SCIENTIFIC MEDICAL CLINICAL AFFAIRS

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Research Compact

Tags preoperative skin antisepsis, chlorhexidine, povidone iodine

Title

Povidone Iodine vs Chlorhexidine Gluconate in Alcohol for Preoperative Skin Antisepsis - a randomized clinical trail

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Aim of the study

Preoperative skin antisepsis is a proven method for preventing surgical site infections (SSI). Guidelines recommend the use of alcohols with residual substances (KRINKO). One of these residual substances is chlorhexidine gluconate. Povidone iodine as an additive is controversial. The purpose of this study was to determine whether povidone iodine in alcohol is non-inferior to chlorhexidine gluconate in alcohol for the prevention of SSIs after cardiac or abdominal surgery.

Methods

Multicenter, cluster-randomized, investigator-masked, crossover, non-inferiority trial; 4403 patients undergoing cardiac or abdominal surgery at three tertiary hospitals in Switzerland (09/2018 – 03/2020) were screened and 3360 patients were included (cardiac, n = 2187 [65%]; abdominal, n = 1173 [35%]). Over the course of 18 consecutive months, study centers were randomly assigned each month to use either povidone iodine (Braunoderm, B.Braun; 10% free available iodine) or chlorhexidine gluconate (Softasept CHX colored 2% B.Braun CH), each formulated in alcohol. The disinfectants and skin application procedures were standardized and followed published protocols. The primary endpoint was the occurrence of SSI within 30 days after abdominal surgery and 1 year (shortened to 90 days due to the COVID-19 pandemic) after cardiac surgery, with a focus on the primary incision site (definitions from the US Centers for Disease Control and Prevention's National Healthcare Safety Network). Secondary outcomes included SSIs stratified by depth of infection and type of surgery.

Results

Baseline patient characteristics such as mean age (65.0 years), female patients (32.7 % PVP-I vs. 33.9 % CHX) and more, length of hospital stay and time between surgery and infection did not differ significantly between the two groups. A total of 3321 patients were included in the analysis (0.5 % lost follow-up, 0.68 % withdrew consent).

Overall, SSIs were detected in 80 of 1570 patients (5.1%) in the povidone iodine group and in 97 of 1751 patients (5.5%) in the chlorhexidine gluconate group. This corresponds to a difference of 0.4 % (95 % confidence interval (CI), -1.1 % to 2.0 %), with the lower limit of the CI not exceeding the predefined non-inferiority limit of -2.5 %. No significant differences were found when stratifying by the type of surgical procedure. For cardiac surgery, SSIs occurred in 4.2% (42 of 1011 patients) of patients in the povidone-iodine group and in 3.3% (38 of 1155 patients) of patients in the chlorhexidine-gluconate group. For abdominal procedures, SSIs occurred in 6.8% (38 of 559 patients) in the povidone-iodine group and in 9.9% (59 of 596 patients) of patients in the chlorhexidine-gluconate group.

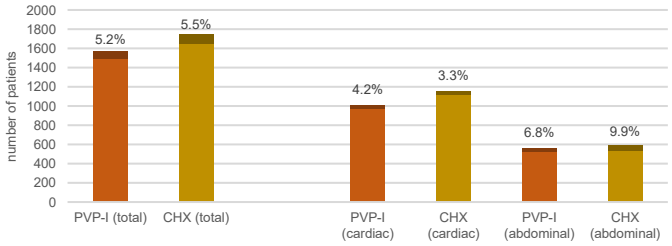

Figure 1: The darker shades show the SSIs that have occurred with the percentage in relation to the treatments without occurring SSIs (lighter shades).

Conclusion

The study results show that povidone iodine in alcohol was not inferior to chlorhexidine gluconate in alcohol as a preoperative skin antiseptic in the prevention of SSIs after cardiac or abdominal surgery. No further studies or comparisons with other residual additives for example octenidine were performed.