Cluster Randomized Trials and Case-Control Studies of Surgical Site Infections with Group Assignments Being the Operating Rooms

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Introduction: We consider designs of observational studies and clinical trials of interventions to mitigate surgical site infections (SSI) in patients receiving care with or without interventions that are 1:1 with operating room (ORs). Our use case is a large teaching hospital buying 5 anesthesia machines (e.g., with modified surfaces) or renovating 5 ORs (e.g., bactericidal OR lighting), and aiming to compare SSI within 1-year between intervention ORs and 5 or 15 control ORs.

Methods: To model heterogeneity of risk factors for SSI among ORs, we used 10 years of accurate OR information system data from a teaching hospital, 221,796 cases.

To model heterogeneity of SSI among 24 procedure categories (e.g., colorectal surgery), we used 2015 California Department of Public Health data, SSI or not, for 676,530 surgical cases performed at 338 hospitals.

Results: Mean OR times of cases were 3.01 hr (standard error SE 0.01) for the hospital surgical suites versus 1.10 hr (0.01) in the outpatient departments. The percentages of cases where the patient was American Society of Anesthesiologists' Physical Status (ASA PS) ≥3 were 50.6% versus 19.9%, respectively. Thus, limiting a study of new equipment to inpatient ORs is warranted. For such ORs, and obtaining consent from patients Monday-Friday, expect ≅600 patients per OR during 1-year study.

Patients' baseline risks of SSI depend on case duration, urgency, and ASA PS. Six specialties each had ≥10,000 cases: orthopedics, general surgery, otolaryngology, urology, neurosurgery, and gynecology, not distributed randomly among ORs (P<0.00001). For each specialty, the Bonferroni adjusted Kruskal-Wallis test for equality of case durations among the 32 inpatient ORs were P<0.00001. For each of the specialties, the proportion of cases added to the schedule after 7 PM the day before surgery differed in distribution among ORs, all 6 Bonferroni adjusted chi-square P<0.00001. Finally, ASA PS ≥3 versus 1-2 varied among ORs, all 6 P≤0.00034. Thus, expect SSI risk to differ among ORs, even if ORs are paired by specialty.

Selection of ORs for the intervention should not be simply the ORs with patients of the greatest risk of SSI or ORs with the most patients exposed to the OR, because the criteria result in different ORs selected. Those ORs with fewer cases per year were those with longer mean OR times (Spearman correlation -0.84 SE 0.10, P<0.00001). Those ORs with fewer cases per year also had larger ASA PS (P<0.00001).

Sample sizes for case-control studies depend on the probabilities of patients listed as receiving the intervention but not receiving it, and vice-versa. This occurs due to error in the listed OR where the patient had surgery. With OR identification based on the machine recording most of the patients' pulse oximeter saturations, error ≅0.016%. Applying this, with 5 intervention ORs and 5 or 1 control patients for each intervention patient, and α=0.05, ≅94% or 78% statistical power, respectively, would be obtained in a 1-year study to detect a reduction in the SSI incidence from 3.6% to 2.4%.

Cluster randomized trials depend on the estimated coefficient of variation of the count of cases among ORs, 24.1% (3.4%). They depend also on the intracluster correlation, ≅0.03 estimated from the State of California hospitals. Applying these values, with either 25 or 5 control ORs, the statistical power is only ≅7%. Matched paired cluster randomization designs have no greater estimated power.

Discussion: Retrospective analysis by pivot table of raw % incidence of SSI among patients having surgery in each OR results in a cluster design. Such tables and/or graphs will inevitably falsely fail to detect benefit even if present, resulting in poor hospital decision-making for OR capital equipment. Instead, when the intervention is the OR itself, evaluate SSI using case-control matching of patients.