Sterile or non-sterile gloves for minor skin excisions?

Non-sterile gloves are just as effective as sterile gloves in preventing surgical site infection after minor skin surgeries.

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PRACTICE CHANGER

Consider using non-sterile gloves during minor skin excisions (even those that require sutures) because the infection rate is not increased compared to using sterile gloves.[1]

STRENGTH OF RECOMMENDATION

B: Based on a randomized controlled trial done in a primary care practice.

Heal C, Sriharan S, Buttner PG, et al. Comparing non-sterile to sterile gloves for minor surgery: a prospective randomized controlled non-inferiority trial. *Med J Aust.* 2015;202:27-31.

ILLUSTRATIVE CASE

A 50-year-old man comes to your office to have a mole removed from his arm. You decide to excise the lesion in your office today. Do you need to use sterile gloves for this procedure, or can you use gloves from the clean non-sterile box in the exam room?

Non-sterile gloves are readily available during a typical office visit and cost up to a dollar less per pair than sterile gloves.[1-3] Studies conducted in settings other than primary care offices have shown that non-sterile gloves do not increase the risk of infection during several types of minor skin procedures.

A partially blinded, randomized controlled trial (RCT) in an emergency department found no significant difference in infection rates between the use of sterile (6.1%) vs non-sterile (4.4%) gloves during laceration repairs.[2] Similarly, a small RCT in an outpatient dermatology clinic and a larger prospective trial by a Mohs dermatologist showed that infection rates were not increased after Mohs surgery using non-sterile (0.49%) vs sterile (0.50%) gloves.[3,4]

Guidelines on the use of sterile vs non-sterile gloves for minor skin excisions in outpatient primary care are difficult to come by. Current guidelines from the Centers for Disease Control and Prevention (CDC) and other agencies regarding surgical site infections are broad and focus on the operating room environment.[5-7]

The American Academy of Dermatology is working on a guideline for treatment of non-melanoma skin cancer that's due out this winter, and this may provide additional guidance.[8] A 2003 review instructed primary care physicians to use sterile gloves for excisional skin biopsies that require sutures.[9]

The 2015 study by Heal et al[1] appears to be the first RCT to address the question of sterile vs non-sterile glove use for minor skin excisions in a primary care outpatient practice.

STUDY SUMMARY

Non-sterile gloves are not inferior to sterile gloves

Heal et al[1] conducted a prospective, randomized, controlled, noninferiority trial to compare the incidence of infection after minor skin surgery performed by 6 physicians from a single general practice in Australia using sterile vs non-sterile clean gloves. They evaluated

Tradition and training die hard. A single study in the primary care office setting may not be enough to sway family physicians from ingrained habits.

576 consecutive patients who presented for skin excision between June 2012 and March 2013. Eighty-three patients were excluded because they had a latex allergy, were using oral antibiotics or immunosuppressive drugs, or required a skin flap procedure or excision of a sebaceous cyst. The physicians followed a standard process for performing the procedures and did not use topical antibiotics or antiseptic cleansing after the procedure.

The primary outcome was surgical site infection within 30 days of the excision, defined as purulent discharge, pain or tenderness, localized swelling or redness or heat at the site, or a diagnosis of skin or soft tissue infection by a general practitioner. The clinicians who assessed for infection were blinded to the patient's assignment to the sterile or non-sterile glove group, and a stitch abscess was not counted as an infection.

The patients' mean age was 65 years and 59% were men. At baseline, there were no large differences between patients in the sterile and non-sterile glove groups in terms of smoking status, anticoagulant or steroid use, diabetes, excision site, size of excision, and median days until removal of sutures. The lesions were identified histologically as nevus or seborrheic keratosis, skin cancer and precursor, or other.

The incidence of infection in the non-sterile gloves group was 21/241 (8.7%; 95% confidence interval [CI], 4.9%-12.6%) vs 22/237 in the control group (9.3%; 95% CI, 7.4%-11.1%). The CI (95%) for the difference in infection rate (-0.6%) was -4.0% to 2.9%. This was significantly below the predetermined noninferiority margin of 7%. In a sensitivity analysis of patients lost to follow-up (15 patients, 3%) that assumed all of these patients were without infection, or with infection, the CI was still below the noninferiority margin of 7%. The per-protocol analysis showed similar results.

WHAT'S NEW

New evidence questions the need for sterile gloves for in-office excisions

Heal et al[1] demonstrated that in a primary care setting, non-sterile gloves are not inferior to sterile gloves for performing excisional procedures that require sutures. While standard practice has many family physicians using sterile gloves for these procedures, this study promotes changing this behavior.

CAVEATS

A high infection rate, other factors might limit generalizability

The overall rate of infection in this study (9%) was higher than that found in the studies from emergency medicine and dermatology literature cited earlier.[2-4] A similarly high infection rate has been found in other studies of minor surgery by Heal et al, including a 2006 study that showed a wound infection rate of 8.6%.[10] The significance of the higher infection rate is unknown, but there is no clear reason why non-sterile gloves might be less effective in preventing infection in environments with lower infection rates.

This was not a double-blinded study, and physicians might change their behavior during a procedure depending on the type of gloves they are wearing. The sterile gloves used in this study contained powder, while the non-sterile gloves were powderless, but this variable is not known to affect infection rates. A study of Mohs surgery avoided this variable by only using powderless gloves, and had similar outcomes in terms of the difference in infection rate between sterile and non-sterile gloves.[4]

CHALLENGES TO IMPLEMENTATION

Ingrained habits can be hard to change

Tradition and training die hard. While multiple studies in several settings have found non-sterile gloves are non-inferior to sterile gloves in preventing surgical site infection after minor skin surgeries, this single study in the primary care office setting may not be enough to sway family physicians from ingrained habits. JFP

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CONTINUED

ZECUITY® (sumatriptan iontophoretic transdermal system)

Table 1: Adverse Reactions Reported by at least 2% of Patients in Study 1

Adverse Reaction	Percent of Subjects Reporting	
	ZECUITY (n = 234)	Control (n = 235)
Application site pain	26%	17%
Application site paresthesia	9%	16%
Application site pruritus	8%	7%
Application site warmth	6%	3%
Application site discomfort	6%	6%
Application site irritation	4%	2%
Application site discoloration	3%	1%

The incidence of "atypical sensations" adverse events (paresthesia, sensation warm/cold) and "pain and other pressure sensations" (chest pain/tightness/pressure/heaviness or neck/throat/jaw pain, tightness, pressure or heaviness) was 2% each in ZECUITY-treated patients, vs. 0% in the control group. Application site bruising was reported in 2 ZECUITY-treated patients (0.9%) vs. no patient in the control group. Subgroup analyses of age (≤41 years, >41 years), race (Caucasian, non-Caucasian) and body mass index (BMI) (≤25.7 mg/kg^2, >25.7 mg/kg^2) showed no difference between subgroups for adverse events.

Skin Irritation Examination

In Study 1, patients performed their own examination of the TDS application site at 4, 12, and 24 hours post TDS activation, and daily thereafter until resolution. The median time to "no redness" was 2.6 days for ZECUITY compared with 0.3 day in the control group.

Application site reactions across clinical studies (Controlled single dose acute migraine study and long term safety studies)

In the controlled and uncontrolled clinical studies combined (n = 796 unique ZECUITY-treated subjects), the frequency of application site reactions of clinical interest was: discoloration (5%), contact dermatitis (4%), irritation (4%), vesicles (3%), bruising (2%), and erosion (0.4%).

DRUG INTERACTIONS

Ergot-Containing Drugs

Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Because these effects may be additive, use of ergotamine-containing or ergot-type medications (like dihydroergotamine or methysergide) and ZECUITY within 24 hours of each other is contraindicated *[see Contraindications]*.

Monoamine Oxidase-A Inhibitors

MAO-A inhibitors increase systemic exposure by 2-fold. Therefore, the use of ZECUITY in patients receiving MAO-A inhibitors is contraindicated *[see Contraindications]*.

Other 5-HT$_1$ Agonists

Because their vasospastic effects may be additive, coadministration of ZECUITY and other 5-HT$_1$ agonists (e.g., triptans) within 24 hours of each other is contraindicated.

Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors and Serotonin Syndrome

Cases of serotonin syndrome have been reported during coadministration of triptans and SSRIs or SNRIs, SNRIs, TCAs, and MAO inhibitors *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. ZECUITY should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether sumatriptan is excreted in human milk following transdermal administration. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from ZECUITY, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Since clinical data to determine the frequency of serious adverse reactions in pediatric patients who might receive subcutaneous, oral, or intranasal sumatriptan are not presently available, the use of ZECUITY in patients under 18 years of age is not recommended.

Geriatric Use

Clinical trials of ZECUITY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. A cardiovascular evaluation is recommended for geriatric patients who have other cardiovascular risk factors prior to using ZECUITY *[see Warnings and Precautions]*.

Brief Summary of ZECUITY Prescribing Information ZEC-001

ZEC-40059 September 2014

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