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Major Article

Potential effectiveness of copper surfaces in reducing health care–associated infection rates in a pediatric intensive and intermediate care unit: A nonrandomized controlled trial

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Background: Studies have consistently shown that copper alloyed surfaces decrease the burden of microorganisms in health care environments. This study assessed whether copper alloy surfaces decreased hospital-associated infections in pediatric intensive and intermediate care units.

Methods: Admitted infants were assigned sequentially to a room furnished with or without a limited number of copper alloyed surfaces. Clinical and exposure to intervention data were collected on a daily basis. To avoid counting infections present prior to admission, patients who stayed in the hospital <72 hours were excluded from analysis. Health care–associated infections (HAIs) were confirmed according to protocol definitions.

Results: Clinical outcomes from 515 patients were considered in our analysis: 261 patients from the intervention arm of the study, and 254 from the control arm. Crude analysis showed an HAI rate of 10.6 versus 13.0 per 1,000 patient days for copper- and non–copper-exposed patients, respectively, for a crude relative risk reduction (RRR) of 0.19 (90% confidence interval, 0.46 to -0.22). Conducting clinical trials to assess interventions that may impact HAI rates is very challenging. The results here contribute to our understanding and ability to estimate the effect size that copper alloy surfaces have on HAI acquisition.

Conclusions: Exposure of pediatric patients to copper-surfaced objects in the closed environment of the intensive care unit resulted in decreased HAI rates when compared with noncopper exposure; however, the RRR was not statistically significant. The clinical effect size warrants further consideration of this intervention as a component of a systems-based approach to control HAIs.

Health care–associated infections (HAIs) are a major public health concern causing significant morbidity and mortality that could be, to some finite extent, prevented. Progress in reducing HAIs has been achieved through the implementation of low technology and low-cost interventions, such as hand hygiene and disinfection of the environment. However, the full efficacy that each approach offers has not been fully realized for many different reasons.[1]

Handwashing is considered the single most effective intervention for controlling infection; however, compliance rates continue to be an issue.[2] Environmental cleaning and disinfection have been overlooked since Spaulding[3] categorized noncritical items as less important in the chain of events leading to infection. Asepsis and antiseptics have completely changed the landscape such that we need to target new reservoirs, new mechanisms of transmission, and new microorganisms. Recently, strong evidence has been generated suggesting that near-patient high-touch surfaces may act as important reservoirs for some hospital pathogens causing HAIs.[4,5]

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In controlled in vitro experiments, and during the conduct of pragmatic clinical trials, copper alloys have consistently displayed a profound and persistent antimicrobial activity.[6-8] Salgado et al[9] evaluated the antimicrobial activity of copper in the context of whether or not lower microbial burdens proximal to the patient would result in lower acquisition rates of HAI and learned that through the reduction in microbial burden on selected surfaces and components in the rooms of patients, a subsequent and significant reduction of HAI rates was observed. However, the study was conducted in adult medical intensive care units, and therefore it remains to be seen how the reduced bacterial burden might impact the HAI rates in different clinical settings and in different patient populations.

The methodologic challenges for estimating a significant reduction in HAI rates, as influenced by copper surfaces in different clinical settings, are manifold. First, a randomized controlled trial (RCT) seems to be the ideal design but presents the following challenges: (1) masking the intervention is challenging; (2) randomization is complicated because the intervention does not act at the level of the individual but rather on the microbes proximate to the care being provided; and (3) for busy critical health care units it may not be feasible to randomly assign patients to a particular room based on their medical need. Further, the very definition of the primary outcome required from such studies, acquisition of an HAI, is problematic because although ideal and detailed definitions of HAIs suited for epidemiologic purposes exist, their utility is limited as a consequence because they are not easily abstracted from medical records with the level of precision expected from a binary outcome. HAI definitions can also vary according to the population involved (eg, bloodstream infections associated with immunocompromised vs immunocompetent patients), from country to country, and from many other perspectives.[10]

In the work from Salgado et al,[9] they reported results of an RCT aimed at estimating the effect of copper-surfaced objects on HAI and colonization rates in adult patients admitted to the intensive care units of 3 hospitals in the United States. They found that the limited introduction of 6 copper components resulted in a statistically significant reduction of HAI rates and methicillin-resistant *Staphylococcus aureus* or vancomycin-resistant *Enterococcus* colonization in the intervention arm of the study compared with the control arm. The observed HAI incidence rates were 0.071 and 0.123 for the intervention and control groups, respectively, with a relative reduction risk (RRR) of 0.42. These promising results encouraged us to run a similar trial with respect to the number of copper components introduced as an additional component of a comprehensive infection control strategy in a different setting to compare estimates of the intervention effect. Our trial objectives were 2-fold. The first, for which results were recently published,[11] compared the microbial burden alleviated by the intervention (the limited introduction of copper components) with the microbial burden associated with the control surfaces. The second, addressed here, was to measure the clinical impact that copper alloy surfaces had on the HAI acquisition rates seen in 2 pediatric intensive care settings.

METHODS

Study design and setting

This study was conducted using a nonrandomized, unmasked, controlled clinical trial. The protocol was registered before the initiation of the study (ClinicalTrials.gov identifier no. NCT01678612). Although the study design was not ideal, it was deemed meritorious and was conducted under the umbrella of a pragmatic trial.[12,13]

The study was conducted in the pediatric intensive care unit (PICU) and intermediate pediatric care unit (PIMCU) of the Roberto del Rio Hospital, Santiago, Chile, which is a 249-bed tertiary hospital. Recruitment lasted 12 months. Eligible participants were all patients admitted to the study site. Although we would analyze only patients staying >3 days in the ward, we included all patients in the study because we could not judge beforehand the length of the patient's stay. The only exclusion criterion was lack of informed consent. The PICU has 6 two-bed rooms and 2 single-bed rooms. The PIMCU has 1 four-bed rooms, 5 three-bed rooms, and 2 single-bed rooms.

Intervention

Half of the rooms (n = 8) were furnished with copper-surfaced items, and the other half remained unchanged. Intervened rooms were located in the space in an alternate fashion.[10] The selected items surfaced with copper were bed rails, bed rail levers, intravenous poles, sink handles, and the nurses' workstation. Handwashing procedures and cleaning routines remained the same before and throughout the study period. The hand hygiene compliance rate of health care workers was assessed by staff not affiliated with the trial and was reported quarterly as a measure of health care worker adherence to the established protocol for hand hygiene before and after patient contact. For the period of the trial, the mean compliance rate for the health care workers observed in the units (N = 153), expressed as the percentage of individuals that complied entirely with the hospital standards for intensive care unit wards, was 93% (range, 80%-100%).

Assignment to experimental arm

On admission, to each unit, patients were sequentially assigned to either an intervened or control room. Swapping patients from one unit to the other was discouraged but was allowed for compelling medical reasons; however, the protocol stated that patients should move to the same type of room (intervened or control) as originally assigned.

Ethics and regulatory requirements

Written informed consent was obtained from each parent or legal guardian within 24 hours of admission. This study was conducted in accordance with the Helsinki Declaration, the International Conference on Harmonization Guidance for Good Clinical Practice, and applicable national regulations. The study protocols and informed consent form were approved by the research ethics committee overseeing clinical research at the local site.

Measurements

Demographic and clinical data were collected at entry for all eligible patients. Thereafter, clinical data regarding installation and removal of invasive catheters (central venous catheters, indwelling urinary catheters, and tracheal intubation for mechanical ventilation), instauration of antimicrobial therapy, room location, and HAI suspicion status were collected on a daily basis until patient discharge from the unit. An inventory log was designed to keep track of the presence or removal of items with and without copper surfaces from their original assigned room.

Bacterial burden was measured on selected surfaces (bed rails, cribs, and faucet handles) from both groups on a bimonthly basis during study duration. Detailed results of this aim of the study are reported elsewhere.[11]