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Antimicrobial Catheter Cap Cuts Bloodstream Infections in Dialysis Patients

— Trial compared use of two catheter caps at hemodialysis facilities

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ORLANDO -- For hemodialysis patients, use of an antimicrobial catheter end cap outperformed a competing cap for infection risk-reduction, according to a manufacturer-sponsored study reported here.

Steven Brunelli, MD, of DaVita Clinical Research in Minneapolis, said use of the ClearGuard HD Antimicrobial Barrier Cap was associated with a 65% lower catheter-related bloodstream infection rate (CRBSI) compared to the Tego Connector with Curoc Disinfecting Cap, with rates of 0.29 versus 1.12 per 1,000 days of central venous catheter (CVC) placement ($P= 0.03$) and an incidence rate ratio of 0.35 (95% CI 0.14-0.90).

In a sensitivity analysis conducted in a subgroup of patients who began dialysis with a new central venous catheter, use of the ClearGuard cap was associated with a markedly lower rate of infection compared to the control (IRR 0.26; 95% CI 0.08-0.85).

The study was presented as a late-breaking abstract at the [National Kidney Foundation's 2017 Spring Clinical Meeting](#).

Said Brunelli, "The vast majority of bloodstream infections in catheter patients are due to intra-luminal spread, meaning that at the time the catheter is exposed to the environment, there's some sort of touch contamination, bacteria sets up shop, proliferates, migrates down the catheter, creates a biofilm, eventually extending into the

lower rate of bloodstream infection," he said. "Those results are consistent with recently reported results in another population, and together those data represent an opportunity for improving outcomes in our hemodialysis who continued to dialyze through CVCs."

Involving 1,428 dialysis patients, the randomized, prospective trial compared Pursuit Vascular's ClearGuard HD cap, which contains threads in the internal roof of the cap that are impregnated with antibacterial agent chlorhexidine. During the thirteen-month trial, this technology was compared to a control group, which included ICU Medical's Tego connector -- a needle-free, closed system to prevent infection, paired with 3M's Curoc disinfecting cap for Tego. The forty participating DaVita dialysis facilities received training in use of both technologies. Brunelli noted written consent was not required for this trial since both devices are FDA-approved. Pursuit Vascular funded the trial.

The primary endpoint of the trial was CRBSI rate, with infection defined as one episode of a positive blood culture. Exclusion criteria included a known allergy or sensitivity to chlorhexidine or heparin, although few exclusions were made.

Because the trial included patients whose catheters were already in place, the at-risk study period began on day 21 after initial intervention, invoking a 21-day attribution rule linked to the average time between initial touch-contamination and the development of bloodstream infection.

No device-related adverse events were reported during the course of the trial. In a clinician survey administered following the conclusion of the study, all participating centers using the ClearGuard technology gave favorable reviews to the device, citing high ease of use, concise directions, overall positive experience, and intention for continued use.

During a Q&A session, a member of the audience inquired whether there were any seasonal variations impacting the outcomes. Brunelli said his research group has not looked at those data on it yet, but agreed that there "typically is a seasonality to bloodstream infection." He added, though, that due to the year-long duration of the study, seasonality should not have a confounding effect on the results, but the dataset may be "fodder for many investigations yet to come."

Brunelli disclosed a relationship with DaVita Clinical Research. The study was funded by Pursuit Vascular, Inc.

Primary Source

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Source Reference: [Brunelli S, et al "Cluster-randomized trial of device to prevent catheter-related bloodstream infection in hemodialysis](#)