Critical Review Form
Therapy

Comparing Non-Sterile with Sterile Gloves for Minor Surgery: A Prospective Randomized Controlled Non-Inferiority Trial, *MJA* 2015; 202: 27-32

Objectives: **"To establish whether non-sterile clean boxed gloves were non-inferior to sterile gloves with regard to surgical site infection with minor skin excisions." (p. 28)**

Methods: **Randomized controlled single-center trial at a private clinical practice (primary care) in Mackay Queensland from July 2012 thru March 2013. Six doctors recruited consecutive patients presenting for minor skin excisions. Exclusion criteria included use of oral antibiotics or immunosuppressive drugs, skin flaps, excision of a sebaceous cyst and history of latex allergy.**

A workshop was conducted to define standard skin excision practice that included chlorhexidine skin prep, standard sterile precautions, hand washing, lignocaine anesthesia, simple interrupted nylon suture closure, dressing with non-woven polyester fabric, no topical (or oral) antibiotics, wound care instructions, and appropriate timing of suture removal (head-neck 7-10 days, torso 12-14 days, arm 14 days, leg 12-16 days).

A practice nurse enrolled and then randomized patients. The primary outcome was incidence of wound infection, as assessed by the practice nurse or GP at the time of suture removal. Practice nurses were asked to culture any infected wounds with drainage. Sample size was based on baseline infection rate of 8% with non-inferiority margin 7% with 80% power and 2-sided 95% CI with 186 patients per group. To adjust for clusters of GPs this sample size was increased to 225 patients per group.

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. "After agreeing to participate, patients were randomly allocated to the intervention or control groups using computer-generated random numbers." (p. 28)

2.	Was randomization concealed (blinded)?	Yes. "Allocation information was placed in opaque-sealed envelopes." (p. 28)
3.	Were patients analyzed in the groups to which they were randomized?	Yes. "All analyses were based on the intention-to-treat principles. Per protocol analyses were conducted to cross-validate the intention-to-treat results…as per protocol analysis was conducted which excluded patients with protocol violations. Further, a sensitivity analysis was performed including patients lost to follow-up: once as treatment successes (no wound infection) and once as treatment failures (with wound infection)." (p. 29)
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. "There were no large differences at baseline between the intervention and control groups." (p. 29)
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. "Patients were not blinded to their group allocation." (p. 28)
2.	Were clinicians aware of group allocation?	Yes. The authors give no clear statement of blinding clinicians who performed excisions so they were personally aware.
3.	Were outcome assessors aware of group allocation?	No. "The assessing practice nurses and doctors were blinded to the allocation." (p. 28)
4.	Was follow-up complete?	Yes. "Follow-up was completed in 478 (97%) of randomized patients." (p. 29)
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• 493 patients were randomized (250 non-sterile, 243 sterile) with one protocol violation (antibiotic prescribed for another infection) • Infection occurred in 9.0% (43/478) with 8.7% (95% CI 4.9%-12.6% in non-sterile glove group versus 9.3% (95% CI 7.4%-11.1) in the sterile glove group, representing a difference of -0.6% (95% CI - 4.0% - 2.9%) which did not reach the pre-determined

		margin of 7%. • Sensitivity analysis of the 15 patients lost to follow-up did not alter non-inferiority.
2.	How precise was the estimate of the treatment effect?	Yes, see the 95% CIs 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?	No, these are primary care patients having elective excisions performed with sterile equipment under controlled conditions by trained provider's not irregular lacerations by dirty sharp objects.
2.	Were all clinically important outcomes considered?	No. "There were inadequate data recorded on suture size and patient occupation, and consequently these factors could not be compared. In addition, the prevalence of diabetes and other medically important conditions was probably under recorded, and power to analyze these subgroups was limited. Surgical training and technique of the GPs involved is a potential confounder that would be difficult to quantify and was not recorded." (p. 30) However, randomization should distribute higher risk (of infection) patients, wounds, and physicians equally.
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes. Non-sterile gloves are about $1 per pair cheaper, a savings that "may be of particular relevance to developing countries with limited health care resources." (p. 31)

4.	How will you communicate the findings of this study with your patients to facilitate shared decision-making?	This Australian primary care study suggests that non-sterile gloves do not increase wound infection rates after excisions of skin lesions by trained professionals. Wounds that occur from accidents that are repaired with sutures in the ED are different because they are dirty (bacteria from the object that cut you and your skin are deep in the wound) so the comparison is imperfect. Nonetheless, this study adds to a growing body of evidence that non-sterile gloves do not increase infection rates repairing skin breaks.

Limitations

1) **Failure to blind clinicians or patients to study arm.**

2) **Inadequate collection of important confounding variables like health literacy, presence of diabetes, occupation, or suture experience.**

3) **Failure to use standardized data collection form (for examples see Maitra 1986, Rutherford 1980, or Gosnold 1977) to assess the presence or absence of infection at follow-up.**

4) **No assessment of reliability for the primary outcome (wound infection).**

Bottom Line

The use of non-sterile gloves in primary care skin biopsies with suture repair is not associated with increased skin infection rates at the time of suture removal. These results should be extrapolated to ED traumatic incisions cautiously, since trauma-related incisions requiring suture repair are often contaminated, irregular, and closed several hours after skin opening.