Cluster-Randomized Trial of Device to Prevent Catheter-Related Bloodstream Infection in Hemodialysis Patients

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Introduction

• Central venous catheters (CVC) contribute disproportionately to bloodstream infection (BSI) and, by extension, to infection-related hospitalization, mortality and morbidity in dialysis patients.
• Recent studies report that novel devices may reduce the rate of catheter-related BSI.1,2,3
  – ClearGuard® HD Antimicrobial Barrier Cap (Pursuit Vascular)
  – Tego® Connector (ICU Medical)
  – Curos™ Disinfecting Cap for Tego (3M)
• A sufficiently powered study to comparatively evaluate these devices in a hemodialysis setting is needed for evidenced-based patient care decisions.

Objective

The aim of this study was to investigate in a real-world dialysis facility setting whether use of ClearGuard HD caps (treatment) is associated with improvements in rates of BSI when compared with facilities using Tego connectors plus Curos caps (control).

Methods

• 13-month prospective, multi-center, cluster-randomized, comparative effectiveness trial
• 40 DaVita dialysis facilities located throughout the United States were pair-matched by a) pre-study BSI rate, b) number of CVC patients and c) geographic location, and then randomized 1:1 to either begin using ClearGuard HD caps (treatment) or continue using Tego connectors, with introduction of Curos caps (control).
• All hemodialysis patients with a tunneled-CVC within each facility participated in the study unless they had a known allergy to chlorhexidine or heparin.
• The study endpoint was a comparison of the overall BSI rate (calculated as the number of episodes of positive blood cultures (PBCs) episodes divided by CVC-days) between treatment versus control facilities.
• Baseline PBC rates were similar (P = 0.9) during the 3-month period immediately prior to study start.

Results

• 1,671 patients (826 in treatment group and 845 in control group) accumulated more than 180,000 CVC-days over the 13-month follow-up period.
• At enrollment, mean age was 62.9 years; 49.1% patients were male; 40.7%, 40.8% and 11.6% were white, black and Hispanic, respectively; mean time on dialysis was 2.2 years.
• Recent studies report that novel devices may reduce the rate of catheter-related BSI.
  – Curos™ Disinfecting Cap for Tego (3M)
  – Tego® Connector (ICU Medical)
  – ClearGuard® HD Antimicrobial Barrier Cap (Pursuit Vascular)
• During the 13-month follow-up period, use of ClearGuard HD caps was associated with a 64% lower overall PBC rate when compared to facilities using Tego connectors plus Curos caps (0.26 vs 0.54/1000 CVC-days, respectively; P < 0.001).
• In a de novo subgroup (defined as patients who entered the study with a new CVC), use of ClearGuard HD caps was associated with a 72% overall lower PBC rate when compared to facilities using Tego connectors plus Curos caps (0.20 vs 0.50/1000 CVC-days, respectively; P < 0.001).
• No device related adverse events were reported.

Conclusions

• These study results are representative of real-world clinical practice in dialysis facilities located in the United States.
• The findings demonstrate the ClearGuard HD cap is superior to Tego Connector plus Curos cap at reducing bloodstream infections in hemodialysis patients using CVCs.
• These findings represent an important breakthrough for improving outcomes in the ESRD population requiring a CVC.

References

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