Critical Review Form
Therapy

Sterile vs. Nonsterile Gloves for repair of Uncomplicated Lacerations in the Emergency Department: A Randomized Controlled Trial, *Ann Emerg Med* 2004:43:362-370

Objectives: **To evaluate whether "using clean nonsterile gloves for the repair of uncomplicated lacerations in immunocompetent patients does not lead to an increase in the incidence of wound infections." (p. 363)**

Methods: **Prospective, randomized, multicentered trial conducted in 3 large community hospitals in the greater Toronto area. The study included all laceration patients over age 1 year who consented to participate. Exclusion criteria included the presence of diabetes, renal failure, asplenia, immunodeficiency (acquired, congenital or immunosuppressive therapy), cirrhosis, keloid prone, current antibiotic use, or treating physician perspective that prophylactic antibiotics were required (prosthetic heart valve, bites, contaminated wounds). Additionally, high risk wounds were excluded: multiple trauma; open fracture; concomitant vascular, nerve or tendon injury; stab wounds; gunshot wounds; intra-articular wounds; animal and human bites; presentations >12 hours after injury; signs of infection at presentation; or suspected foreign body.**

Patients were randomized in blocks of 60 stratified by laceration site (head/neck, extremities, trunk/buttocks). An algorithm suggesting ideal laceration repair including obligatory high pressure irrigation was provided along with 2 orientation sessions per site, but the adherence of any particular physician was not assessed.

The primary endpoint was the presence/absence of a significant wound infection on the follow-up assessment. The Follow-up assessment was by a physician who was asked to complete a self-addressed pre-stamped data sheet that combined wound infection scales used in multiple previous studies (Maitra 1986, Rutherford 1980, Gosnold 1977). Tardy or missing follow-up forms resulted in follow-up telephone calls. When discrepancies in the outcome reporting form were noted (example no erythema, but purulent drainage noted) the wound was considered infected. The study was powered as a comparative superiority trial with 380 patients per group to detect a 50% relative risk reduction in infection rates with α=0.05 (one-sided) and ß=205. Differences in the primary outcome were evaluated statistically with the χ^2 test.

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. "Block randomization in blocks of 60 was used to ensure comparable patient profiles in both groups (sterile and clean nonsterile gloves) in each site. Patients were randomized in strata according to the site of laceration." (p. 363) "After the patient consented to participate, the emergency physician randomized the patient by using a specially designed randomization table in the study package." (p. 364)
2.	Was randomization concealed (blinded)?	Yes to patients and outcome assessors not to clinicians closing the wound (see below).
3.	Were patients analyzed in the groups to which they were randomized?	Uncertain. There is no clear statement of intention to treat but the Figure on page 365 does not indicate any crossovers.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. "There were no differences in the baseline characteristics of the clean-boxed and sterile glove study groups (Table 1)." (p. 365)
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. "To blind the patients to the type of gloves used, the physicians were instructed not to inform participants of the randomization results and to put gloves on out of sight of the patients so that they were no able to observe what type of gloves were used." (p. 364)

2.	Were clinicians aware of group allocation?	Yes. "This study was only partially blinded because the sterile and nonsterile gloves are packaged differently. Had the study been conducted by using nonsterile gloves that were individually packaged as the sterile gloves were, it would not be possible to extrapolate the results to actual practice. Packaging nonsterile gloves would have eliminated another important confounding factor, which was the possibility of cross-contamination of an open-box of gloves by various personnel." (p. 367)
3.	Were outcome assessors aware of group allocation?	No. "The follow-up physician was not informed of the type of gloves used." (p. 364)
4.	Was follow-up complete?	Yes. "Follow-up" information was obtained for 96.6% of the clean gloves group and 98.0% of the sterile gloves group. Written follow-up was obtained in 48.7% of cases." (p. 365)
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• 816 patients randomized, mean age 30 years, 73% male, 62% of lacerations were extremities, 66% were from sharp objects, and 15% were contaminated. • 88% of wound repairs used lidocaine without epinephrine, 95% used single layer closure, 92% used non-absorbable monofilament suture material and 25% used topical antibiotic. • The observed infection rate was 6.1% (95% CI 3.8% to 8.4%) in the sterile glove group versus 4.4% in the clean gloves group (95% CI 2.4% to 6.4%). • **The difference in infection rates was not statistically or clinically significant (RR 1.37, 95% CI 0.75-2.52, p = 0.295).** • Culture results for infected wounds were available in 8 cases and all demonstrated mixed skin flora

		with predominance of gram-positive cocci.
2.	How precise was the estimate of the treatment effect?	Yes – see 95% CI above
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. No ethno demographic, socio economic, health literacy or insurance status is provided. The ability to understand and comply with wound care instructions is an important unmeasured variable, but should have been equally distributed across both groups. Also, access to primary care differs markedly between Canada (universal health insurance and strong emphasis on training primary care providers) and the urban US.
2.	Were all clinically important outcomes considered?	Yes. Post wound repair infection rates are the most important outcomes, but other significant outcomes include wound dehiscence and cosmetic appearance, neither of which was assessed.
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes. In 2004 clean nonsterile gloves cost 10¢ per pair, whereas sterile gloves cost 70¢ per pair. Using nonsterile gloves "would lead to direct-cost savings of more than US $2,000 (Canada $3,000) per year in an ED that manages an average of 10 uncomplicated lacerations per day." (p. 368)
4.	How will you communicate the findings of this study with your patients to facilitate shared decision-making?	Trauma-related lacerations (cuts) differ from incisions made by surgeons under sterile conditions in the operating room. Bacteria (and other organisms) live on your skin and on the object that cut you. This study demonstrates that using sterile gloves to repair your laceration will not lower infection rates and they cost 7 times more than non-sterile gloves. No benefit to using sterile gloves exists from the perspective of preventing infections.

Limitations

1) **Lack of blinding of clinicians opens possibility of Hawthorne effect but increases external validity.**

2) **Lack of supervision of physician-level factors (experience, adherence to ideal wound repair algorithm, completeness and clarity of wound care instructions) so variation in the sterility of wound closure is an unmeasured variable.**

3) **Insufficient details of patient-level factors (health literacy, access to primary care, socio economic status).**

Bottom Line

Using non-sterile gloves in immunocompetent ED patients with uncomplicated traumatic lacerations repaired within 3 hours of injury do not increase post-wound infection rates. Although this study represents the highest quality, least biased, most directly relevant research as of January 2016 to assess the infection risk of using non-sterile, clean gloves to repair traumatic wounds in ED settings, concerns about selection bias (26% of approached patients were either ineligible or did not consent) and the post-2004 effect of MRSA rates limited Journal Club attendees confidence in the conclusiveness of this research. This single study is convincing, but additional high quality research is needed.