Bowel Preparation Before Vaginal Prolapse Surgery: A Randomized Controlled Trial

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1. One of the exclusion criteria for entry into the study was constipation as determined by the Rome criteria. Review the Rome criteria for constipation. How are the Rome criteria created? Do you think that these criteria are an adequate assessment of women with constipation?

2. The primary outcome was surgeons’ intraoperative assessment of surgical field regarding bowel contents, as measured on a 4-point Likert scale. What are the potential weaknesses of this choice of primary outcome? Is this a validated measure? Is a difference in the surgeon’s assessment of the operative field likely to influence your decision to order a bowel preparation?

3. Discuss surrogate outcome measures and why they are chosen for clinical trials. What are alternative outcome measures that may have been of greater importance in the evaluation of the efficacy of this intervention?

4. Patient satisfaction with the intervention was a secondary outcome measure in this study. How can satisfaction be accurately measured? What factors influence patient satisfaction? Review the referenced article for the secondary outcome measure. The authors state that this measure is not validated. Discuss what validation means, including face validity, construct validity, and criterion validity. Also, review what is meant by reliability testing. What are the differences between the two? Why is it important to use valid, reliable, and responsive questionnaires?

5. The authors utilized a block randomization scheme. What does block randomization mean? Why is this method of randomization often used in randomized trials? What are the advantages and disadvantages of using block randomization to assign interventions?

6. What is a sensitivity analysis? Why did the authors perform one? How does a sensitivity analysis strengthen or weaken the evidence presented?

7. The authors report that mechanical bowel preparation has not been shown to be of benefit in a Cochrane Review of over 5,000 patients undergoing colorectal surgery. Discuss whether or not further trials of specific surgical procedures should continue to be performed given the evidence that has been published. What ethical considerations should go into the consideration of conduct of a trial for an intervention that has been previously studied?

8. What are the conclusions of the study? Should women undergo bowel preparation prior to undergoing pelvic reconstructive surgery? Do your patients undergo bowel preparation prior to gynecologic surgery? Discuss what influences your decision to administer or not administer a bowel preparation.