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Risk Factors for Surgical Site Infections Following Neurosurgical Spinal Fusion Operations: A Case-Control Study—Methodological issue

To the Editor—We read the paper by Walsh et al[1] in a recent issue of *Infection Control & Hospital Epidemiology* with great interest.[1] They examined risk factors for the development of surgical-site infections (SSIs) in neurosurgery patients undergoing spinal fusion. They conducted as case-control study on 159 patients with SSIs and 161 controls. Previous methicillin-resistant *Staphylococcus aureus* (MRSA) carriage was associated with SSIs both in the univariate model (odds ratio [OR] = 24.96; 95% confidence interval [CI], 5.90–105.52) and the multivariate model (OR = 20.30; 95% CI, 4.64–88.78).[1] Although this study makes a valuable contribution to the field, an important methodological issue needs to be noted.

The authors examined the association between previous MRSA carriage and SSIs. They reported large ORs with wide CIs in both the univariate and multivariate models. Several researchers have stated that a large measure of association with wide CI does not necessarily mean large effect; this result may be attributable to the lack of sufficient data for the different combinations between the independent and dependent variables.[2,3] Also, multivariate models are more susceptible to sparse data because the number of combinations between the independent and dependent variables is higher than in corresponding univariate models.[2]

We extracted the data provided by Walsh et al regarding the univariate association between previous MRSA carriage and SSIs (Table 1). The number of the events is low in one of the combinations and sparse data bias is expected. This bias can be removed or decreased in the analysis stage, and several statistical methods have been proposed to address this problem.[2–5] Penalization via data augmentation is an efficient method introduced in 2016.[2] We used this method to re-estimate the crude association between previous MRSA carriage and SSIs. The OR and 95% CI shrank and narrowed considerably, which demonstrates the high statistical efficiency of this method (Table 1). Penalization can also be applied to more susceptible

TABLE 1. The Crude Association Between the Previous MRSA Carriage and SSIs Through Ordinary and Penalized Logistic Regression

Variable	SSIs (n = 159)	No SSIs (n = 161)
Previous MRSA carriage, no.		
Yes	38	2
No	121	159
Estimated odds ratio (95% CI)		
Ordinary logistic regression	24.96 (5.90–105.52)	
Penalized logistic regression	12.71 (4.42–36.57)	

NOTE. MRSA, methicillin-resistant *Staphylococcus aureus*.

models to address data sparsity, such as multivariate models, but the individual data are needed. Hence, we suggest that Walsh et al reanalyze their adjusted association between previous MRSA carriage and SSIs using the efficient method introduced here to report a more valid and precise measure of association.

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Concerns Associated With Cleaning Robotic Surgical Instruments—Response to Wallace

To the Editor—We acknowledge the letter by Wallace.[1] We are greatly concerned by the fact that the opposite opinion was raised by the principal scientist of the manufacturer of the da Vinci Surgical System. Before our discussion, it should be recognized that the author's argument might be intrinsically biased from the commercial standpoint. We would like to respond to the issues raised in the letter.

Interpretation of "Published Evidence" of Cleaning Efficacy

The author stated that the amount of residual protein in the robotic instruments was too much, referring to the study by Wallace et al.[2] However, the study protocols were different from each other, as mentioned below.

First, Wallace et al[2] did not assess the housing of the instruments connecting to the shaft, in which surgical soil could "travel up by gravity." In fact, our central sterile supply department staff sometimes observe leakage of bloody ascites from the housing after surgical use. Our data values were higher than those in the previous study because our results reflected the protein remaining on the whole surface area of robotic instruments including inside the lumen of shafts and housings.[3]

Second, their study was based on a protocol proposed to assess the cleanliness of robotic instruments.[4] In this article, robotic instruments were soiled with 200–500 μg protein before measurements. The assumed initial contamination was even lower than residual protein after cleaning in our study.[3] Our data clearly demonstrated that this assumption did not reflect the actual case in clinical settings.

Consideration of Experimental Protocol

The author stated that washer disinfectors should not have been used in our study because they are not allowed in ISO 15883-1. However, in this standard, nonthermal disinfection is adopted only for testing the function of machines and not for testing the cleanliness of surgical instruments. This claim does not make sense. The cleaning conditions in our study were based on the method described in the manufacturer's instructions. Our data reflect more precisely the situation of surgical instruments at use in operations.

Negative controls were not employed in our study nor in the Wallace et al study.[2] The author claimed that negative controls could interfere through residues from the manufacturing process.[1] However, the effects could be minimized by 3 reprocessing cycles, as employed in previous studies.[3,5] The robotic instruments we assessed for residual protein had undergone 10 reprocessing cycles followed by 10 clinical uses.[4] Thus, the use of a negative control was not necessary in our study.

The author assumed that the iron and tungsten particles were released in the ultrasonication process and influenced the results in the bicinchoninic acid assay.[1] However, this assumption is not true according to the manufacturer's instructions for the assay kit we used. The author also stated that 30-minute ultrasonication was harsh and could result in instrument damage.[1] However, it is necessary to clean instruments for a total of 150 minutes of ultrasonication prior to each set of 10