Critical Review Form

Therapy

Antibiotics in Surgical Treatment of Septic Lesions, Lancet 1970; 1: 1077-1080

Objectives: To test the efficacy of antibiotics as an adjunct to incision and drainage of septic lesions (abscess).

Methods: Randomized, non-placebo controlled trial of 542 subjects at the ED of Royal Victoria Hospital in Belfast, Ireland during unspecified time period with hand infections (other than tenosynovitis, deep palmar abscesses or vascular disease related), subcutaneous pyogenic abscesses and infected sebaceous cysts. Subjects were randomized by unspecified method to incision and drainage (I&D) and cloxacillin pre-procedure and 5-day, post-procedure versus I&D alone without any antibiotics. Although no placebo was provided authors note "only the nursing sister who gave the patients their treatment … had access to this plan during the trial." (p 1077) Patients had follow-up every 48-hours for dressing changes.

Outcomes included healing time (defined in days between the operation and days when dressing change revealed dry dressing). Power calculations were based on a 3-day healing time judged as clinically significant. Unclear is whether any exclusion criteria were used, whether all patients had cultures, whether compliance was assessed and who judged the outcome of dressing = wound healing, or whether any reproducibility assessment (Kappa) of this subjective outcome was assessed.

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, by unspecified mechanism.
2.	Was randomization concealed (blinded)?	Although authors note that only the nurse administering daily medications knew which arm patient was in, patients could easily have noted whether they were receiving pills and/or had IM injection. Furthermore, physicians could have worked the patient and/or nurse.

3.	Were patients analyzed in the groups to which they were randomized?	Presumably, but not clearly stated.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No demographic information was provided to assess baseline risk.
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?	Presumably yes.
2.	Were clinicians aware of group allocation?	Possibly, if they worked or were observant.
3.	Were outcome assessors aware of group allocation?	Yes.
4.	Was follow-up complete?	No. 192/542 lost to follow-up (p.1078)
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• 85% of cases were solely staphylococci. • Decreased healing-time for abscesses/boils with antibiotics (7.6 days versus 9.8 days), a difference not observed for hands or sebaceous cysts. • No difference with antibiotics noted for age >50 or with previous antibiotic exposure. • Trail halted early when “no difference” threshold crossed.

2.	How precise was the estimate of the treatment effect?	No Confidence Intervals reported so cannot 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?	Uncertain because few demographic (gender, socio-economic status, co-mobidities) or abscess unspecific (size, fever, tenderness) are provided for comparison.
2.	Were all clinically important outcomes considered?	No. Patient important outcomes like: antibiotic side-effects, wound cosmesis, and healing abscess pain not assessed.
3.	Are the likely treatment benefits worth the potential harm and costs?	If no benefit in wound healing-time cost/risk of antibiotic in abscess management probably not indicated.

Limitations

1) No clear method of randomization described.
2) Limited patient demographics provided to permit assessment of generalizing results to reader's patients.
3) Methods poorly described: Who performed the I&D? Who assessed wound healing and the endpoint of "dry-dressing"?
4) No sensitivity analysis performed with fairly large number lost to follow-up.

Bottom Line

Dated study of heterogeneous collection of Irish abscess subjects randomized to receive cloxacillin with I&D or I&D alone with no difference in wound healing rates or post-procedure complications noted between groups. Based upon this study the role of antibiotics in the management of appropriately incised superficial cutaneous abscesses is uncertain.