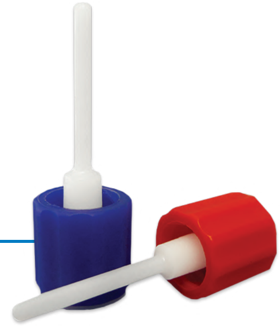
ClearGuard™ HD

Συσκευή Αντιμικροβιακού φραγμού



Dialysis Catheter-Related Bloodstream Infections: A Cluster-Randomized Trial of the ClearGuard HD Antimicrobial Barrier Cap

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AJKD
Original Investigation

Dialysis Catheter–Related Bloodstream Infections: A Cluster-Randomized Trial of the ClearGuard HD Antimicrobial Barrier Cap

Jeffrey L. Hymes, MD,[1] Ann Mooney, MSN, RN, CNN,[2] Carly Van Zandt, MS,[2] Laurie Lynch, PhD,[3] Robert Ziebol, BS,[3] and Douglas Killion, MBA[3]

Background: The rate of bloodstream infections (BSIs) is disproportionately high in hemodialysis (HD) patients with central venous catheters (CVCs) versus those with permanent accesses, contributing to poorer outcomes, such as increased rates of death and hospitalizations.

Study Design: 12-month, prospective, cluster-randomized, multicenter, open-label trial.

Setting & Participants: 40 Fresenius Medical Care North America dialysis facilities were matched and paired by positive blood culture rate and number of patients with CVCs and then cluster-randomized with 20 in each study group. 2,470 patients participated in the study (1,245, intervention group; 1,225, control group), accruing approximately 350,000 CVC-days.

Intervention: Use of ClearGuard HD Antimicrobial Barrier Caps versus use of standard CVC caps; assigned at the facility level.

Outcome: Primary end point was positive blood culture rate as an indicator of BSI rate.

Measurements: Positive blood cultures, hospital admissions for BSI, hospitalization-days for BSI, intravenous antibiotic starts, and CVC-days.

Results: Baseline positive blood culture rates were similar ($P = 0.8$) between groups. Use of ClearGuard HD caps for 12 months was associated with a 56% lower BSI rate versus use of standard CVC caps (0.26 vs 0.59/1,000 CVC-days, respectively; $P = 0.01$). When considering sustained use (defined as last 6 months of the study), the intervention versus the control was associated with a 69% lower BSI rate (0.22 vs 0.72/1,000 CVC-days, respectively; $P = 0.01$), 43% fewer hospital admissions for BSI (0.28 vs 0.48/1,000 CVC-days, respectively; $P = 0.04$), and 51% fewer hospitalization days for BSI (2.42 vs 4.94/1,000 CVC-days, respectively; $P = 0.04$). No device-related adverse events were reported.

Limitations: Study was open label; patients occasionally received HD at nonresearch facilities; patients did not receive the intervention when hospitalized.

Conclusions: The findings show that use of ClearGuard HD Antimicrobial Barrier Caps, when compared with standard CVC caps, significantly lowers rates of catheter-related BSIs and hospital admissions for BSI in HD patients using CVCs.

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INDEX WORDS: Hemodialysis; central venous catheter (CVC); chlorhexidine acetate; bloodstream infection (BSI); positive blood culture; infection prevention; end-stage renal disease (ESRD); ClearGuard HD antimicrobial barrier cap; antimicrobial lock; catheter-related bloodstream infection (CRBSI); central line–associated bloodstream infection (CLABSI); cluster-randomized trial.

Significant efforts have been made over the past 25 years to reduce the number of bloodstream infections (BSIs) that are caused by use of hemodialysis (HD) central venous catheters (CVCs) in patients with end-stage renal disease. These efforts include the Centers for Medicare & Medicaid Services Fistula First initiative,[1] Centers for Disease Control and Prevention (CDC) guidelines including Scrub-the-Hub protocol,[2] education and training of health care personnel,[3] and using antimicrobial locks.[3-8] Despite these efforts, the use of CVCs for HD continues to be a leading contributor to higher rates of BSI, hospitalization, morbidity, and mortality, as well as increased health care costs.[9,10]

From [1]Fresenius Medical Care North America; [2]Frenova Renal Research, Waltham, MA; and [3]Pursuit Vascular, Inc, Maple Grove, MN.

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Trial registration: www.ClinicalTrials.gov; study number: NCT02604264.

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220 Am J Kidney Dis. 2017;69(2):220-227

ClearGuard™ HD Caps έναντι Απλά πώματα

Hymes, JL et al. Dialysis catheter-related bloodstream infections: A cluster-randomized trial of the ClearGuard HD antimicrobial barrier cap. Am J Kidney Dis. 2017; 69(2):220-227.

ΑΠΟΤΕΛΕΣΜΑΤΑ:

Η χρήση του **ClearGuard™ HD** έναντι της χρήσης των κοινών πωμάτων σχετίστηκε με χαμηλότερα ποσοστά BSI κατά:

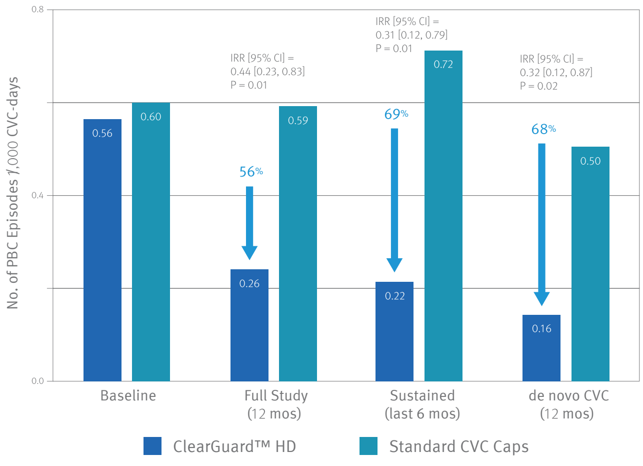
- **56%** σύνολο περιόδου **(P=0.01)**
- **68%** σε de novo καθετήρες **(P=0.02)**
- **69%** κατά την εδραιωμένη χρήση **(P=0.01)**

ΤΑΥΤΟΤΗΤΑ ΜΕΛΕΤΗΣ

12-μηνη προοπτική, τυχαιοποιημένη πολυκεντρική, ανοικτή, συγκριτική δοκιμή αποτελεσματικότητας σε αιμοκαθαιρόμενους ασθενείς με Κεντρικούς Καθετήρες

- **2.470 ασθενείς**
  - 1.245 Ομάδα ClearGuard™ HD
  - 1.225 Ομάδα αναφοράς
- Σύνολο **350.000 ημέρες** CVC
- **40 κέντρα** Αιμοκάθαρσης στις ΗΠΑ

Βασικό τελικό σημείο: η συχνότητα θετικών καλλιεργειών (PBC) ως δείκτης συχνότητας βακτηριαιμιών (BSI)



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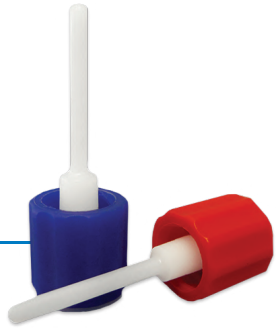
ClearGuard™ HD

Συσκευή Αντιμικροβιακού φραγμού

Cluster-Randomized Trial of Devices to Prevent Catheter-Related Bloodstream Infections



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CLINICAL RESEARCH www.jasn.org

Cluster-Randomized Trial of Devices to Prevent Catheter-Related Bloodstream Infection

Steven M. Brunelli,[1] David B. Van Wyck,[2] Levi Njord,[2] Robert J. Ziebol,[3] Laurie E. Lynch,[3] and Douglas P. Killion[3]

[1]DaVita Clinical Research, Minneapolis, Minnesota; [2]DaVita, Inc., Denver, Colorado; and [3]Pursuit Vascular, Inc., Maple Grove, Minnesota

ABSTRACT

Central venous catheters (CVCs) contribute disproportionately to bloodstream infection (BSI) and, by extension, to infection-related hospitalization, mortality, and health care costs in patients undergoing dialysis. Recent product advancements may reduce BSIs, but a sufficiently powered comparative-effectiveness study is needed to facilitate evidence-based patient care decisions. In a 13-month, prospective, cluster-randomized, open-label trial, we compared BSI rates in facilities using ClearGuard HD antimicrobial barrier caps (ClearGuard group) with those in facilities using Tego hemodialysis connectors plus Curos disinfecting caps (Tego+Curos group). Forty DaVita dialysis facilities in the United States were pair-matched by BSI rate, number of patients using CVCs, and geographic location, and then cluster randomized 1:1. We enrolled all adult patients undergoing dialysis with CVCs at these facilities, except those allergic to heparin or chlorhexidine. Overall, 1671 patients participated in the study, accruing >183,000 CVC-days. The study outcome was positive blood culture (PBC) rate as an indicator of BSI rate. We calculated results at the cluster level and adjusted for the facility cluster effect. During a 3-month run-in period immediately before study interventions, the groups had similar BSI rates ($P=0.8$). During the 13-month intervention period that immediately followed, the ClearGuard group had a BSI rate significantly lower than that of the Tego+Curos group (0.28 versus 0.75 PBCs per 1000 CVC-days, respectively; $P<0.001$). No device-related adverse events were reported. In conclusion, compared with Tego connectors plus Curos caps, ClearGuard HD antimicrobial barrier caps significantly lowered the rate of catheter-related BSIs in patients undergoing hemodialysis using CVCs, representing an important advancement in hemodialysis patient care.

J Am Soc Nephrol 29: 1336–1343, 2018. doi: https://doi.org/10.1681/ASN.2017080870

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Significance Statement

Catheter-related bloodstream infections are a common complication related to hemodialysis central venous catheter (CVC) use and they contribute to increased infection-related hospitalization, mortality, and health care costs. Devices are currently available that are designed to reduce these infections, but published comparative effectiveness data are needed to allow evidence-based patient care decisions. This manuscript describes a large, multicenter, randomized clinical trial comparing BSI rates in facilities using ClearGuard HD Antimicrobial Barrier Caps, when compared with Tego connectors plus Curos caps, results in a significantly lower rate of catheter-related BSIs in patients undergoing hemodialysis using CVCs. This represents an important advancement in hemodialysis patient care for patients dialyzing with CVCs.

1336 ISSN : 1046-6673/2908-1336 J Am Soc Nephrol 29: 1336–1343, 2018

ClearGuard™ HD έναντι Tego™+Curos™

Brunelli, SM et al. Cluster-randomized trial of devices to prevent catheter-related bloodstream infection. J Am Soc Nephrol 2018 Apr; 29(4):1336-1343.

ΑΠΟΤΕΛΕΣΜΑΤΑ

Η χρήση του **ClearGuard™ HD** έναντι της Ομάδας αναφοράς (Tego+Curos) σχετίστηκε με μικρότερη συχνότητα BSI κατά

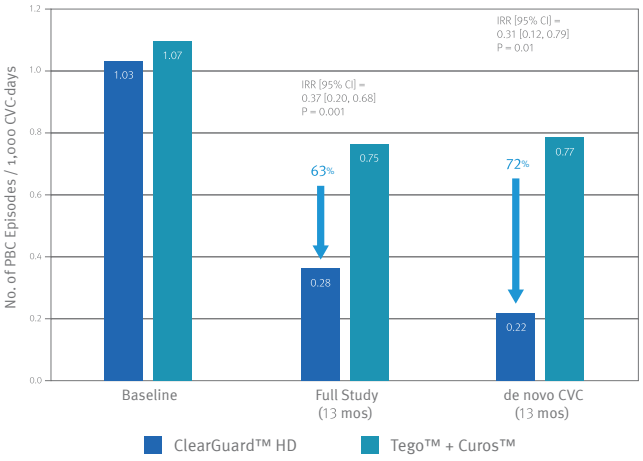
- **63%** σύνολο περιόδου **(P=0.001)**
- **72%** σε de novo καθετήρες **(P<0.001)**

ΤΑΥΤΟΤΗΤΑ ΜΕΛΕΤΗΣ

13-μήνη προοπτική, ομαδοποιημένη, τυχαιοποιημένη πολυκεντρική ανοικτή δοκιμή

- **1.671 ασθενείς**
  - 826 Ομάδα ClearGuard™ HD
  - 845 Ομάδα αναφοράς
- Σύνολο **183.000 ημέρες** CVC
- **40 κέντρα** Αιμοκάθαρσης στις ΗΠΑ

Βασικό τελικό σημείο: η συχνότητα (PBC) ως δείκτης συχνότητας (BSI)



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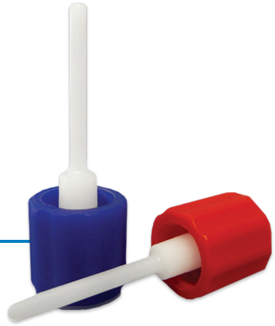
ClearGuard™ HD

Συσκευή Αντιμικροβιακού φραγμού



Evaluating a Novel Hemodialysis Central Venous Catheter Cap in Reducing Bloodstream Infections: A Quality Improvement Initiative

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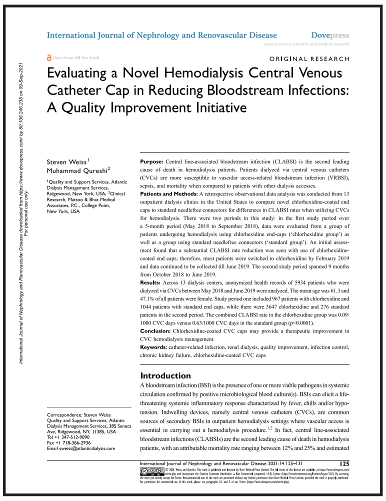

International Journal of Nephrology and Renovascular Disease — Dovepress

ORIGINAL RESEARCH

Evaluating a Novel Hemodialysis Central Venous Catheter Cap in Reducing Bloodstream Infections: A Quality Improvement Initiative

Steven Weiss[1]
Muhammad Qureshi[2]

Introduction

ClearGuard™ HD έναντι Απλά πώματα

Weiss S., Qureshi M Evaluating a Novel Hemodialysis Central VenousCatheter Cap in Reducing Bloodstream Infections:A Quality Improvement Initiative., Intl J Nephrol Renovascular Dis, 2021:14 125–131

ΑΠΟΤΕΛΕΣΜΑΤΑ

Η συνδυασμένη συχνότητα CLABSI στην ομάδα **ClearGuard™ HD** ήταν **0.09/1000** ημέρες καθετήρα έναντι **0.63/1000** ημέρες καθετήρα στην ομάδα ελέγχου **(P<0.0001)**.

ΣΥΜΠΕΡΑΣΜΑ: *'Τα πώματα **Κεντρικού φλεβικού καθετήρα με επικάλυψη Χλωρεξιδίνης** ενέχεται να παρέχουν μια **θεραπευτική βελτίωση** στην διαχείριση του **κεντρικού καθετήρα αιμοκάθαρσης**.'*

ΤΑΥΤΟΤΗΤΑ ΜΕΛΕΤΗΣ

14-μήνες (περίοδος Α: 9μήνες, περίοδος Β: 5μήνες) αναδρομική, πολυκεντρική μελέτη παρατήρησης

- **5.934 ασθενείς**
  - 4.614 Ομάδα ClearGuard™ HD
  - 1.320 Ομάδα απλά πώματα
- Σύνολο **238.260 ημέρες** Κεντρικού Καθετήρα
- **13 κέντρα** στις ΗΠΑ

Table 1 Comparison of CLABSI Rates by Study Group

Study Group	Patients (N)	CVC Days	CLABSI	CLABSI/1000 CVC Days	*p*-value
First Study Period					
Chlorhexidine	967	29,010	1	0.03	<0.0001
Standard Therapy	1044	31,320	22	0.70	
First + Second Study Periods					
Chlorhexidine	4614	138,420	13	0.09	<0.0001
Standard Therapy	1320	39,600	25	0.63	

Abbreviations: CLABSI, central line-associated bloodstream infection; CVC, central venous catheter.

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