

THERAPY UNIT

Objectives:

The objective of this unit is to determine the risk of bias of a randomized controlled trial, determine the results, and how the results might apply to a clinical scenario.

Assignment:

1. Review the clinical scenario, and read the attached randomized trial. Use the relevant chapter of the Users' Guides to critically appraise the trial using the attached worksheet. (What were the relevant risks of bias? What were the results? How do the results relate to the clinical scenario?)
2. Then read the ACP Journal Club article. The ACP-JC reviewers cited several reasons that weakened their beliefs in the results. Are they valid? How would you expect each potential issue to affect the RRR and NNT for the primary outcome and the safety outcome?
3. Does the patient described in this scenario meet the description of patients enrolled in the LIPPSMAck-POP trial? How might a deviation from the LIPPSMAck-POP eligibility affect the applicability of the results to this patient?
4. Come prepared to discuss your work in the context of the scenario.

Clinical Scenario:

You are an attending physician in a pre-operative assessment clinic. You are seeing a 60 year old female who will undergo an elective unilateral nephrectomy for a renal mass in 3 weeks. She is a former smoker with a recent history of a respiratory tract infection, which her family physician told her was bronchitis, and then treated her as an outpatient with an oral antibiotic. The remainder of her medical history is unremarkable. During your interview she discloses that her mother had bowel surgery many years ago, developed a post-operative pneumonia and died in hospital. She is very anxious about the surgery because of this and asks if there is anything she can do to prevent this from happening to her.

Enclosed Materials:

1. Boden I, Skinner E, Browning L, Reeve J, Anderson L, Hill C, Robertson I, Story D, Denehy L. Preoperative physiotherapy for the prevention of respiratory complications after upper abdominal surgery: pragmatic, double blinded, multicentre randomized controlled trial. *British Medical Journal*. 2017; 360:j5916.
2. Marshall J. A single preoperative physiotherapy session reduced pulmonary complications after upper abdominal surgery. *Annals of Internal Medicine ACP Journal Club*. 2018; SJ51.

3. Walsh M, Perkovic V, Manns B, Srinathan S, Meade M, Devereaux PJ, and Guyatt G. Therapy (Randomized trials). In: Guyatt G, Meade MO, Cook DJ, Rennie D. Users' Guides to the Medical Literature: A Manual for Evidence-based Clinical Practice. 3rd ed. New York, NY: McGraw-Hill; 2014.
4. Worksheet for the evaluation of an article on Therapy.

Notes:

Whether you are using this package to teach or to learn how to practice EBCP yourself, there are multiple take-home lessons in this package.

- New evidence is typically generated quickly for new treatments and the consistency of effects (i.e., the reproducibility of the treatment effect) is powerful evidence. This requires clinicians to update their knowledge regularly.
- Smaller trials have a lower probability of balancing baseline prognosis but it can be difficult or impossible to determine the extent to which the results are ultimately influenced by the known differences in characteristics
- Generalizability / external validity requires the reader to estimate whether the results apply to the patient(s) they are treating and in particular, whether differences between their patients or methods of using the treatment will change the expected benefits and risks of the treatment.
 - Trials enrolling active, engaged patient or relying on a skilled provider call into question the generalizability of the results. Simpler interventions that require less engaged the patients and less skilled providers are more likely to be generalizable.
- Risk of bias is established by assessing the methods of the trial to ensure they are robust
 - Trials that utilize behavioral interventions can be difficult to blind. Understanding whether behaviors changed in the manner expected from the intervention may aid in understanding if the treatment effects are really due to the intervention