Critical Review Form

Therapy

Treatment of Cutaneous Abscess: A Double-Blind Clinical Study**,** *Annals EM* 1985; 14: 15-19

Objectives: "To compare the outcomes of patients with drained cutaneous abscesses who were treated with antibiotics with those who were not." (p 15)

Methods: Prospective randomized trial over six-months of 1981 – 1982 at University of Cincinnati's adult ED of a subset of patients requiring incision and drainage of a cutaneous abscess. Exclusion criteria included those requiring hospitalization or operative management, DM, sickle cell disease, immunosuppressed conditions (unspecified), cephalosporin allergies, or non-paronychial hand infections. An abscess was defined as "a localized collection of pus causing a fluctuant soft tissue swelling and surrounded by firm granulation tissue and erythema" (p 15).

All subjects had abscesses incised, drained, probed, copiously irrigated and packed in standard sterile fashion. Cultures were not routinely obtained. Only pharmacy was aware of the content of vials containing cephradine or lactose placebo with patients instructed to take one capsule every six-hours for seven days. All subjects had packing removed at 24-48-hours and wound re-check at seven-days. For those who did not return at one week, researchers attempted telephone contact using a standardized (though unvalidated) assessment protocol. Medication compliance was assessed by a pill count at 7 days. Treatment failure was defined by any sign of fluctuance, drainage, induration, warmth or tenderness at seven days.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	Yes, using a balanced randomized and prepared coded vials with randomized medications (placebo/antibiotic) known only to the pharmacy staff p.16
2.	Was randomization concealed (blinded)?	Yes – to patients, clinicians and study investigators.

3.	Were patients analyzed in the groups to which they were randomized?	Not clearly stated, but presumably yes.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	The study population (Table 1, p16) is predominantly young adults and AA with perineum abscessed. No significant demographic difference like treatment and control group. Abscess size not noted.
B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	No – unless they can test a difference b/w lactose and cephradine capsules and have opportunity to do both.
2.	Were clinicians aware of group allocation?	No.
3.	Were outcome assessors aware of group allocation?	No – until pharmacy decoding after authors assessed.
4.	Was follow-up complete?	No! 27/81 (38%) lost to follow-up. This situation authors ought to determine whether analysis would change if all lost had one outcome or another.

II.	What are the results (answer the questions posed below)?	
1.	How large was the treatment effect?	• The authors estimate 360 patients at the clinic during study interval with abscesses requiring drainage, but they don't know the actual number or 81 not eligibility criteria (23%) of these 81, 27 were eliminated because they didn't follow-up. Another four were lost due to protocol violations. The authors note "no difference between the study population and the 31 patients eliminated from the study in regard to race, age, sex, or abscess location. (p 16) • 66% subjects had physician-investigator follow-up, 34% telephone follow-up. • Treatment group 26/27 (96%) clinically improved; placebo group 22/23 (96%) improved. There were two treatment failures, one in each arm of the study. • Compliance rates (defined as at least 22/28 capsules missing) were equivalent in the treatment (67%) and placebo (70%) groups. • No assessment of side effects or healing rates occurred. • Post-hoc power analysis indicated 13 0.5 (power 50%). A larger study would have improved the power.
2.	How precise was the estimate of the treatment effect?	No CI reported so unable to assess precision.

III.	How can I apply the results to patient care (answer the questions posed below)?	
1.	Were the study patients similar to my patient?	No – excluded elderly subjects, diabetics, sickle cell and immunosuppressed. However, among young adults with wounds and an intact immune system, the results indicate that antibiotics play no role in uncomplicated abscesses after I&D.
2.	Were all clinically important outcomes considered?	No, did not assess patient-important outcomes like medication side-effects, wound healing rates and effect of patient comorbidities on outcome.
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes – if adequately powered well – conducted studies confirm these findings the body of evidence suggest that antibiotics are unnecessary in a large subset of ED abscess patients. Therefore the potential harm of antibiotics (cost, SE, resistance) can be avoided.

Limitations

1. Selection bias – clinicians choose which abscess pts to approach to enter the study.
2. Under powered – why didn't authors power their study appropriately from the beginning?
3. Unacceptable loss to follow-up with sensitivity analysis.
4. Non-validated telephone follow-up.
5. No Kappa analysis of treatment failure (or abscess),
6. Incomplete assessment of pt important outcomes.

Bottom Line

Dated, single-center, underpowered study which adds to a growing body of evidence indicating that sterile incision, drainage, abscess wall disruption, irrigation and packing with close follow-up in immunocompetent adults is sufficient ED management of uncomplicated cutaneous abscesses and the addition of antibiotics does not reduce failure rates. Although updated research on this topic is necessary, including

immunocompromised subjects, the current evidence suggests that antibiotics offer no benefit to abscess healing and risk medication side-effects, selecting resistant organisms, and substantial expense and therefore should not be used.