

HARM

Objective:

To evaluate an article about harm and answer the following questions:

1. Was the study valid?
2. What were the results?
3. Do these findings apply to your patient?

Assignment:

1. Read the scenario and decide how you would respond to the problem.
2. Read the attached guidelines for reading articles concerning harm.
3. Critically appraise the attached article using the worksheet.
4. Decide how you would respond to the problem after appraising the article.

Clinical Scenario:

You are an urologist in West Palm Beach, Florida and your next patient is a 65 year old gentleman who is a new patient. Based on his outside records, he was diagnosed with high grade (Gleason score 8) node positive prostate cancer at the time of radical prostatectomy and subsequently placed on androgen ablation. He was also found to have a single area of increased radiotracer uptake in his right pelvis consistent with metastatic disease. The patient has recently moved from Maine and seeks to establish care with you. His past medical history is only notable for hypertension which is well controlled on a single agent.

He asks your opinion about the need for continued androgen ablation (medical castration) which you assure him is indicated. He then expresses concerns about the long-term side effects of androgen ablation which he has been on for over three years; in particular that of debilitating fractures. You assure him that such events are unlikely, although you are unable to quote him any specific figures. You therefore signal to him that you will research his question and provide him with a more detailed answer when he returns for his next hormone injection.

Relevant Materials

1. Levine M, Ioannidis JP, Haines A, Guyatt G: Chapter 14: Harm (Observational Studies). In Guyatt G, Rennie D, Meade MO, Cook DJ. *Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice*, 3rd Ed. New York, NY: McGraw-Hill; 2015.
2. Shahinian VB, Kuo YF, Freeman JL, Goodwin JS: Risk of fracture after androgen deprivation for prostate cancer. *N Engl J Med* 2005, 352(2):154-164.
3. Kennedy CC, Jaeschke R, Keitz S, Newman T, Montori V, Wyer PC, Guyatt G: Tips for teachers of evidence-based medicine: adjusting for prognostic imbalances (confounding variables) in studies on therapy or harm. *J Gen Intern Med* 2008, 23(3):337-343.