Critical Review Form
Therapy

Comparison of the Prevalence of Surgical Site Infection with Use of Sterile Versus Nonsterile Gloves for Resection and Reconstruction During Mohs Surgery, *Dermatology Surgery* 2014; 40: 234-239

<u>Objectives:</u> To determine "whether sterile gloves help prevent surgical site infection during Mohs micrographic surgery (MMS) and thus helping determine a set protocol for which type of glove should be used during MMS and reconstruction." (p. 235)

<u>Methods:</u> A time series of MMS cases from one surgeon who used sterile gloves from November 2011 – May 2012 and non-sterile gloves from June 2012 – December 2012 at the University of Cincinnati. The surgeon reported using the same pre-procedure prep, procedural methods, and post-procedure education/follow-up instructions during these two periods. Follow-up was only "if necessary" and occurred 1-2 weeks post-procedure. The authors do not explain the indication for "necessary follow-up" nor do they describe who assessed for presence/absence of surgical site infection. However, "a wound infection was suspected if the patient complained of or presented with pain, erythema, and purulence." (p. 235) Exclusion criteria included patients taking systemic antibiotics, or used post-operative systemic or topical antibiotics. Patients referred to plastic surgery where also excluded.

To assess differences in proportions between SG and NSG groups, χ^2 analysis was used. Logistic regression was performed to determine variables that independently predicted SSI. No logistic regression model details (inclusion criteria, goodness of fit assessment) are described.

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?	No. Patients were not randomized but were instead studied in two groups from November 2011 – May 2012 (sterile gloves used) and June 2012 – December 2012 (non-sterile gloves used). Failure to randomize opens possibility of multiple biases. For example, what if different proportions of patients had immunocompromising disorders? Or if wounds healed differently in summer-fall (NSG) versus winter/spring (SG)?
2.	Was randomization concealed (blinded)?	No randomization, no randomization to blind.
3.	Were patients analyzed in the groups to which they were randomized?	No randomization and no intention to treat analysis reported. No cross overs are reported though.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Uncertain. "Similar percentages of patients in both groups were smokers or took aspirin, other anticoagulants, or immunosuppressant's ($p>0.05$ in all cases)." The authors do not provide p-values for all of the variables in Table 1 and some appear to be significant: diabetes (14% SG vs. 11.7% NSG, $p = 0.132$) and systemic steroids (1.2% SG vs. 2.9% NSG, $p = 0.009$) (p. 236) Also, "the difference between pre and post-operative sizes and the number of squamous cell carcinoma *in situ* cases between the NSG and SG group was statistically significant." (p. 238)
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, the patients were not blinded (nor is there a clear statement that they were consented).
2.	Were clinicians aware of group allocation?	Yes. There was only one clinician performing the Mohs surgery and presumably he is one of the authors on this manuscript. Failure to blind clinicians can increase risks of co-intervention bias.

3.	Were outcome assessors aware of group allocation?	Uncertain. Only a portion of patients followed up and "if the patient did not call the office and could not be reached by telephone, it was assumed they had not developed an infection." (p. 235) However, who evaluated patients in the office, whether they were blinded to the intervention or study, what criteria (other than "presented with pain, erythema, and purulence" p. 235) defined "SSI", how reliable those criteria were and who had wound cultures obtained were not described.
4.	Was follow-up complete?	Uncertain. The authors do not report what % were referred for follow-up, what % follow-up as instructed and what % had only phone follow-up or no follow-up. Dozens of other hospitals are in the Cincinnati area so patients could have had a SSI managed at another hospital.
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• 942 patients in SG group and 941 in NSG group with mean age 70. • Culture positive SSI occurred in 0.56% SG and 0.65% NSG (p = 0.82) with staphylococcus aureus accounting for all but one SSI. • Logistic regression analysis demonstrated no single variable (including SG or NSG) was associated with developing SSI.
2.	How precise was the estimate of the treatment effect?	No CI provided.
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 (mostly geriatric) Dermatology patients with skin lesions managed operatively under controlled, sterile conditions, which is very different from traumatic lacerations.

2.	Were all clinically important outcomes considered?	No. Wound infections are important, but insufficient details are provided to be confident that SSI were fully assessed (by whom, using what criteria, in what % of patients).
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes. "The cost of using SG is 3.5 times as great as the cost of NSG." (p. 238)
4.	How will you communicate the findings of this study with your patients to facilitate shared decision-making?	This Dermatology study suggests using non-sterile gloves for skin biopsies does not increase infection rates, but this has limited applicability to your traumatic laceration in the ED today, which is deeper, dirtier, and more irregular.

Limitations

1) **No randomization or blinding so subject to observational trial bias.**

2) **No explicit definition of outcome (for examples see Maitra 1986, Rutherford 1980, or Gosnold 1977) or outcome assessor. This could affect both the accuracy and the reliability of whether wound infection was present or absent.**

3) **Limited external validity to surgeons (only 1 surgeon performed every procedure) and to EM (different patients, different environment, and different injuries then Dermatology patients) so this is essentially an "N of 1" study for that surgeon.**

4) **Uncertain lost to follow-up.**

5) **No parameters for logistic regression (inclusion criteria, goodness of fit).**

6) **Incomplete reporting of p-values/confidence intervals and seemingly significant baseline prognostic differences between sterile glove and non-sterile glove groups.**

Bottom Line

One surgeon performing thousands of MMS did not detect significant change in SSI when using NSG. This has limited application to the average ED where many

physicians repair traumatic lacerations that are frequently irregular, deep and contaminated.