Critical Review Form
Therapy

A Pilot Study on the Repair of Contaminated Traumatic Wounds in the Emergency Department Using Sterile Versus Non-Sterile Gloves, *Hong Kong J EM* 2014;21:148-152

Objectives: **To compare "the infection rates of contaminated lacerations required with sterile versus non-sterile gloves in a setting of emergency department." (p. 149)**

Methods: **Prospective convenience-sampling randomized, 2-center pilot study in EDs of Hazrat Rasoul Akram and 7-tir Hospitals from June 2010-November 2010, enrolling "patients with any type of visible contaminated soft tissue lacerations with no exclusion criteria." The investigators defined "contaminated lacerations" as "organic or non-organic materials such as soil and feces, detectable with unarmed eyes." (p. 149) Exclusion criteria included renal failure, immunodeficiency, DM, cirrhosis, current use of antibiotics, bite wounds (human or animal), presentation >12 hours after injury, suspected foreign body, signs of infection at prevention, or complicated lacerations (open fractures, tendon/nerve/vascular injury).**

All patients were treated with nylon sutures after randomization to clean-boxed non-sterile rubber latex-free gloves of sterile gloves. All patients were given an oral first generation cephalosporin (cephalexin) for 3-days and "visited by the physician for removal of sutures within 7-10 days." (p. 150) Patients were educated about signs of infection including cellulitis >1 cm or purulent drainage and advised to follow-up if these outcomes occurred. The authors do not report any standardization of wound prep (lidocaine, lidocaine with epi), wound irrigation (see July 2008 Journal Club), post-repair dressing or topical antibiotics, or provider training/patient education. They report no sample size calculation, regression analysis to adjust for unequal distribution of prognostic variables, or sensitivity analysis for lost to follow-up.

Guide	Comments
Are the results valid?	
Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?	

1.	Were patients randomized?	Yes. "The patients were selected according to convenience sampling technique and divided into two groups using random number table." (p. 149)
2.	Was randomization concealed (blinded)?	No randomization concealment is described.
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?	No, although not statistically significant ($p < 0.05$) the sterile glove group is younger ($p = 0.126$) and more likely to have limb wounds ($p = 0.029$) with sharp object ($p = 0.163$)
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, no blinding of randomization so significant risk of co-intervention bias.
2.	Were clinicians aware of group allocation?	Yes, no blinding of randomization.
3.	Were outcome assessors aware of group allocation?	Uncertain. No clear statement of blinding outcome assessors.
4.	Was follow-up complete?	No. "36 were excluded as they lost to follow-up." (p. 150) This represents significant (16% of the patients, 36/222) lost to follow-up and there were twice as many lost to follow-up in the clean glove (21.6%) as in the sterile glove group (10.8%)
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• 89% male with mean age 27.5 years and mean wound size 4.1 cm • Almost all wounds occurred on either the extremity or the head/neck. • Overall infection rate 3.2% with 2% in sterile glove group and 4.6% in the clean glove group, respectively
2.	How precise was the estimate of the treatment effect?	No 95% CI provided 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?	Uncertain. What do Iranian EDs look like? Who staffs the ED (trainees, non-EM trained physicians, physician extenders)? Who performed the wound repairs? Do they routinely irrigate wounds prior to suture repair? Do patients have health insurance and reliable access to follow-up care?
2.	Were all clinically important outcomes considered?	Uncertain. The authors do not provide an explicit definition of wound infection, nor do they describe who assessed for the presence or absence of wound infection. In addition, more patient-centric outcomes than wound infection would include pain, lost work-days, ED revisits, or hospital admissions.
3.	Are the likely treatment benefits worth the potential harm and costs?	Uncertain. The authors do not report a sample size computation so uncertain of probability of a Type II error (significant difference between clean glove and sterile glove groups exists, but not detected due to inadequate sample size). Also, the authors do not contemplate cost difference between clean and sterile gloves.
4.	How will you communicate the findings of this study with your patients to facilitate shared decision-making?	This study of traumatic lacerations contaminated with dirt or stool with suture repair within 12 hours of injury and treated with 3 day course of antibiotics **does not** inform whether clean non-sterile gloves are non-inferior or equal to sterile gloves to reduce the rate of post-wound repair infection. **However, there is a trend favoring sterile gloves with NNH 39 (95% CI 16 – α).**

Limitations

1) **No blinding so significant potential for bias (skewed estimates of "truth" in observed outcomes) with biases by patients (ascertainment bias by better follow-up), physicians (co-intervention bias), or outcome assessors.**

2) **High lost to follow-up rates with no sensitivity analysis to assess best-case scenario (no wounds infected) or worst-case scenario (all wounds infected).**

3) **No regression analysis to determine whether unequal distribution of confounders (age, limb, wound, sharp objects) accounted for differences in wound infection rate rather than sterile vs. non-sterile gloves.**

4) **No standardization of either wound repair (irrigation? Topical antibiotic?) or determining if "wound infection" occurred.**

5) **Uncertain external validity to U.S. EDs (staffing of EDs, availability of outpatient follow-up).**

6) **No assessment of patient compliance with oral antibiotics.**

7) **No sample size calculation so uncertain Type I and Type II error.**

8) **No confidence intervals presented so unable to assess precision.**

Bottom Line:

This is a potentially very biased study with incomplete statistical analysis that does not inform the equivalency or non-inferiority of non-sterile gloves for traumatic, contaminated wound closure.