

THERAPY UNIT

Objectives:

To learn how to assess the risk of bias of an article about therapy and how to apply the findings to your clinical practice.

Assignment:

- 1) Read the clinical scenario below.
- 2) Read the article by Baharoglu *et al.*
- 3) Assess the risk of bias (also known as trustworthiness, or internal validity) of the study reported in the article, guided by a series of questions on the attached critical appraisal form.
- 4) Apply the findings of the article to your clinical practice, guided by additional questions on the critical appraisal form.
- 5) **Note:** This article presents the results in an unusual format for a randomized trial (Odds Ratios). For the purpose of this assignment, you can treat as Relative Risks and be prepared to discuss the difference in tutorial. Interested learners can attempt to calculate the Relative Risk of a modified Rankin Score 4-6 at 3 months in the intervention vs. placebo arm.

Clinical Scenario:

You are on-call for the internal medicine service at a small community hospital and have been asked to see a 78 year old male in the emergency department with acute confusion and left-sided face and arm weakness, with no history of recent head trauma. He has a past medical history of diabetes, gout, and coronary artery disease, and has been taking aspirin and clopidogrel after a non-ST elevation myocardial infarction and placement of a drug-eluting stent 9 months ago. His platelet count is $180 \times 10^9/L$. A computed tomography scan shows a deep intracerebral hemorrhage of moderate size (2 cm in largest diameter) with minimal mass effect.

The neurosurgeon on-call, who reviewed the case over the phone with you and concluded that no surgery is needed, mentions just before hanging up: "... but the patient is on two antiplatelet drugs, so I would give him a platelet transfusion." You wonder if there is any evidence to support this practice and, after conducting an online literature search, find the attached article by Baharoglu *et al.*

Enclosed Materials:

1. Baharoglu MI, et al. Platelet transfusion versus standard care after acute stroke due to spontaneous intracerebral hemorrhage associated with antiplatelet therapy (PATCH): a randomised, open-label, phase 3 trial. *Lancet* 2016;387:2605-13.
2. Therapy (Randomized Trials). In Guyatt G, Rennie D, Meade MO, Cook DJ. Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice, 3rd Edition, New York, NY: The McGraw-Hill Companies, Inc. 2014.

3. Blank critical appraisal form

Activities:

1. Review the article, complete the critical appraisal form, and prepare to discuss.