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Intraoperative door openings and surgical site infection: a causal association?

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London, September 9, 2019

Dear Editor,

We are submitting a letter entitled " **Intraoperative door openings and surgical site infection: a causal association?**". This manuscript is commenting the article from Roth et al assessing the effect of operating room doors openings of the occurrence of surgical site infection. Even if this article is the first to approach the topic prospectively and with a clinical meaning, we agree and extend the comment of Yoshioka et al, on methodological issues and then provide several methodological specifications. A cluster-randomised trial is currently ongoing and we hope it will bridge the existing gap. All coauthors have contributed significantly to the work, have seen and approve the manuscript. Of course, this authorship can be edited according to your considerations.

This manuscript has not been published and is not being submitted for publication elsewhere. The paper has been read and approved by the other coauthor. Potential conflicts of interest have been disclosed.

I hope our work will be considered favourably for publication. If so, I will deal with the prepublication matters and will be the corresponding author.

Sincerely,

Dr. Gabriel Birgand, PharmD PhD

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Intraoperative door openings and surgical site infection: a causal association?

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Dear Editor,

The impact of operating room (OR) door opening on the risk of surgical site Infection (SSI) is a controversial issue. Roth *et al* recently published an article demonstrating a positive adjusted association between an increased frequency of door opening and SSI in cardiac surgery.[1] A previous literature review on the influence of staff behavior on infectious risk in OR highlighted the heterogeneity of studies in this field, failing to cover all relevant areas, and concluded to a low level of evidence.[2] The study published by Roth *et al* is the first to accurately analyze this relationship, with relevant results and clinical meaning. Following this publication, Yoshioka *et al* highlighted potential biases[3], with blood transfusion being a potential confounding factor, associated both with an increased frequency of door openings and SSI risk by disruption of the immune system. We agree and extend the comment of Yoshioka *et al*, since higher frequency of door opening may mostly reflect a higher severity or difficulty during the surgical procedures, at risk for SSI. As acknowledged by Roth *et al*, statistical association does not prove a causal relationship. Observational studies, even prospective, may not be adapted to treat this question by lacking to consider all confounding factors.

To bypass potential biases, studies need to consider several methodological specifications. (i) Randomization should avoid biases due to potential confounding factors. In studies with risk of contamination between groups (i.e. team behaviors), a cluster-randomized study is better suited. (ii) The statistical analysis requires enough events to obtain significant results. One way would be to extend the list of outcomes by including other complications than SSI which are also potentially linked to OR behaviors. Door openings increase the airborne contamination.[5] Since an increased frequency of door openings may also disrupt the teamwork and the performance of the surgical team, broadening the range of postoperative complications (POC) is logical. (iii) The selection of the surgical procedure is another tricky challenge. Contaminated surgery provides a higher number of events but with debatable causality of an exogenous contamination. On the other hand, contamination of the surgical wound in clean surgery mostly occurs from exogenous sources, but with lower rate of events, therefore requiring a high number of included operating rooms and patients.

According to these points, we designed a cluster-randomized trial aiming to optimize staff behavior intraoperatively and prevent POC in orthopedic surgery, based on automatic feedback of door openings to the surgical staff.[6] The population includes patients undergoing knee or hip arthroplasty (replacement or resurfacing) as a primary, elective or urgent referral, for an expected total of 9,945 procedures from 30 orthopedic centers. The primary outcome is the occurrence of any major POC (SSI and non-SSI events) during the postoperative period, up to 30 postoperative days (90 days for SSI). These events will be identified through routinely collected data on hospital discharge (acronym PMSI, hospital billing records) based on the International Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) details. We hope this trial will bridge a gap in this field, and promote best practices during surgical procedures.

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