Editorial

All care bundles are equal, but some are more equal than others

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Surgical site infections (SSIs) are one of the most common hospital-acquired infections in surgical patients (1). On average, SSI rates vary between 2–4%, but there is significant variation across surgical specialties and procedures. For patients undergoing colorectal surgery, the infection rates are among the highest, as 15% to 30% of the patients will develop an infection (2). SSIs increase patient morbidity because they can have serious consequences for postoperative recovery. On average, they are associated with a two to three fold increase in costs (3).

In the past decades, efforts have been made to reduce SSI rates. Improvements in infection control practice have led to an impressive reduction in infection rates for most surgical procedures, as was published in a recent report of the European Centers for Disease Control (4). However, the SSI rates after colorectal procedures remain high. The number of surgical procedures continues to rise, and likewise, the number of patients at risk for an SSI increases as well (5,6). This underlines the urgency of further improvement of infection control practice for colorectal surgery to achieve a reduction in the infection rates.

High-quality studies have delivered important insights into patient-related and perioperative risk factors for the development of SSIs. Based on this knowledge, several preventive measures were developed and studied. Proven measures to lower the risk of SSI include the administration of a perioperative intravenous antibiotic prophylaxis, chlorhexidine/alcohol skin preparation, maintenance of normothermia and normoglycemia, the use of electrical clippers instead of razors for hair removal, and preoperative bowel preparation with oral antibiotics (7). These measures have all been shown to be effective when tested individually under well-controlled conditions (8). Unfortunately, implementation of these measures in routine surgical practice has been difficult so far. In order to improve this, the Institute of Healthcare Improvement (IHI) suggested combining the individual evidence based measures into bundles with the aim to improve patient outcomes. A bundle of infection control measures was shown to be extremely successful in reducing catheter-related blood stream infections (9) and ventilator-associated pneumonia (10). A similar approach has been proposed to be used for SSI prevention, since there is a number of evidence-based interventions available (11).

The retrospective study by Jaffe *et al.* (12) investigated the impact of a "bundle of care" on the SSI rate after colon surgery in Michigan State. The study was performed by 24 hospitals of the Michigan Surgical Quality Collaboration, a network of 73 hospitals, and included patients who underwent elective colon surgery from 2012 to 2015. Primary outcomes were deep or organ/space SSIs within 30 days after surgery and 30-day episodic costs. The bundle of care was composed of six elements: prophylactic intravenous antibiotics administered within 60 minutes before surgical incision and with an appropriate selection of antimicrobial agents, minimally invasive surgery, short operative duration, maintenance of postoperative normothermia, preoperative mechanical bowel preparation with oral antibiotics and control of postoperative blood glucose levels. Risk of SSIs was adjusted for hospital level clustering, case mix of left and right sided hemicolectomy and for patient risk factors including body mass index >30 m^2, history of alcohol abuse, history of corticosteroid therapy, age >70 years, wound class, ASA classification,

functional status, race, diabetes, albumin and ICD9 diagnosis group. The analysis was conducted to determine the effect of the bundle compliance on SSI rate and on the value of colectomy procedures. The study reported SSI rates as low as 0.9% (95% CI, 0–3.0%) when there was compliance to all six bundle components. On the contrary, a rate of 17.9% (95% CI, 10.8–27.0%) was found when bundle adherence was lowest (1 or none of the components). Surgeons were consulted to assess their perceptions of poor compliance. As such, compliance to the bundle was stratified into low compliance (to 0–2 components) and high compliance (to 3–6 components). After stratification and adjustment, a risk-adjusted SSI rate of 8.2% (95% CI, 7.2–9.2%) in the high compliance group and 16.0% (95% CI, 12.9–19.1%) in the poor compliance group was found, which correlates to a relative risk reduction of 48.7%. The authors also reported that high compliance to the bundle leads to an average reduction in episodic costs of 23.8% or $4,664 (P<0.01) compared to poor compliance.

The results of this study are in line with findings of previous studies on the implementation of a bundle of care with the aim to reduce SSIs after colorectal surgery. Two recent meta-analyses reported pooled unadjusted risk ratios of 0.55 (95% CI, 0.39–0.77, P=0.005) (13) and 0.598 (95% CI, 0.496–0.722, P<0.001) (14) on SSI development when a bundle was used, compared to patients in whom no bundle of care was applied. Even though Jaffe *et al.* did not use a proper control period or group for comparison, which may have resulted in a dilution of the intervention's effect, the study reported a substantial reduction in SSIs with the use of an infection prevention bundle.

A couple of remarks should be made after critical appreciation of this study. First of all, the authors did not report several basic and essential elements in their paper. These elements are essential for readers to appreciate the findings and as such they are included in the STROBE guidelines' checklist of items that should be included in the report of cohort studies. For example: absolute numbers of patients and events are lacking, but also the distributions of patients across the different groups are not mentioned. An overview of the baseline demographics is missing, and more importantly, the distribution of patient risk factors, used for multivariable analysis, is not available. This information is crucial for the reader to understand the study design as well as to reflect on the results. Also, it is essential to report the final multivariable model in order to understand the analysis and its results. This also includes reporting the unadjusted and adjusted effect estimates of all the co-variables that are used to correct for confounding. The reader of this paper is left guessing about the approach the authors used to correct for confounding bias. Correction for confounding is an important issue, especially in observational studies. When the correction is not performed carefully, the observed treatment effect can be severely affected by other factors and unjustified conclusions can be drawn. Although the authors discuss that their risk standardization cannot account for all the patient factors and that other factors might influence infection risk, as well as bundle compliance they do not include this limitation in their conclusions. These flaws in the report make the data unsuitable to draw conclusions about the effect of bundle adherence.

A second point to consider is the choice of the bundle elements. In order to create an effective bundle of care, several factors are important. Like the interventions used in the bundle of Jaffe *et al.*, the individual measures must all be evidence-based. Secondly, the number of components must be limited as increasing the number of measures will lead to decreased motivation of the health-care personnel involved and to a lower compliance rate. Ideally, three to five components are used (15). A final aspect to take into consideration, is to select measures that could be applied to every patient. In this study, it can be debated whether the components 'minimally invasive procedure' and 'short duration of surgery' are appropriate bundle components, reflecting on their applicability. The practice of minimally invasive surgery and the duration of the surgical procedure both depend on patient-related factors and underlying morbidity. Modification of these bundle components in order to reduce infection rates is therefore problematic since this often lies beyond the control of the surgeon or the surgical team. It may be questioned if these bundle components are appropriate.

A different aspect that deserves some discussion is the definition of a bundle of care. Most bundles that are reported in the literature are not fulfilling the definitions and underlying concepts of the IHI care bundles (15). The IHI bundles are much more than tying some interventions together. It is a strategy that aims to implement a culture of safety, which assumes full adherence to all bundle elements in all patients. The IHI states the following: "Successfully implementing a bundle is clear-cut: "Yes, I completed the ENTIRE bundle, or no, I did not complete the ENTIRE bundle". There is no in between; no partial "credit" for doing some of the steps some of the time" (15). This important aspect is totally different from what is observed in the study by Jaffe *et al.* where only a fraction of all patients

had full adherence to all six bundle elements (we estimate that it is a fraction as the infection rate was extremely low in the group with adherence to six bundle elements, but the exact numbers are not provided in the paper). High bundle compliance with a zero-tolerance approach is considered crucial to achieve a culture change (16-18). By aiming for zero-tolerance, failure to comply with any bundle element is considered a serious mistake, and thereby a culture of safety is created (19). For the bundle to remain effective after its implementation, it is essential that long-term compliance is ensured. Teamwork, including active engagement of everyone involved in the procedure is essential to achieve and maintain compliance. A change of attitude and alteration of culture are vital in achieving this (14). Making surgeons and their surgical teams aware of the results of their operations, for example by recording and reporting bundle compliance and SSI rates, can significantly improve motivation to adhere to the bundle. Regular communication meetings could be encouraging and helpful in creating a united attitude towards improving infection control as well (20). Unfortunately, the authors do not mention the methods used for implementation nor if a zero-tolerance approach was applied.

Besides a change of culture, formal testing of the bundle in relation to the outcome also precedes successful implementation of the bundle in daily practice. This is illustrated by the findings of a large randomized controlled trial that investigated the effect of a bundle of infection control measures for SSI reduction after colorectal surgery, compared to a control arm (21). Even though evidence-based components were selected for the bundle, an unexpected and strong increase in SSI rates was observed in the intervention arm. These findings suggest a cautious approach must be taken in bundling evidence-based measures without formal testing of the bundle in the target population as a bundle does not necessarily produce the expected effect.

In line with the authors' conclusion, bundling infection control measures is a promising strategy in reducing SSI rates after colorectal surgery and could therefore have a serious impact on patient outcomes and costs. The unaffectedly high SSI rates after colorectal surgery force us to adapt our strategies. Previous studies have provided important insights into risk factors and interventions for SSIs that have not led to a reduction in postoperative infection rates so far. Bundling this knowledge by combining evidence-based interventions could be the first step in reducing SSI rates after colorectal surgery. However, a care bundle is more than just a compilation of evidence-based interventions. The full strength of a bundle is achieved when it is implemented using a zero-tolerance approach, with the aim to implement a safety culture. Finally, bundles are no magic bullets and the effects on outcome should be carefully monitored and reported using appropriate methods.

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