Journal Club Eastern Virginia Medical School
Therapy Article

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CITATION: Schmitz GR et al. Randomized controlled trial of trimethoprim-sulfamethoxazole for uncomplicated skin abscesses in patients at risk for community-associated methicillin-resistant Staphylococcus aureus infection. Ann Emerg Med. 2010 Sep;56(3):283-7

I. **WHAT IS BEING STUDIED?**	
1. Study Objective	To determine whether treatment with Bactrim reduces the rate of treatment failures (by 15%) for uncomplicated skin abscesses at 7 days and whether it reduces new lesion formation within 30 days.
2. Study Design	Multicenter, double-blind randomized, placebo-controlled trial at four military hospitals
3. Inclusion Criteria	Patients aged 16 and over with uncomplicated skin abscesses requiring incision and drainage
4. Exclusion Criteria	- immunocompromised - Pregnant or breast feeding - allergic to Sulfa drugs - fever or signs systemic illness - abx in prior week - hospitalized in previous month - abscesses to face - deep space abscess - requiring OR drainage
5. Interventions Compared	Trimethoprim-sulfamethoxazole 160/800 bid x 7 days vs placebo
6. Outcomes Evaluated	**Primary**: treatment failure within 7 days (defined as no improvement after 2 days, development of new lesion within 7 days, worsening infection within 7 days) which led to intervention (additional abx, repeat I&D, or admission) **Secondary**: development of new lesions within 30 days
II**. Are the results of the study valid**	
1. Was the assignment of patients randomized?	Yes. Block randomization scheme using sealed envelopes.
2. Was randomization concealed (blinded)?	Yes.
3. Were patients analyzed in the groups to which	Most were. The authors lost 31% of patients to 30

they were randomized?	day follow up and did not include an ITT calculation of those patients.
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes (see table 1 – though no P values given for inter-group differences)
III. **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 – placebo controlled
2. Were clinicians aware of group allocation?	No – double blinded
3. Were outcome assessors aware of group allocation?	No – recheck physicians were blinded to study arm
4. Was follow-up complete?	No – 90% (190/212) at 7 day follow up and only 69% (96/139) at 30 day follow up (though 69% of patients from centers who participated in 30 day follow up) No ITT analysis calculations included. "Post hoc sensitivity analyses assuming extreme opposite outcomes for patient lost to follow-up would change the statistical significance of both primary and secondary outcomes"
IV. What were the results? Answer the questions posed below	
1. How large was the treatment effect? (Difference between treatment and control group).	No statistically significant difference in treatment failure at 7 days: 17% in treatment group vs 26% in placebo group, (95% CI= -2-21) p-value 0.12 Statistically significant difference in new lesions within 30 days: 28% placebo vs 9% (95% CI= 4 to 34%) treatment group, p-value 0.02
2. What was the estimated treatment effect at a 95% confidence interval? (Precision)	As above
V. **Will the results help me in caring for my patients? (Applicable?)**	
1. Were the study patients similar to my patient?	Not really. These were all healthy patients from military hospitals. Average age was 27 y/o, Median cellulitis was <5cm and abscess size was <3 cm.
2. Were all clinically important outcomes considered?	Mostly. No economic analysis regarding work time losses which could be relevant to this patient population. Not powered to assess AB side effects or development of resistance.
3. Are the likely treatment benefits worth the potential harm and costs?	Based on their study, no benefit so any harms/costs of antibiotics not justified.

Study Limitations:

1) Significantly underpowered – why did they choose 15% as cut off
2) Lack of follow up and no ITT calculations on those lost.
3) Convenience sample, slow enrollment – took 4 centers with combined ~220,000 annual census 18 months to enroll 220 patients with uncomplicated abscess. Likely predisposes to selection bias.
4) No standardization of I & D process
5) No compliance reporting regarding meds
6) Majority of these lesions did not meet IDSA criteria for AB's
7) Healthier population than we are likely to encounter in the civilian world.

Clinical Bottom Line:

Based on this study, I would not prescribe antibiotics for uncomplicated abscess in a similar patient population. However, this study was significantly underpowered to detect clinical treatment effect or harm from antibiotics.