

Discussion Questions for Intro to Critical Appraisal Small Group Discussion – Instructor Copy

**These discussion questions relate to the following article:**

Grobman WA, Rice MM, Reddy UM, et al. Labor induction versus expectant management in low-risk nulliparous women. *N Engl J Med*. 2018;379:513-523.

**Start by playing the quick take video (1min 31sec) for the students at:** <https://www.nejm.org/doi/full/10.1056/NEJMoa1800566>

Then go over the discussion questions below as a group. **Note: Correct answers have been are marked in bold in the instructor copy.**

1. One of the limitations of the study was that **masking/blinding** was not feasible (p. 522 in “Discussion” section and 514 under “Methods: Trial Oversight”).
2. What problems are caused when studies are not blinded?
3. **Lack of blinding could create bias/unequal treatment between groups.**
4. Would it have been possible to blind the patients/clinicians?
5. **Perhaps they could’ve done a placebo-controlled trial but they were purposeful about not using a standard protocol in hopes the study results would be more generalizable.**
6. Who should be blinded in trials?
7. **Patients, clinicians, data collectors, data analysts, and adjudicators of outcomes.**
8. Were any groups blinded in the study (top of p. 516 under “Methods: Trial Outcomes”)?
9. **Adjudicators of outcomes**

1. Women in the study were randomly assigned to either labor induction or expectant management. The randomization sequence was prepared by an independent data coordinating center. (p. 515 under “Methods” Section)
2. How did the researchers ensure that the participants were randomized to the correct group according to the randomization sequence “list” prepared by the independent data coordinating center?
3. **It doesn’t say, so we don’t know if the allocation was concealed until the assignment occurred.**
4. **Ordinarily this is reported under the Methods section**
5. What potential effect could it have on the results of the study if allocation was not concealed?
6. **Inadequate allocation concealment can cause selection and confounding biases, and lead to exaggerated estimation of treatment effects.**

1. Let’s see if the randomization worked by comparing the prognostic factors of the two groups at the start of the trial. Turn to Table 1. Maternal Characteristics at Baseline on page 518.
2. Are both groups similar at baseline?
3. **“The two groups were similar at baseline, except that fewer women in the induction group than in the expectant-management group had a previous pregnancy loss (22.8% vs. 25.6%, P=0.01) (Table 1) p.518”**
4. **This difference is unlikely to have affected the outcome because these were all women at low risk of having poor maternal-fetal outcomes but it’s likely not powered to detect a difference in the outcome.**
5. **This is an opportunity to reinforce how difficult it is to detect rare findings in a research study, especially in low-risk populations, and why the power of a study is so important.**

1. Now let’s take a look at who was included and excluded from the study. Turn to Figure 1 on page 517 of the article.
2. What do you notice about who was excluded? What stands out to you?
3. **Only 27% of the eligible women chose to participate in the study**
4. What effect could the low participation rate have on the results of this study?
5. **The low participation rate could mean that selection bias has occurred and this sample isn’t representative of the general population.**
6. Let’s go back to Table 1. Do the patients in this trial have characteristics that might not be representative of the general population?
7. **Participants were young, overweight, married/living with a partner, employed (either full-time or part-time), whose method of conception was spontaneous.**

1. The researchers used intention-to-treat analysis. (p.516)
2. What does that mean?
3. **Participants are analyzed in the groups they were randomized.**
4. **“Once randomized, always analyze.”**
5. Why is it important to use intention-to-treat analysis?
6. **Protects randomization, keeps prognostic factors balanced, mimics real life**

1. According to the authors, “the data suggest that 1 cesarean delivery may be avoided for every 28 deliveries among low-risk nulliparous women who plan to undergo elective induction of labor at 39 weeks.” (p. 522). This is known as the number needed to treat (NNT).
2. How would you explain this information to a patient?
3. **28 patients would need to be treated for 1 to benefit**

1. What do you think of the power of the study in this population with respect to the outcome the authors were trying to measure? (p.516 & p.522)
2. **Population is low risk. More power is needed for rarer outcomes.**