis being done. The results of such work are practically helpful in decision taking and patient and family education. Further studies into the effects of different surgical or interventional methods and treatment options on quality of life outcomes for MIO patients are pivotal. More researches are definitely required that focus on the impact of health-related quality of life (HRQOL) problems at patient priorities and preferences with MIO. The impact of palliative care team involvement and its effect in managing patients with MIO is needed for future research.

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Footnote

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