Critical Review Form
Therapy

A Multicenter Comparison of Tap Water Versus Sterile Saline for Wound Irrigation
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Objective: **"To conduct a multicenter comparison of wound infection rates in simple lacerations when irrigated with TW (tap water) versus SS (sterile saline) before primary closure in the ED." (p 405)**

Methods:

From June 1999 – August 2003, all patients over age 17 with uncomplicated skin lacerations requiring staple or suture closure were enrolled at 1 of 3 hospitals (Hennepin County Medical Center, Erie County Medical Center, and Millard Fillmore Suburban Hospital) in a prospective, randomized, non-blinded fashion. Exclusion criteria included puncture wounds, bite wounds, self-inflicted wounds, wounds >8 hours old, tendon/bone/joint wounds, gross contamination requiring scrubbing or surgical debridement, patients taking antibiotics or corticosteroids, patients with diabetes or peripheral vascular disease or HIV, pregnant patients, prisoners, or patients who are unable to consent.

Allocation occurred at each site by selection of "the next numbered study envelope for that institution" with pre-randomization by a computer-based random number generator. In the TW group patients were instructed on use of the sink (upper extremity) or a non-sterile single-use 3-ft clear plastic tubing pipe for a minimum of 2-minutes. No maximum volume or time was specified and the provider did not have to remain in the room. The SS group used a minimum of 200 mL delivered by a 35 cc syringe with a splash shield. No prophylactic antibiotics were given and post-irrigation wound care was at the discretion of the treating physician.

All subjects were instructed to return within 5 – 14 days (depending on the wound site). Those who did return received a $10 stipend. Those who did not return were contacted by phone to ascertain the possible presence of wound infection. The primary outcome was wound infection defined by "wounds that after closure required a significant change in their course of treatment, such as surgical debridement, antibiotics, or early removal of sutures or staples." (p 405)

Additionally, investigators analyzed costs of supplies paid by hospitals (for sterile saline, syringe, splash guard, etc.).

Based on a 5% difference in wound infection rates, the study was powered at 80% with $\alpha = 0.05$ and a projected 15% attrition rate. TW was considered equivalent to SS if the TW infection rate was <10%, representing twice the SS expected infection rate based upon the literature.

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. "Subjects were randomized to SS or TW irrigation by opening the next numbered study envelope for that institution." (p 405)
2.	Was randomization concealed (blinded)?	No, subjects and treating clinicians knew the allocation arms. For this particular question blinding subjects and clinicians would be impractical, through not impossible. For example, one could use tap water bottled in saline bottles as a sham.
3.	Were patients analyzed in the groups to which they were randomized?	No clear intention-to-treat analysis is stated, although Figure 1 (p 406) suggests analysis within treatment arms.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	The anatomic distribution (Table 1, p 407) and wound mechanism/length/ repair did not differ between the two groups. No details are provided on patient factors (age, gender, race, time-to-repair, follow-up proportion) by which to gauge patient-specific confounding variables.
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?	Yes
2.	Were clinicians aware of group allocation?	Yes
3.	Were outcome assessors aware of group allocation?	No – "providers in the ED removing staples or sutures were blinded to the subject's allocation" (p 405)
4.	Was follow-up complete?	71/715 subjects were lost to follow-up (35 SS, 36 TW). Of those who were followed, 54% returned to the ED and **46% were contacted by phone!**

II.	**What are the results (answer the questions posed below)?**	

1.	How large was the treatment effect?	• 634/715 eligible subjects were enrolled and analyzed. Most of those not analyzed were lost to follow-up (71). • The SS infection rate was 3.3% (11 subjects), while the TW infection rate was 4% (12 subjects, difference 0.7% with 95% CI = – 2.2% - 3.6%). Only one infection required admission. All others were managed on outpatient basis. • Based on a patient charge of $9.11 for SS irrigation supplies, 13.5/L of water for 2-minutes TW irrigation at $0.00011/L (cost per patient $0.0015) and $0.60 per 3 feet of tubing for 36% of TW patients ($0.22 per patient) the authors extrapolate a savings of $65.6 million/year in the US if TW is used in place of SS. <u>This savings is based upon the worst case scenario 3.6% increased infection risk in TW all treated with Keflex.</u>
2.	How precise was the estimate of the treatment effect?	Narrow CI for infection rate. The upper margin of 3.6% would not dissuade most from using TW instead of SS.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	Yes, ED patients presenting to academic medical centers with acute lacerations.

2.	Were all clinically important outcomes considered?	No, the authors do not assess patient comfort or wound cosmetic appearance. Patient expectations may an be important, unmeasured impediment to routinely using TW rather than SS.
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes, TW appears to be equivalent to SS for acute traumatic laceration requiring EM closure at a substantial cost-savings.

Limitations:

1) **Unblinded (to patients and treating clinicians) convenience sampling. Because patients and clinicians were aware of allocation arm, bias (ascertainment bias, co-intervention bias) is possible. In addition, convenience sampling could produce a selection bias.**

2) **Potential Hawthorne effect in the SS group since clinicians knew their patient outcomes were being monitored in a study setting. Did they irrigate longer, more carefully, or with greater volumes of saline than they otherwise would have?**

3) **Substantial lost to follow-up without any sensitivity analysis. Fortunately, equal numbers lost in SS and TW groups.**

4) **Non-validated telephone follow-up for 46% of those analyzed. Does anybody really think wound infection can be diagnosed over the phone as well as via face-to-face evaluation?**

5) **No statement of intention-to-treat analysis although CONSORT diagram (Fig 1, p 406) suggests groups analyzed according to allocation assignment.**

6) **Under-powered study. Investigators calculated an *a priori* sample size of 1000 based upon a 10% infection rate. Doubling the observed 3.3% infection rate would re-calculate a 1500 subject sample size. The current study only recruited 715 subjects (and only analyzed 634!), so they may have suffered a Type I error (failed to detect significant difference because insufficient sample size).**

Bottom Line:

Under-powered multi-center convenience sampling with substantial lost-to-follow up and no sensitivity analysis suggests that TW may be equivalent to SS in uncomplicated traumatic lacerations requiring ED closure. If validated, these findings could simplify ED wound irrigation while saving $65.6 million/year in the US alone.