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Concise Communication

Immediate-use steam sterilization and the effect on surgical site infection risk in an acute care facility

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Abstract

Immediate-use steam sterilization (IUSS) shortens the time of sterilization but may increase the risk of surgical site infection (SSI). Among 23,919 procedures with 416 (1.7%) procedures resulting in SSI, IUSS was associated with a 1.52 (95% CI, 1.10–2.11) times higher risk of SSI. IUSS should be minimized.

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Introduction

Compared to conventional sterilization techniques, immediate-use steam sterilization (IUSS) shortens the time from sterilization to the aseptic transfer of a medical device onto the surgical sterile field. IUSS should be utilized following the manufacturer's instructions for use and within evidence-based guidelines, but not for convenience purposes.[1] In the operating room, there are competing pressures such as efficient turnover time, on-time start of surgery, and case cart preparation that factor into the utilization of IUSS and potential surgical site infection (SSI) risk resulting from a non-sterile device.[2,3] Few published data have quantified the risk of SSI following IUSS, compared to the standard sterile reprocessing method.[4–6] We aimed to measure the association between IUSS use for surgical instrument reprocessing and SSI risk in a facility where IUSS use increased due to staffing constraints and case volumes.

Methods

This retrospective observational study took place, between January 2022 and December 2023, at a tertiary care hospital with a diverse mix of surgery types. The hospital comprises 2 buildings with 2 separate operating suites and 2 sterile processing departments. Outside of the sterile processing departments, each operation suite houses autoclaves available for prion reprocessing and IUSS within the above evidence-based guidelines[1]. Each autoclave is tested daily to ensure the vacuum system is functioning appropriately, and each IUSS cycle requires documentation of indication and a chemical indicator for validation. Within the sterile processing department, steam and low-temperature gas sterilization methods are used, according to the manufacturer's instructions for use, for standard reprocessing. For each standardly reprocessed load, a biological and chemical indicator is used to validate the sterilization process. In addition, each tray has exterior sterilization indicator tape and an internal chemical indicator. Regardless of the sterilization method (standard vs IUSS), all instruments go through a manual and/or mechanical decontamination and washing per hospital policy within the sterile reprocessing department.

We utilized internal databases of patient-linked device reprocessing, including sterile reprocessing logs, to document the exposure as "standard reprocessing" or IUSS. SSI outcomes and surgery types were defined using National Health and Safety Network (NHSN) definitions; surgery types were categorized by the surgical service.[7] We compared SSI rates among surgeries using one or more surgical devices preoperatively sterilized using IUSS compared to standard reprocessing methods and calculated a risk ratio (RR) and 95% confidence interval (95% CI) for all NHSN-defined surgery types and stratified by 7 surgical services that had ≥1 reported SSIs in the study time frame. Indication for IUSS was summarized across NHSN and non-NHSN procedures during the study period. Analyses were performed using STATA (version 12.1). This investigation was approved as a quality improvement intervention by the UPMC Quality Review Committee.

Results

Among 23,919 surgical procedures, 416 (1.74%) developed SSIs, including 2.56% (39 of 1,524) and 1.68% (376 of 22,395) of procedures for which IUSS and standard reprocessing was used to sterilize instruments prior to the procedure, respectively (Table 1). IUSS was associated with a 1.52 times higher risk of SSI (95% CI, 1.10–2.11). Two surgical services had statistically significant RRs for SSI development after IUSS: transplant surgery (RR 2.47; 95%

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Table 1. Frequency of surgical site infection, by preceding reprocessing method

	Surgical site infection	No surgical site infection	Total
Immediate-use steam sterilization	39 (2.6%)	1,485 (97.4%)	1,524
Standard reprocessing	376 (1.7%)	22,018 (98.3%)	22,395
Total	416 (1.7%)	23,503 (98.3%)	23,919

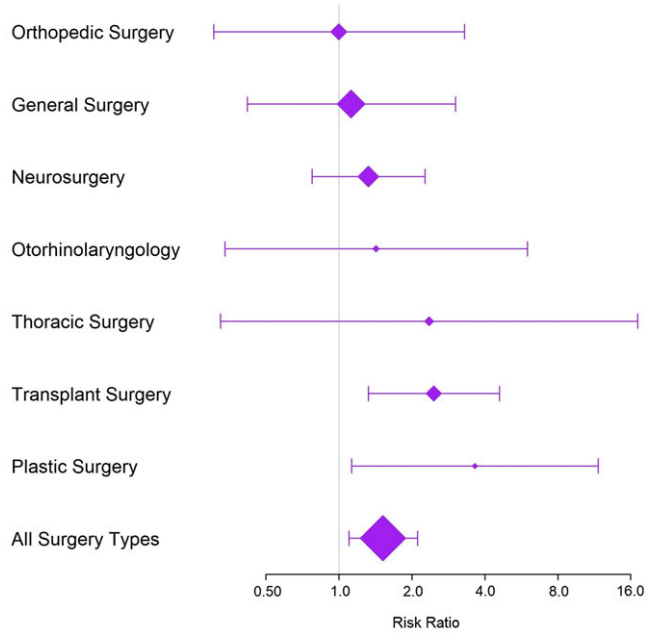

Figure 1. Risk of national healthcare safety network-defined surgical site infection among procedures with and without preceding immediate-use steam sterilization, by surgery type.

CI, 1.32–4.60) and plastic surgery (RR 3.64; 95% CI, 1.13–11.74) (Figure 1, Supplemental Table).

The reasons for IUSS rather than standard reprocessing among the 2,069 IUSS instances were insufficient reprocessing time before surgery started (1,284, 62.1%), missing instruments in set identified during surgery (646, 31.2%), crucial device contaminated in the operating room (112, 5.4%), incoming vendor trays (24, 1.2%), and implants (3, 0.1%).

Discussion

In this observational study of SSI risk following NHSN-defined procedures for which surgical devices were reprocessed prior to the procedure with either IUSS or standard reprocessing, we observed a 1.52 times higher overall risk of SSI following IUSS and statistically significantly higher risk for transplant and plastic surgery procedures. These findings support the avoidance of IUSS to reduce the risk of SSI.

The most robust study to date defining the SSI risk associated with IUSS identified no significant difference in SSI risk among 111 propensity-matched patients (61 IUSS, 50 non-IUSS reprocessing) undergoing orthopedic or spine surgeries.[4] Reasons for findings discordant with this investigation may relate to the procedure types studied: the familiarity, acceptance, indication, and workflow disruption associated with IUSS may vary between procedures, making the strength of causal or incidental association with SSI differ between surgery types. For example, a surgical procedure for which IUSS is commonly used and part of the perioperative workflow may not incur significant SSI risk compared to a procedure where IUSS represents an interruption of usual process and urgency that may lead to other lapses in SSI prevention practices (eg, operating room entries).

Our study is limited by a lack of modeling of patient and procedure-associated factors associated with SSI risk.[8] Due to the nature of documentation of autoclave device indication and IUSS use prior to a surgical case, we could not report the SSI rate stratified by IUSS indication. During the course of this investigation, there were no new interventions to modify these factors, reducing the likelihood that these differed in the IUSS versus standard reprocessing groups except by random chance.

Ethical reasons prohibit a randomized trial of IUSS versus standard reprocessing. Larger studies in diverse patients, procedures, and facility types with quasi-experimental study designs are needed to provide a clearer estimation of SSI risk associated with IUSS.

Given our findings and regulatory guidance,[1] IUSS utilization should be minimized. The reasons for IUSS use may be complex. An in-depth root cause analysis—as our team performed in this investigation—can reveal issues broader than and indirectly related to surgical device reprocessing, such as staffing levels, supply chain operations, surgical staff education, patient throughput, and organizational culture. A regular review of IUSS use rates with root cause analyses may help identify underlying factors related to quality of care.

In this observational study of SSI risk among patients undergoing surgical procedures with surgical equipment reprocessed prior to the procedure using IUSS or standard methods, we identified a 1.52 times higher risk of SSI following IUSS device reprocessing and significantly increased procedure-specific risk for transplant and plastic surgeries. Although the analysis does not precisely identify why IUSS confers the risk of SSI, our findings add the most robust information to a very limited amount of published data supporting recommendations to minimize IUSS use.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/ash.2024.408.

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