

Session on critical appraisal of RCTs

Rod Jackson September 2017

Should antibiotic prophylaxis be used routinely in clean surgical procedures: A tentative yes

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Background. *The incidence of surgical site infection (SSI) after clean surgical procedure has traditionally been regarded as too low for routine antibiotic prophylaxis. But we now know that host factors may increase the risk of SSI to as high as 20%. We assessed the value of prophylactic cefotaxime in patients stratified for risk of SSI in a randomized double-blind trial.*

Methods. *Patients admitted for clean elective operations were enrolled, stratified for risk by National Nosocomial Infection Survey criteria, and randomized to receive intravenous cefotaxime 2 gm or placebo on call for operation. They were followed for 4 to 6 weeks for SSI diagnosed by Centers for Disease Control and Prevention criteria.*

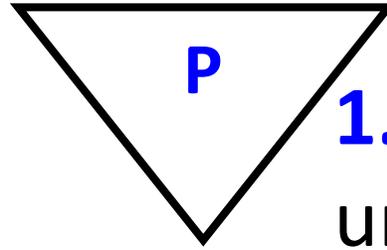
Results. *Analysis of 775 patients showed that the 378 evaluable patients who received cefotaxime had 70% fewer SSIs than those who did not—Mantel-Haenszel risk ratio (MH-RR) 0.31; 95% confidence intervals (CI) 0.11 to 0.83. Benefit was clear in the 616 low risk patients—0.97% versus 3.9% SSI (MH-RR 0.25, CI 0.07 to 0.87, $p = 0.018$), but only a trend was seen in 136 high risk patients—2.8% versus 6.1% SSI (MH-RR 0.48, CI 0.09 to 2.5).*

Conclusions. *The results indicate clear benefit for routine antibiotic prophylaxis in clean surgical procedures. High risk patients need more study. (SURGERY 1995;118:742-7.)*

patient problem

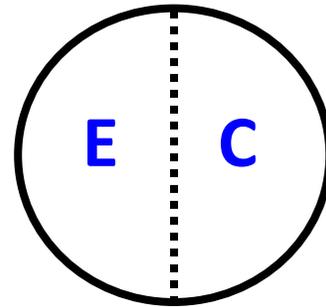
- 67 year-old male with history of multiple episodes of cholecystitis
- you first see him at post-op ward round after routine elective cholecystectomy
- he has a wound infection (& did not receive prophylactic antibiotics pre-op)
- in your previous run (orthopaedic surgery) pre-op antibiotics were given routinely
- you ask consultant why patient didn't receive pre-op antibiotics
- she says its not routinely used in gen. surgery but asks you to review the current evidence

a focussed 5-part clinical question



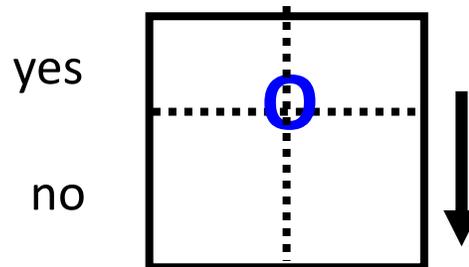
1. in patients undergoing routine cholecystectomy

2. will prophylactic antibiotics given pre-op



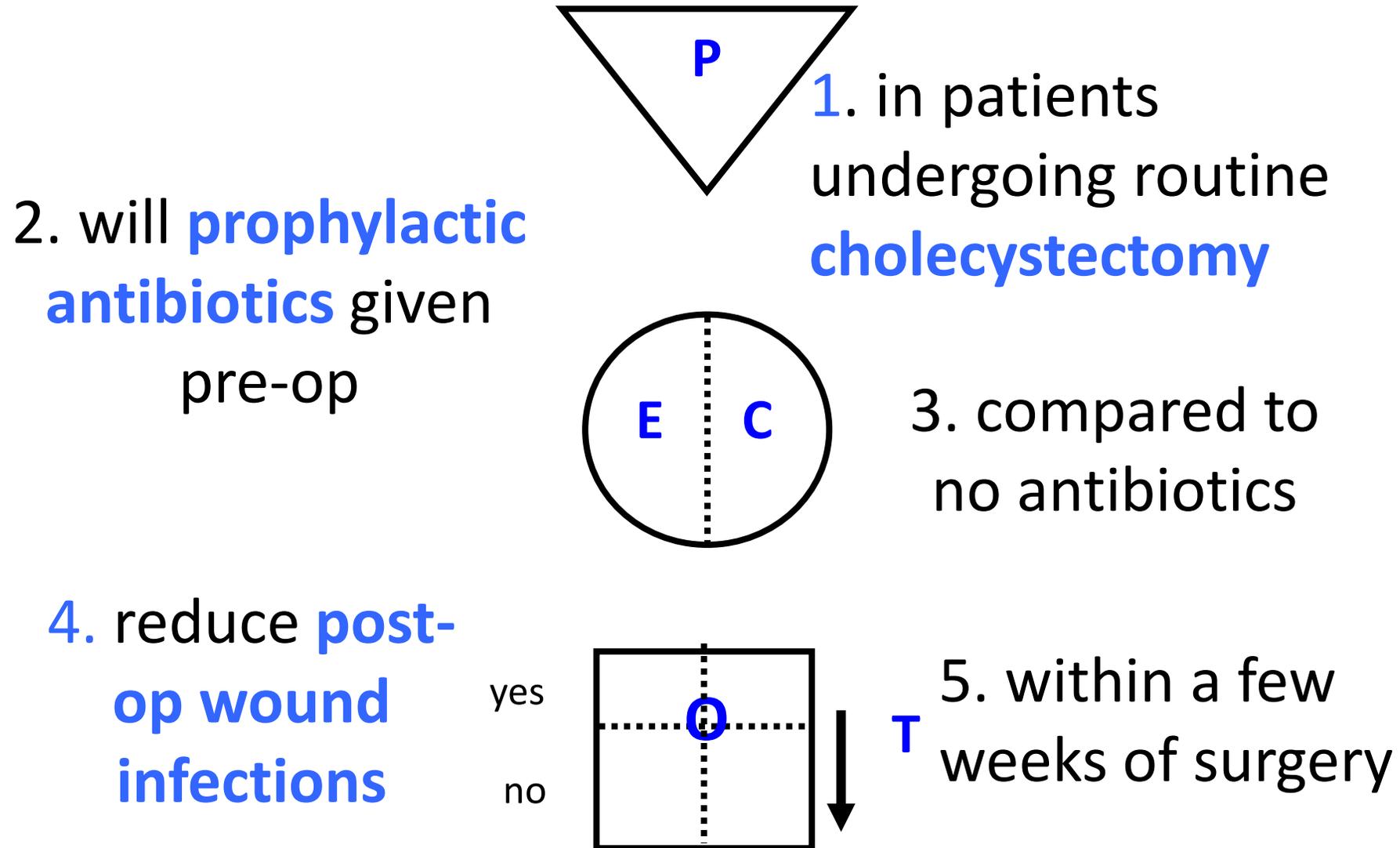
3. compared to no antibiotics

4. reduce post-op wound infections



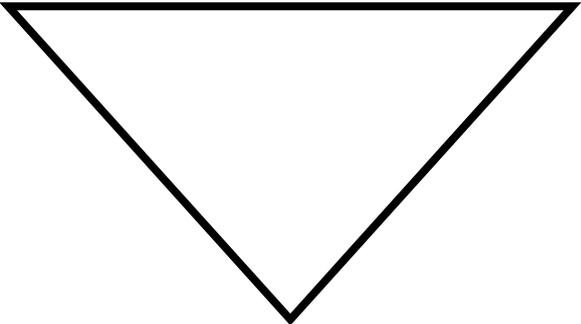
5. within a few weeks of surgery

use question to chose search terms

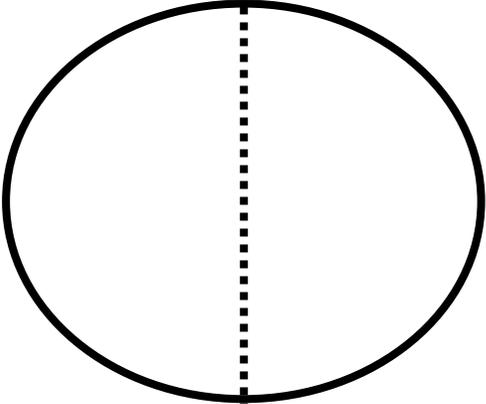


Study design: PECOT

Participants

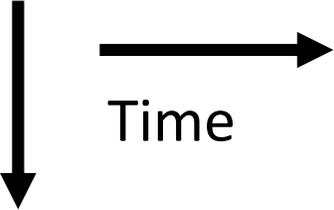
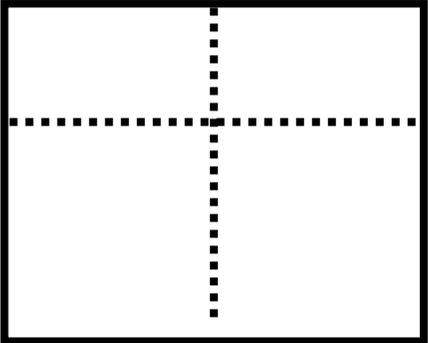


Exposure (Intervention)



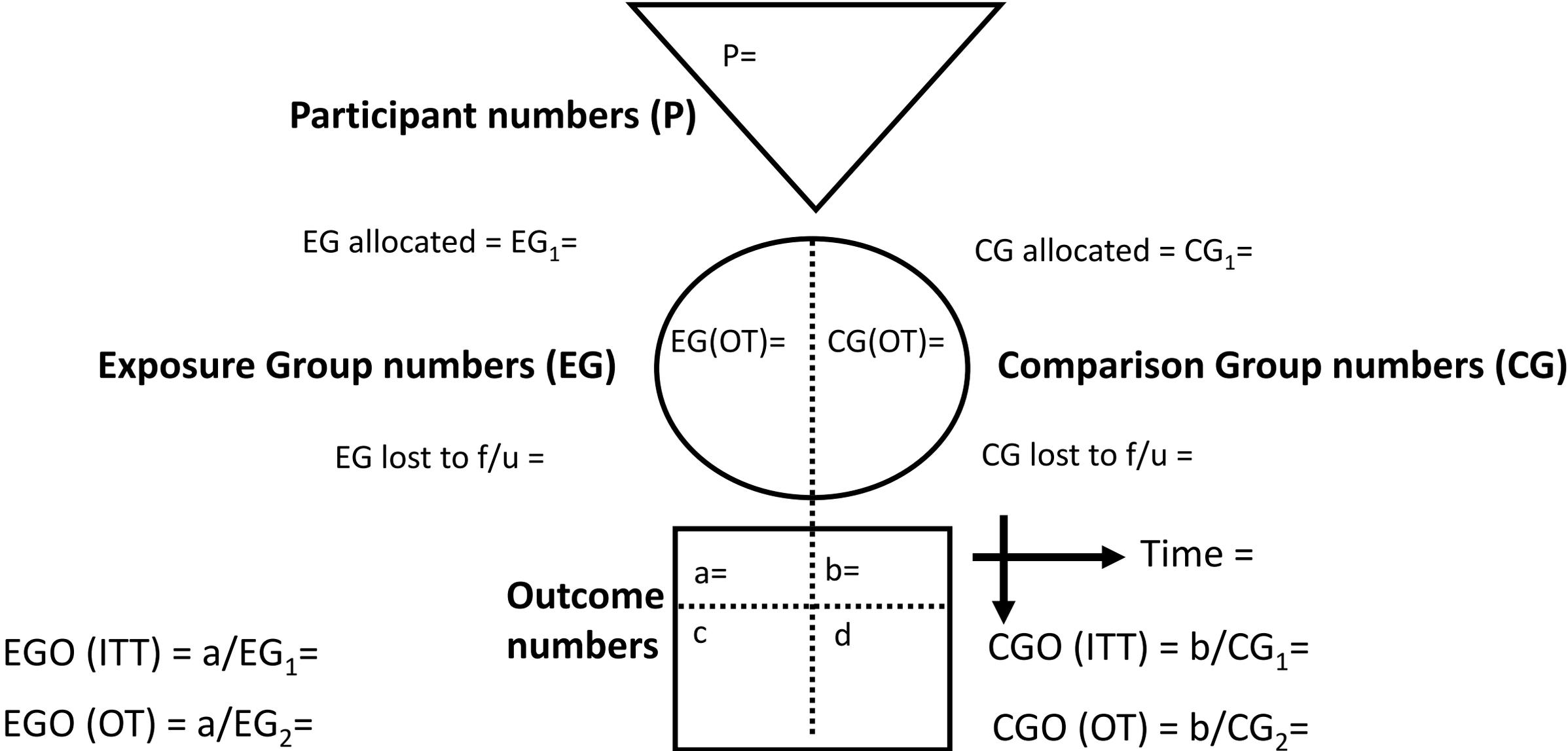
Comparison (Control)

Outcome



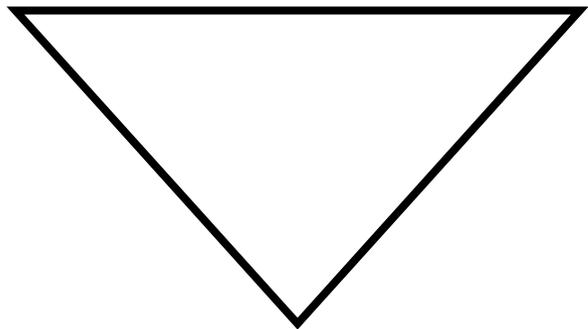
Time

Study analysis: EGO & CGO

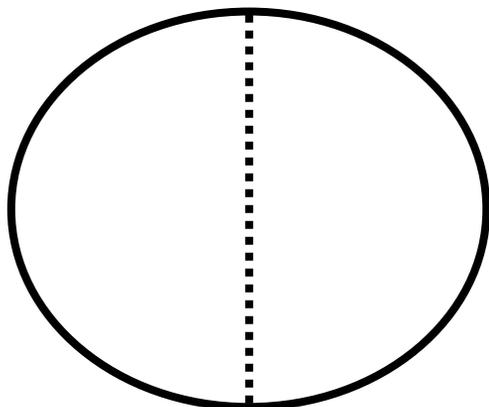


Study error: RAMBOMAN

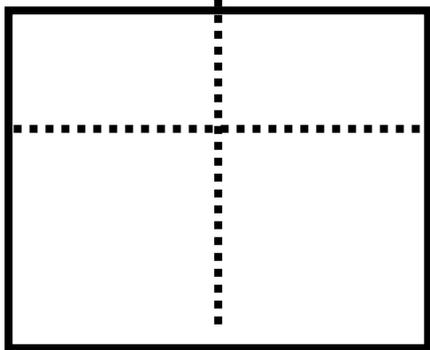
Recruitment



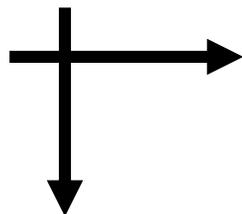
Allocation



Maintenance

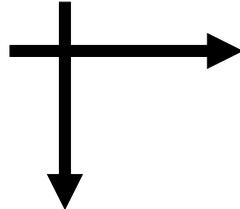
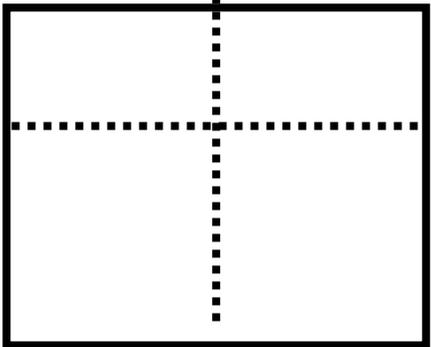
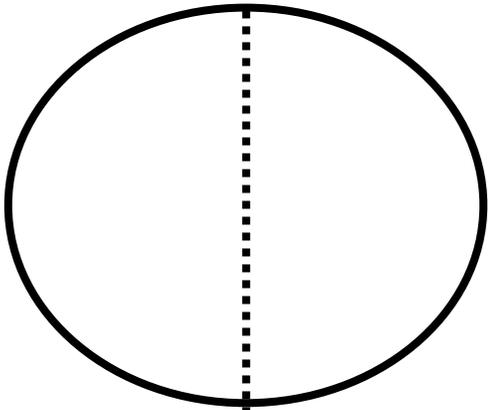
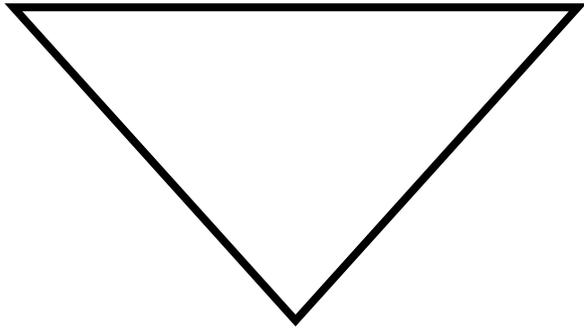


Blind/Objective Measurements



Analysis: Adjustment for confounding/ ITT

Study error: 95% CI for EGO, CGO, RR, RD, NNT



X-factor: making evidence-based decisions

