



The Role of Bundle Size for Preventing Surgical Site Infections after Colorectal Surgery: Is More Better?

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Dear Editors,

The successful implementation of clinical guidelines to prevent hospital-acquired infections (HAI) represents a challenge for health care workers. Potential barriers are the frequent multitude of recommendations and their lacking prioritization.¹ To address these problems, the Institute for Healthcare Improvement (IHI) developed the concept of “bundles”.² By definition, a bundle comprises generally 3–5 evidence-based measures which are contemporaneous and more effective when implemented together. The inherent theory of change implies that bundling fosters multidisciplinary teamwork and quality-improving interventions.^{1,2} To date, several HAI-prevention bundles have been evaluated.² In June 2017, Zywoot and colleagues published a systematic review and meta-analysis in the *Journal of Gastrointestinal Surgery* on bundles to prevent surgical site infections (SSI) after colorectal surgery.³ They identified 35 studies, with 21 scrutinizing SSI of all wound depths. The meta-analysis revealed a SSI-risk reduction of 40.2% after bundle implementation. Given this result, we unequivocally agree with the authors that bundles can effectively prevent SSI after colorectal surgery.

Simultaneously, Zywoot and colleagues did not analyze *bundle size*, a parameter which varied from 2 to 14 elements per bundle across studies.³ This attribute may relate to bundle effectiveness for several reasons. On the one hand, the IHI-definition defined 3–5 elements as a rule, mainly since

compliance with *all* elements would be more attainable than with comprehensive care protocols.² Moreover, tailored interventions to promote compliance, e.g., those recently developed and successfully implemented based on psychological theory for hand hygiene as an individual measure,⁴ would probably be more complex, and maybe inappropriately so, for large bundles. On the other hand, larger bundles may be even more effective simply because they include more evidence-based measures and thus impact more processes relevant to SSI.

Thus, we performed a supplementary analysis focusing on bundle size of the 21 studies on SSI of all wound depths,³ in which we recoded the number of elements in the bundle by Anthony and colleagues⁵ from 4 to 3 since it included the *omission* of mechanical bowel preparation (MBP), which does not conform with guidelines.^{6,7} On average, these bundles had 7 elements (standard deviation: 3.7), with the median at 7 and the mode at 3. Given the number of studies and distribution of bundle size, we grouped bundles as follows: 2–4 elements ($n = 9$ studies), 5–7 elements, 8–10 elements, and 11 or more, i.e., 11+ elements ($n = 4$ each, respectively). For SSI-risks, we summed up the baseline- and cohort-sample sizes and baseline- and cohort-SSI outcomes reported by Zywoot and colleagues in Table 1, respectively, to calculate risk differences and risk ratios for each group using OpenEpi.⁸

As Fig. 1 shows, for bundles with 2–4 components the post- vs. pre-intervention SSI-risk difference was 5.3%, and the risk reduction of 27.1%. For the groups with 5–7 and 8–10 elements, these parameters were –6.8 and –5.8%, and 41.9 and 29.8%, respectively. The largest effect pertained to bundles with 11+ components, with a risk difference of –12% (risk reduction 63.3%). As a Breslow-Day test shows, risk differences significantly differed across groups, and confidence intervals indicate that bundles with 11+ elements most strongly contributed to this. Also, baseline SSI-rates (Fig. 1) did not significantly differ across groups ($\chi^2 = 7.5, p = 0.059$), and this rate was not highest in bundles with 11+ components.

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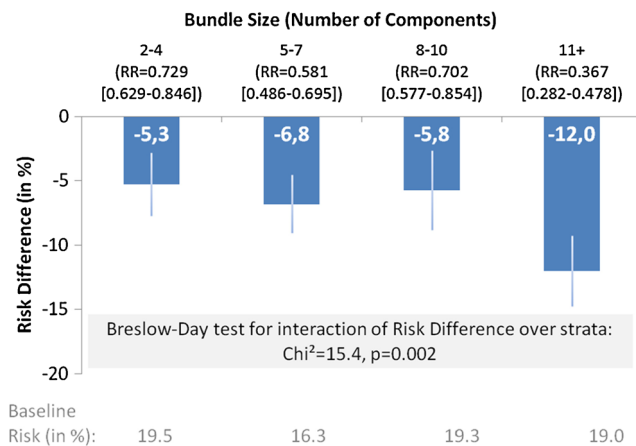


Fig. 1 Absolute risk differences and relative risk reductions regarding SSI after colorectal surgery for bundles of different sizes (21 studies to prevent SSI from the meta-analysis by Zywt and colleagues³)

In sum, while this supplementary descriptive analysis revealed significant SSI-reductions for all bundle sizes, bundles of 11 or more elements, with a risk ratio of 0.367, stood out. The reasons for this remain undetermined, and thus also whether larger bundles should be recommended for SSI-prevention after colorectal surgery, or whether the success of large bundles “only” depends on specific components. Indeed, *all* four studies with 11+ elements included at least one of three measures highlighted by Zywt and colleagues as particularly effective (sterile closure trays, MPB with oral antibiotics, and pre-closure glove changes), while only 7 of 17 of smaller bundles did (41%). Also, proportions of bundles with all three measures were 75 vs. 6%, respectively. Moreover, the slightly higher effectiveness of bundles with 5–7 vs. 2–4 or 8–10 elements may be explained by MPB with oral antibiotics being part of 2 of 4 bundles in the former group, but nonexistent in the latter groups. Possibly, larger bundles with key elements are especially effective. More in-depth analysis of Zywt and colleagues’ original meta-analytic data might clarify reasons for bundle size differences. Finally, further studies should evaluate which bundles of which size, and including

which elements, are associated with highest compliance and most sustainable effects, especially in view of the abovementioned tension between implementation feasibility and potential effectiveness.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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