Randomised controlled trial

In intensive care and bone marrow transplantation settings, daily bathing with chlorhexidine wash cloths reduces the risk of hospital-acquired infection

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Commentary on: **Climo MW, Yokoe DS, Warren DK, et al.** Effect of daily chlorhexidine bathing on hospital-acquired infection. *N Engl J Med* 2013;**368**:533–42.

Implications for practice and research

- Chlorhexidine-impregnated wash cloths have been shown to have some effect on multidrug-resistant acquisition and hospital-acquired blood stream infections in intensive care settings.
- Further research, including cost-effectiveness, is required to confirm these findings in intensive care units and in other healthcare settings.

Context

Hospital-acquired blood stream infections (BSI) remain as an important cause of morbidity and mortality in intensive care units (ICUs) and other high-risk settings. Incidence rates vary considerably, depending on factors such as patient characteristics, type of invasive procedures, infection control practices, definitions and duration of hospital stay. Recently reported BSI rates in intensive care settings range between 0.28 and 22 per 1000 ICU patient-days^{1,2} and mortality may be as high as 48%. Interventions to reduce the incidence of BSI have had some success but it is important to explore other strategies.

Methods

The study was a multicentre, cluster-randomised, non-blinded crossover trial. Twelve units from seven hospitals were initially randomised to perform daily bathing with either a chlorhexidine-impregnated wash cloth (the intervention) or with a non-antimicrobial wash cloth (the control) for a 6-month period. During the following 6-month period, the intervention was swapped with the control, and vice versa. There was no washout period between the two phases. Sage products supplied the wash cloths and provided educational and technical support for staff. Outcome measures were the acquisition of multidrug-resistant organisms (MDROs), hospital-acquired BSI and skin reactions. A power calculation (from the study protocol) indicated that 16 000 patients would be required to detect a 30% reduction in BSI and MDROs.

Findings

Data from 9 of the original 12 units (7727 participants) were available for analysis. The rate of MDRO acquisition was lower in the chlorhexidine group (5.10 cases per 1000 patient-days) compared with the non-antimicrobial

group (6.60 cases per 1000 patient-days, $p=0.03$). Hospital-acquired BSI was also lower in the chlorhexidine group (4.78 cases per 1000 patient-days vs 6.60 cases per 1000 patient-days, $p=0.007$). There were no reported skin reactions in either group.

Commentary

Chlorhexidine-impregnated wash has been introduced to the market without rigorous effectiveness testing, so this is an important study. Nevertheless, there are a number of potential biases in the trial, which may limit the applicability of results. The study was designed to recruit 16 000 patients but less than half of this number were enrolled; it is unclear why the study was stopped early. In addition, 3 of the original 12 units failed to complete the trial. This is important because, at the outset, units were stratified for the presence of active surveillance culturing. Effective, balanced randomisation may have been compromised by the three units who did not complete the trial.

Of more concern is the claim that an intention to treat analysis was used, when two of the units were excluded because of 'low compliance with the study protocol'. An intention to treat analysis is important for testing interventions in the 'real world' and should include all participants randomised, irrespective of adherence to the protocol. It is very likely that manufacturer instructions for wash cloths may not be rigorously adhered to in a busy ICU setting, so excluding the units who did not comply with instructions potentially biases results.

Baseline characteristics were provided for the units, but baseline data for individuals was very limited. Without this information, it remains unclear if participants in the intervention and control groups were similar in their risks for BSI and MDRO acquisition (eg, Acute Physiology and Chronic Health Evaluation (APACHE) score, antibiotic use, etc).

The data were analysed using hierarchical modelling for the analysis of individual-level outcome measures, without discussion of alternative methods (eg, cluster-level). The analysis appears to have failed to make allowance for the correlation of outcome measurements within clusters and time periods.³ It is possible that participants were qualitatively different in one period, or that conditions had changed over time,⁴ again introducing potential bias.

Finally, the trial was conducted among critically ill patients, where BSI rates are higher than in other

hospital settings. Consequently, results from this study should not be extrapolated to areas of low-risk for BSI.

Competing interests None.

References

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