Critical Review Form

Therapy

Tap Water for Irrigation of Lacerations

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Objective: "To show the safety and efficacy of tap water irrigation in children for the management of extremity laceration repairs in the ED." (p 469)

Methods: Single center (UT-Southwestern) randomized trial from June 1999 thru August 2000 of pediatric patients (ages 1 – 18 years) presenting to the ED within 8-hours of simple traumatic extremity lacerations. Exclusion criteria included hand lacerations, immunocompromised children dog bites, or pre-injury antibiotics. Simple laceration was defined as not extending to muscle or bone, and no joint involvement.

Using a randomization schedule a non-investigator staff member prepared a sterile basin with either 500 cc of tap water (TW) or sterile saline (SS) before giving it to the blinded investigator for wound irrigation. Wounds were irrigated with a 35 cc syringe attached to an irrigation shield.

The primary outcome was wound infection as defined by >4 mm tender erythema (cellulitis), purulent wound discharge, ascending lymphangitis, or >2 mm wound dehiscence. A secondary outcome was post-irrigation positive wound culture (before primary closure). All wounds were cultured both before and after irrigation. Antibiotic ointment was applied to all wounds and 48-hour follow-up was recommended. The study had no *a priori* (or *post-hoc*) power analysis.

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, although the details of the "randomization schedule" are not described.
2.	Was randomization concealed (blinded)?	Yes, to patients and treating clinicians.
3.	Were patients analyzed in the groups to which they were randomized?	No clear statement of intention-to-treat.

4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	"There was no significant difference between the two groups in relation to gender, injury mechanism, length of wound or location of laceration." (p 470)

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
2.	Were clinicians aware of group allocation?	No
3.	Were outcome assessors aware of group allocation?	Not clearly stated, but outcome assessors were probably not aware of group allocation.
4.	Was follow-up complete?	No CONSORT diagram or lost to follow-up was reported. Of 46 enrolled patients 44 returned and 2 were contacted by phone.
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• Infections occurred at 48-hours in 9.5% (2/21) TW subjects and 8.3% (2/24) SS subjects (no significant difference). No details are provided on the severity or outcomes of the infected subjects. • A post-irrigation culture was positive in 52% (11/21) TW subjects and 29% (7/24) SS subjects (p=0.2). Investigators made no attempts to distinguish contaminants from pathogens.
2.	How precise was the estimate of the treatment effect?	No Confidence Intervals are provided by which to judge 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. Was this a convenience sampling? If not, 46 lacerations over 14 months seem rather small (sampling bias).

2.	Were all clinically important outcomes considered?	No, the authors do not assess patient comfort or wound cosmetic appearance. Patient expectations may be an important, unmeasured impediment to routinely using TW rather than SS.
3.	Are the likely treatment benefits worth the potential harm and costs?	The authors do not quantify the cost-difference between SS and TW, nor do they estimate the cost of any increase in wound infection rate.

Limitations

1) **Vastly under-powered study. They recruited 46 subjects, but based upon a baseline infection rate of 3% they'd have to recruit 300-1500 patients to avoid a Type I or Type II error.**

2) **Very poorly described methods. How was the randomization schedule implemented? (Odd-even days? Opaque envelope? Random-numbered generator)? Who assessed the primary outcome? Was that person(s) blinded to the allocation arm?**

3) **Only 46 patients recruited over 14-months. This low number suggests either a very low volume pediatric center or an (unreported) convenience sampling. Either way, a *selection bias* is likely limiting both internal and external validity.**

4) **The authors limited selection to extremity lacerations. Why?**

5) **In wound cultures, contaminants were not distinguished from likely pathogens.**

6) **Tap water was not cultured.**

7) **Wound closure method (staple, suture) was not reported.**

8) **Intention-to-treat was not clearly described and no CONSORT diagram was provided.**

9) **No CI's are provided.**

Bottom Line:

Poorly reported, under-powered single-center randomized trial of pediatric extremity lacerations suggesting no significant difference in post-repair infection rates of <8-hour old traumatic laceration repair when irrigated with TW or SS. The current report might be useful as part of a meta-analysis, but as an isolated trial lacks internal and external validity and should not change practice.