O115

2-hour Oral Session

Randomized, placebo-controlled, double-blind clinical trial to evaluate the efficacy of polyhexanide for topical decolonization of methicillin-resistant *Staphylococcus aureus* (MRSA) carriers

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Objectives

Due to increasing resistance, there is an unmet clinical need to evaluate alternatives to mupirocin and chlorhexidine for decolonization of MRSA carriage. The aim of this study was to evaluate the efficacy of topical treatment of MRSA-colonized patients with polyhexanide (Prontoderm®) in eliminating MRSA carriage at day 28 (D28) after the end of treatment compared with placebo.

Methods

In a 1,900-bed teaching hospital in Switzerland with endemic MRSA, patients colonized with MRSA, but without active MRSA infection, were randomized into a double-blind, placebo-controlled superiority trial. Patients were treated with either polyhexanide (antiseptic and surface-active substances; group I) or placebo (only surface-active substances; group P) applied to the anterior nares and skin for 10 days. Patients were allocated 1:1 to either regimen by an internet-based randomization generator with a block size of 10. The primary outcome was MRSA decolonization at D28 assessed by both intention-to-treat (ITT) and per-protocol (PP) analyses. All patients with complete microbiological follow-up (D28 +/- 7 days) and topical treatment ≥ 5 days were included in the PP analysis. Secondary outcomes included MRSA decolonization at D2, safety, emergence of resistance and MRSA genotype. Missing outcomes were treated by responder analysis. This trial is registered, number ISRCTN02288276.

Results

Of 2590 patients screened, 150 patients were randomized between January 2011 and July 2014 and 146 (group I, 71; group P, 75) were included in the ITT analysis. Baseline characteristics were comparable between the 2 groups except for malignancy (18/71 [25.4%] in group I versus 8/75 [10.7%] in group P; *P*=0.02). Primary outcome was missing for 11 (7.5%) patients. A total of 24/71 (33.8%) patients in group I and 22/75 (29.3%) in group P were MRSA-free at D28 (risk difference, 4.5%; 95% confidence interval [95% CI]: -10.6% to 19.5%; *P*=0.56). The results were confirmed by the PP analysis, with 19/53 (35.8%) decolonized patients in group I versus 17/56 (30.4%) in group P (risk difference, 5.5%; 95% CI: -12.2% to 23.0%; *P*=0.54). MRSA decolonization rate at D2 was similar in the 2 groups: 11/71 (15.5%) in group I versus 11/75 (14.7%) in group P (*P*=0.89). Nine serious adverse events occurred in group I versus 12 in group P; none was attributable to study medication. Emergence of polyhexanide resistance or cross-resistance between polyhexanide and chlorhexidine was not observed. No case of exogenous recolonization by a genotypically different MRSA strain was documented.

Conclusion

This study suggests that under real-life conditions a single polyhexanide decolonization course is marginally effective in eradicating MRSA carriage. The physical cleansing activity of the placebo solution may have played a more important role than expected.

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