

Surgical Glove Perforation and the Risk of Surgical Site Infection

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Hypothesis: Clinically apparent surgical glove perforation increases the risk of surgical site infection (SSI).

Design: Prospective observational cohort study.

Setting: University Hospital Basel, with an average of 28 000 surgical interventions per year.

Participants: Consecutive series of 4147 surgical procedures performed in the Visceral Surgery, Vascular Surgery, and Traumatology divisions of the Department of General Surgery.

Main Outcome Measures: The outcome of interest was SSI occurrence as assessed pursuant to the Centers of Disease Control and Prevention standards. The primary predictor variable was compromised asepsis due to glove perforation.

Results: The overall SSI rate was 4.5% (188 of 4147 procedures). Univariate logistic regression analysis showed

a higher likelihood of SSI in procedures in which gloves were perforated compared with interventions with maintained asepsis (odds ratio [OR], 2.0; 95% confidence interval [CI], 1.4-2.8; $P < .001$). However, multivariate logistic regression analyses showed that the increase in SSI risk with perforated gloves was different for procedures with vs those without surgical antimicrobial prophylaxis (test for effect modification, $P = .005$). Without antimicrobial prophylaxis, glove perforation entailed significantly higher odds of SSI compared with the reference group with no breach of asepsis (adjusted OR, 4.2; 95% CI, 1.7-10.8; $P = .003$). On the contrary, when surgical antimicrobial prophylaxis was applied, the likelihood of SSI was not significantly higher for operations in which gloves were punctured (adjusted OR, 1.3; 95% CI, 0.9-1.9; $P = .26$).

Conclusion: Without surgical antimicrobial prophylaxis, glove perforation increases the risk of SSI.

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DESPITE THE SUBSTANTIAL effort deployed to maintain asepsis during surgery, the risk of the transfer of pathogens remains. Transfer mechanisms include, among others, contact with the skin or blood. Pathogens may be transferred from the surgical staff to patients^{1,2} and vice versa.^{3,4} In surgical settings, skin-borne pathogens on staff hands are particularly susceptible to

See Invited Critique at end of article

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transfer. Consequently, all surgical staff members wear sterile gloves as a protective barrier to prevent hand-to-wound contamination during operations. When gloves are perforated, the barrier breaks down and germs are transferred. With the growing awareness among operating room staff of their risk of exposure to disease from patients, primarily human immunodeficiency virus and hepatitis B virus,^{5,6} gloves have begun to be regarded as a requirement for their own protection. To-

day, surgical gloves must provide an effective germ barrier for both patients and surgical staff.

The risk of perforation increases with the duration of operating time—significantly so after 2 hours^{7,8}—and occurs more often when gloves do not fit properly.⁹ The factors favoring glove perforation include, most commonly, puncture by needles, spiked bone fragments, or sharp surfaces on complex instruments.^{10,11}

The frequency of glove perforation during surgery has been studied extensively and found to range from 8% to 50%.^{7,9,12-16} The impact of glove perforation on the risk of surgical site infection (SSI), however, is unknown. The present study was conducted to test the hypothesis that clinically visible surgical glove perforation is associated with an increased SSI risk.

METHODS

PATIENTS AND PROCEDURES

The data for this prospective observational study were collected from January 1, 2000, through De-

ember 31, 2001, at University Hospital Basel. The study was approved by the institutional review board as part of a broader quality improvement program, which was supported by the hospital executive board. As an observational study, it was exempt from the written informed consent requirement. All inpatient procedures performed in the divisions of Vascular Surgery, Visceral Surgery, and Traumatology of the Department of General Surgery were consecutively enrolled. Operations requiring no incision (eg, closed reductions of joint dislocations) were excluded, along with procedures classified as wound class 4 (dirty infected) according to the Centers for Disease Control and Prevention (CDC) criteria.¹⁷ Such patients received perioperative and postoperative antimicrobial therapy, and it was assumed, moreover, that in these cases the minimal bacterial transfer due to glove perforation might be irrelevant in the context of such high rates of surgical site bacterial contamination.

OUTCOME OF INTEREST, PRIMARY PREDICTOR VARIABLE, AND COVARIATES

The outcome of interest was the incidence of SSI, which was assessed during the hospital stay by the surgical resident on a prospective surveillance form. The attending surgeon cross-checked each form pursuant to CDC standards.¹⁷ Three approaches were used for postdischarge monitoring. The forms and supplementary documents, along with a description of the quality control strategy, were sent to the primary care practitioners conducting postsurgery clinical controls. As many as 2 reminders were sent, emphasizing the need to fully ascertain the presence of SSI. The second step consisted of screening all patients' medical records to identify readmissions and outpatient visits to University Hospital Basel. The forms for most patients in the Division of Traumatology were completed on the occasion of such routine visits. When the first 2 steps for postdischarge follow-up could not be performed, 1 of the physicians on the study team (H.M., W.P.W., S.R., R.R., or P.F.) interviewed the patients by telephone, using a standardized questionnaire. All incidents of SSI were validated by a board-certified infectious disease specialist (A.F.W.), on the basis of a comprehensive review of the patient history, initial microbiology results, and outcome at least 30 days after surgery when no implants were involved or more than 1 year after surgery if an implant was in place.

The main predictor variable was compromised asepsis due to glove perforation. The use of single gloves was standard practice, whereas double gloving was left to the surgeon's discretion in each procedure and depended on the surgeon's assessment of the risk of glove perforation. The operating room nurse was responsible for detecting and recording breaches of asepsis, directly when perforation/leakage was obvious or indirectly when liquid was visible inside a glove. When double gloves were used, perforation/leakage of the inner glove was recorded. The gloves used included a powder-free latex surgical glove with a thin inner coating of acrylate terpolymer (gauge, 0.27 mm at the cuff and 0.15 mm at the tip of the index finger) (Biogel; Regent Hospital Products, Mölnlyche Health Care, Kullim, Malaysia); a powdered latex surgical glove (gauge, 0.205 mm at the palm and 0.235 mm at the tip of the middle finger) (Gammex; Ansell Healthcare Europe NV, Munich, Germany); and another powder-free latex surgical glove (gauge, 0.205 mm at the palm and 0.22 mm at the tip of the middle finger) (Nutex; Ansell Healthcare Europe NV).

A total of 82 patient and procedural characteristics were prospectively recorded and included age, sex, underlying disease, additional diagnoses, American Society of Anesthesiologists score, type of procedure, division of surgical specialty, CDC wound class, and duration of surgery. The data were entered on an electronically readable 4-page data sheet created by com-

mercially available software (Cardiff TELEForm Desktop, version 8.0; Verity Incorporated, Sunnyvale, California).¹⁸ Missing data were reviewed and completed as necessary with data from the respective medical histories. Each completed form was cross-checked by a second member of the research team (H.M., W.P.W., S.R., R.R., or P.F.).

SURGICAL ANTIMICROBIAL PROPHYLAXIS

Prophylactic antimicrobial administration was standardized to the CDC guidelines.¹⁷ Patients received antimicrobial prophylaxis if they underwent surgery classified as CDC wound classes 3 (contaminated), 2 (clean contaminated), and 1 (clean) involving a nonabsorbable implant or, at the discretion of the surgeon, any clean operation in which a subsequent SSI would have posed high risk to the patient. Antimicrobial prophylaxis, which was regarded to be perioperative for no longer than 24 hours, consisted of a single intravenous infusion of 1.5 g of cefuroxime sodium, in conjunction with 500 mg of metronidazole phosphate in colorectal surgery. Pursuant to our internal hospital guidelines, this dose was readministered at 4-hour intervals through the end of the procedure. In fractured bone osteosynthesis, prophylaxis lasted for 24 hours, with injection of 0.75 g of cefuroxime sodium 8 and 16 hours after the first dose.

STATISTICAL ANALYSIS

For data description we calculated frequencies of surgical procedures according to patient and procedure characteristics, and we used the χ^2 test to assess difference in the distributions between procedures with and without glove perforation. To assess the association of SSI with characteristics of the patient and surgical procedure, we fitted logistic regression models. The simplest models included only an indicator variable for glove perforation and an indicator for use of antimicrobial prophylaxis. Adjusted models included the sex and age of the patient, the CDC wound class (3 classes), the duration of surgery, the number of operations that surpassed the T time (the 75th percentile [in hours] of the duration of surgery as defined in the National Nosocomial Infections Surveillance System),¹⁹ and the American Society of Anesthesiologists score (4 groups). To test for the effect modification between glove perforation and the use of antimicrobial prophylaxis, an interaction term was included in the adjusted model. Because this effect modification was statistically significant, separate logistic regression models were fitted for procedures with and without the use of antimicrobial prophylaxis. In these separate analyses, glove perforation was the main predictor variable of interest.

All *P* values are 2 sided, and all analyses were performed using Stata statistical software, version 9 (StataCorp, College Station, Texas).

RESULTS

From January 1, 2000, through December 31, 2001, a total of 6540 inpatient invasive procedures were performed in the Department of General Surgery at University Hospital Basel. Full in-hospital data records were created for 6283 procedures (96.1%) performed on 4808 patients. A long-term follow-up data set was built for 5721 of these 6283 procedures (91.1%). In 4768 of the 5721 procedures (83.3%), follow-up was performed by a physician, and the remaining 953 patients (16.7%) were surveyed by telephone. Seven hundred forty-seven procedures of the 6283 procedures (11.9%) were ex-

Table. Patient and Procedure Characteristics and Incidence of SSI by Glove Integrity

Characteristic	No. (%) of Interventions ^a		P Value
	With Perforated Gloves	With Intact Gloves	
Total	677 (100.0)	3470 (100.0)	<.001
SSIs	51 (7.5)	137 (3.9)	<.001
Surgical antimicrobial prophylaxis			<.006
Yes	605 (89.4)	2628 (75.7)	
No	72 (10.6)	842 (24.3)	
Sex			<.001
Female	292 (43.1)	1791 (51.6)	
Male	385 (56.9)	1679 (48.4)	
Age, y			.40
<30	56 (8.3)	284 (8.2)	
30-39	69 (10.2)	421 (12.1)	
40-49	89 (13.2)	490 (14.1)	
50-59	103 (15.2)	560 (16.1)	
60-69	137 (20.2)	597 (17.2)	
70-79	123 (18.2)	607 (17.5)	
80-89	87 (12.9)	417 (12.0)	
≥90	13 (1.9)	94 (2.7)	
Division			.85
Visceral surgery	285 (42.1)	1501 (43.3)	
Traumatology	273 (40.3)	1377 (39.7)	
Vascular surgery	119 (17.6)	592 (17.1)	
ASA score			<.001
I	75 (11.1)	512 (14.8)	
II	281 (41.5)	1704 (49.1)	
III	263 (38.8)	1112 (32.0)	
IV	53 (7.8)	140 (4.0)	
V	5 (0.7)	2 (0.1)	
Wound class (class No.)			.51
Clean (1)	459 (67.8)	2372 (68.4)	
Clean contaminated (2)	133 (19.6)	625 (18.0)	
Contaminated (3)	85 (12.6)	473 (13.6)	
T time exceeded			<.001
Yes	286 (42.2)	553 (15.9)	
No	391 (57.8)	2917 (84.1)	
Duration of surgery, h			<.001
≤2	279 (41.2)	2697 (77.7)	
>2	398 (58.8)	773 (22.3)	

Abbreviations: ASA, American Society of Anesthesiologists; SSI, surgical site infection; T time, 75th percentile (in hours) of the duration of surgery as defined in the National Nosocomial Infections Surveillance System.¹⁹

^aPercentages have been rounded and may not total 100.

cluded owing to CDC class 4 surgical wounds. In 1389 cases (22.1%), the state of asepsis during surgery was not prospectively recorded. The remaining 4147 procedures (66.0%) were accepted for further analysis. The main characteristics of these surgical interventions are summarized in the **Table**.

A total of 188 instances of SSI (4.5%) were detected in the 4147 procedures studied. We classified SSI as follows: superficial (n=56), deep (n=62), and organ/space (n=70). Asepsis was compromised by glove leakage in 677 interventions (16.3%) and maintained in the remaining 3470 (83.7%).

In the 677 procedures with compromised asepsis, 51 instances (7.5%) of SSI were recorded, compared with 137 instances in 3470 procedures (3.9%) when asepsis was not breached (crude odds ratio [OR], 2.0; 95% con-

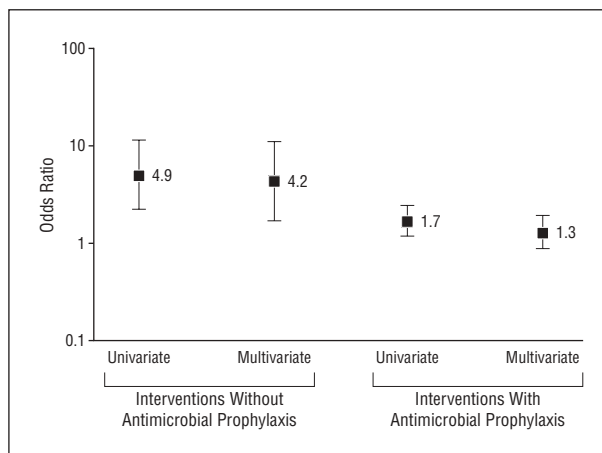


Figure 1. Crude and adjusted odds ratios and 95% confidence intervals for the association of surgical site infection with glove perforation (yes vs no) stratified for use of antimicrobial prophylaxis. Variables included in the adjusted models were wound class, the duration of surgery, the number of operations that surpassed the T time (75th percentile [in hours] of the duration of surgery as defined in the National Nosocomial Infections Surveillance System), the American Society of Anesthesiologists score, and patient age and sex.

fidence interval [CI], 1.4-2.8; $P < .001$). Gloves were perforated in 398 of the 1171 procedures (34.0%) that lasted longer than 2 hours, compared with only 279 of 2976 (9.4%) that lasted 2 hours or less.

Multivariate logistic regression analyses showed that the increase in the SSI risk with perforated gloves was different for procedures with vs those without antimicrobial prophylaxis (test for effect modification, $P = .005$). We therefore analyzed the risk association separately for glove perforations in surgeries with and without antimicrobial prophylaxis. Surgical antimicrobial prophylaxis was applied in 3233 interventions; glove perforations were detected in 605 of these operations (18.7%).

In the presence of surgical antimicrobial prophylaxis, the rate of SSI (6.9% vs 4.3%; crude OR, 1.7; 95% CI, 1.2-2.4; $P = .007$) was higher in procedures involving perforated gloves compared with procedures with maintained intraoperative asepsis. After adjusting for 6 confounders in multivariate logistic regression analysis, however, the odds of contracting SSI in the event of glove puncture were not significantly higher when compared with procedures with intact gloves (adjusted OR, 1.3; 95% CI, 0.9-1.9; $P = .26$) (**Figure 1**).

In the absence of surgical antimicrobial prophylaxis (n=914), glove leakage was associated with an SSI rate of 12.7%, as opposed to 2.9% when asepsis was not breached (**Figure 2**). This difference proved to be statistically significant when assessed with both univariate (OR, 4.9; 95% CI, 2.2-11.0; $P < .001$) and multivariate (OR, 4.2; 95% CI, 1.7-10.8; $P = .003$) analyses.

The risk of developing SSI is therefore significantly higher in surgical procedures in which gloves are perforated and no antimicrobial prophylaxis is administered.

COMMENT

As early as 1915, Brewer²⁰ studied the impact of asepsis on the risk of SSI and reported that rigorous observa-

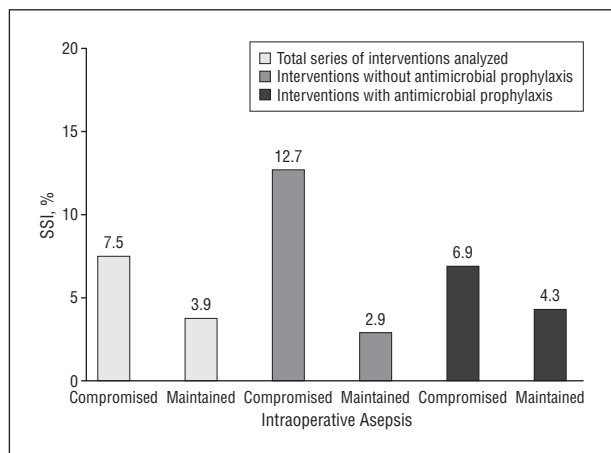


Figure 2. Rate of surgical site infections (SSIs) in 4147 surgical procedures by use of surgical antimicrobial prophylaxis and maintenance of intraoperative asepsis.

tion of surgical staff's aseptic practices could reduce the rate of SSI in clean wounds. He concluded that a heightened awareness of the importance of asepsis and more effective teamwork in the creation of a low-risk environment⁵ could therefore reduce the risk of SSI. Today, strict rules are in place to maintain asepsis in all types of surgical interventions. Despite the precautions taken to prevent glove perforation, the risk of such accidents is still relevant. Several studies have addressed the frequency of breaks in the glove barrier.^{7,9,12-16} Little information is available, however, on the association between glove perforation and SSI risk. Al-Habdan et al²¹ detected only 3 instances of SSI related to punctured gloves in 150 procedures. Although 2 reports have been published on randomized trials conducted to analyze glove perforation as a primary predictor,^{22,23} neither reported the SSI assessment method used, and not a single SSI was found in either. To our knowledge, this is the first study to explore the correlation between SSI and glove leakage in a large series of surgical procedures. The results clearly show that, in the absence of surgical antimicrobial prophylaxis, there is a significant correlation between clinically visible glove perforation and the occurrence of SSI.

The most effective method for lowering the frequency of leakage is double gloving, which reduces glove failure significantly from rates as high as 51% with single gloves to as low as 7% of inner glove puncture when 2 pairs are used.^{15,24-26} Furthermore, inner glove perforation rates are proving to be significantly lower with the use of indicator gloves (colored latex undergloves to alert operators to perforations) than with the conventional variety.^{16,27,28} Irrespective of possible precautions, however, the risk of glove perforation continues to be a clinical problem.^{21,29,30} Latex is more resistant than vinyl, for instance, and provides better protection against infection.³¹ In the present study, only latex gloves were used, with the exception of surgical staff members with a documented latex allergy.

Another way to lower the risk of glove perforation is to routinely replace gloves after a specified period of time. A standard cutoff time would be 2 hours because the overall risk of glove puncture has been reported to rise sig-

nificantly in procedures lasting more than 2 hours.⁷ Such reports and the recommendation to change gloves regularly during long operations are consistent with the present data, which show that the duration of surgery directly affects the incidence of perforations.

The use of surgical microbial prophylaxis is still controversial. Several randomized controlled trials and observational studies have addressed the efficacy of different antimicrobial agents for patients undergoing breast surgery, hernia repair, and neurosurgery.³²⁻⁴² Most of these studies showed significantly lower SSI rates in patients receiving prophylaxis,^{32-37,42} and many hospitals therefore require the use of perioperative antibiotics for all wound classes. However, the incidence of SSI after clean surgical procedures traditionally has been regarded as too low for routine antimicrobial prophylaxis. Current CDC guidelines recommend a restricted use of antibiotics and are supported by studies that failed to demonstrate that prophylactic antimicrobials significantly reduce the incidence of SSI after clean procedures.³⁸⁻⁴¹ Indications for prophylactic antimicrobials approved by the CDC are clean operations involving prosthetic material and any operation in which a potential SSI would pose catastrophic risk.¹⁷ Examples are all cardiac operations, most neurosurgical and major vascular operations, and some operations on the breast. A 2006 Cochrane meta-analysis⁴³ concluded that prophylactic antimicrobials reduce the risk of SSI in patients undergoing surgery for breast cancer. In these patients, the presence of an infected breast wound delays the beginning of adjuvant anticancer therapy, and surgical antimicrobial prophylaxis seems justified. Our series of 1917 clean procedures with prophylactic antimicrobials involved trauma in 1219 procedures (63.6%), mesh hernia in 292 (15.2%), the breast in 109 (5.7%), and vascular operations in 297 (15.5%).

Our study had several limitations. First, 22.1% of the information on glove perforation was missing. Nonetheless, the 1389 procedures involved did not appear to bias the results because the SSI rate did not differ significantly from the rate found for the study population (4.9% vs 4.5%; $P = .58$). Second, because this was a prospective observational study rather than a randomized controlled trial, a number of characteristics, such as the T time, the duration of surgery, the American Society of Anesthesiologists scores I through V, and patient sex differed significantly between study groups. However, the distribution of other patient and procedure characteristics (age, division of surgical specialty, and, most importantly, wound classes 1 through 3) did not differ significantly between the study groups. To adjust the results where appropriate, all characteristics exhibiting significant misdistribution were included in the multivariate analysis. That notwithstanding, residual confounding by unknowns can never be ruled out entirely in observational studies. The study was further limited by the non-validated techniques used to detect glove leakage. In many studies, gloves are tested by air insufflations after use to detect even minor uncontrolled perforations. Inasmuch as the study hypothesis focused on the implications for SSI, detection was restricted to the macroscopic evidence of punctures during surgery or the visible effu-

sion of fluid inside the glove, which may cause a more substantial transfer of germs. Finally, because this study was conducted from 2000 to 2001, one might debate that significant changes in circulating relevant bacteria (eg, methicillin-resistant *Staphylococcus aureus*) could diminish the current value of these data. Since 1994, however, the Division of Infectious Disease and Hospital Epidemiology at University Hospital Basel routinely performs ongoing full-house surveillance of bloodstream infections and compiles yearly statistics of microbiological results. All strains of emerging pathogens, methicillin-resistant *S aureus*, gram-negative pathogens expressing broad-spectrum betalactamases, and multiresistant *Pseudomonas aeruginosa* and *Acinetobacter* are saved and stored at -70°C and routinely typed by means of pulsed-field electrophoresis, polymerase chain reaction analysis, spa typing (DNA sequence analysis of the protein A gene variable repeat region), or multilocus sequencing as appropriate. The distribution of pathogens and the resistance pattern basically remained unchanged during the past decade, despite quite different trends in other hospitals. The incidence of methicillin-resistant *S aureus* is stable at a very low rate of 0.14 to 0.17 per 1000 patient days, or approximately 1% of all *S aureus* infections.⁴⁴ The only changes recorded are an increase in pathogens expressing broad-spectrum betalactamases in the outpatient clinics and an increase in *Clostridium difficile*-associated diarrhea.⁴⁵

CONCLUSIONS

Although many authors have studied the frequency of glove perforation, the clinical consequences in terms of SSI have been largely neglected. The present study shows that, in the absence of surgical antimicrobial prophylaxis, glove perforation is a risk factor for SSI. Efforts to decrease the frequency of glove perforation, such as double gloving and the routine changing of gloves during lengthy surgical procedures, are therefore encouraged. These measures are effective and safe. However, implementing them in clinical practice can be difficult. Although surgical antimicrobial prophylaxis has been demonstrated to prevent SSI after clean surgery in several randomized controlled trials,^{32,34-37,42} there is no current consensus regarding its use in this area. The present results support an extended indication of surgical antimicrobial prophylaxis to all clean procedures in the absence of strict precautions taken to prevent glove perforation. The advantages of this SSI prevention strategy, however, must be balanced against the costs and adverse effects of the prophylactic antimicrobials, such as drug reactions or increased bacterial resistance.

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INVITED CRITIQUE

This 2-year study by Misteli and colleagues relates SSI to the incidence of surgical glove perforation in more than 4100 general surgery patients. Glove perforation occurred in 16.3% of cases and rose dramatically in cases lasting longer than 2 hours (34.0% vs 9.4%). Surgical site infection was identified in 7.5% of the cases in which there was a glove perforation vs 3.9% when there was none. The essence of the study resides in the multivariate logistic regression analysis, by which glove perforation was found to be a significant risk factor for SSI but only in cases in which prophylactic antibiotics were not used.

Although the authors handled the limitations of this study nicely, a few issues persist:

- Nearly 70% of the cases (n = 2831) were class 1 (clean), yet antibiotic prophylaxis was withheld in only 914 (32.3%) of the class 1 cases. This implies that the other two-thirds of class 1 cases had a nonabsorbable implant or involved a patient for whom SSI posed a “high risk.” The specific factors guiding the surgeons’ decision regarding antibiotic prophylaxis in this group would be useful to know.

- I do not believe the recommendation to extend antibiotic prophylaxis guidelines is justified. The recommendation is based on 9 or 10 patients of the 72 without antibiotic prophylaxis whose surgeon had a perforated glove and who went on to develop an SSI. Although the risk of SSI (with vs without glove perforation) among patients without antibiotic prophylaxis was significant on multivariate analysis, the data in this and other studies cited by the authors much more strongly support the measures suggested for lowering the risk of glove perforation. These measures would be substantially cheaper, more promising for efficacy, and less likely to produce allergies or adverse effects than giving prophylactic antibiotics to all patients.

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