

Taurolidine-citrate-heparin lock reduces catheter-related bloodstream infections in intestinal failure patients dependent on home parenteral support: a randomized, placebo-controlled trial

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ABSTRACT

Background: In patients with intestinal failure who are receiving home parenteral support (HPS), catheter-related bloodstream infections (CRBSIs) inflict health impairment and high costs.

Objective: This study investigates the efficacy and safety of the antimicrobial catheter lock solution, taurolidine-citrate-heparin, compared with heparin 100 IE/mL on CRBSI occurrence.

Design: Forty-one high-risk patients receiving HPS followed in a tertiary HPS unit were randomly assigned in a double-blinded, placebo-controlled trial. External, stratified randomization was performed according to age, sex, and prior CRBSI incidence. The prior CRBSI incidence in the study population was 2.4 episodes/1000 central venous catheter (CVC) days [95% Poisson confidence limits (CLs): 2.12, 2.71 episodes/1000 CVC days]. The maximum treatment period was 2 y or until occurrence of a CRBSI or right-censoring because of CVC removal. The exact permutation tests were used to calculate *P* values for the log-rank tests.

Results: Twenty patients received the taurolidine-citrate-heparin lock and 21 received the heparin lock, with 9622 and 6956 treatment days, respectively. In the taurolidine-citrate-heparin arm, no CRBSIs occurred, whereas 7 CRBSIs occurred in the heparin arm, with an incidence of 1.0/1000 CVC days (95% Poisson CLs: 0.4, 2.07/1000 CVC days; *P* = 0.005). The CVC removal rates were 0.52/1000 CVC days (95% Poisson CLs: 0.17, 1.21/1000 CVC days) and 1.72/1000 CVC days (95% Poisson CLs: 0.89, 3.0/1000 CVC days) in the taurolidine-citrate-heparin and heparin arm, respectively, tending to prolong CVC survival in the taurolidine arm (*P* = 0.06). Costs per treatment year were lower in the taurolidine arm (€2348) than in the heparin arm (€6744) owing to fewer admission days related to treating CVC-related complications (*P* = 0.02).

Conclusions: In patients with intestinal failure who are life dependent on HPS, the taurolidine-citrate-heparin catheter lock demonstrates a clinically substantial and cost-beneficial reduction of CRBSI occurrence in a high-risk population compared with heparin. This trial was registered at clinicaltrials.gov as NCT01948245. *Am J Clin Nutr* doi: <https://doi.org/10.3945/ajcn.117.158964>.

Keywords: antimicrobial catheter lock, bacteremia, catheter infections, catheter-related bloodstream infections, central venous catheter, home parenteral support, intestinal failure, parenteral nutrition, taurolidine

INTRODUCTION

In the United States, approximately 100,000 patients receive home parenteral support (HPS) each year. HPS is a life-long therapy for patients with intestinal failure, and it is associated with a high risk of catheter-related bloodstream infections (CRBSIs). CRBSIs are a major cause of morbidity and mortality in HPS patients, and they are associated with high costs. The use of antimicrobial catheter lock solutions (CLS) to reduce the risk of CRBSIs is a promising strategy. The aim of this study was to evaluate the efficacy and safety of the taurolidine-citrate-heparin CLS compared with heparin 100 IE/mL in high-risk HPS patients.

Patients receiving HPS are at a high risk of CRBSIs because of the long duration of catheter use, the need for frequent catheter manipulations, and the use of home care. The use of CLS has been shown to reduce the risk of CRBSIs in various studies. The taurolidine-citrate-heparin CLS is a novel antimicrobial CLS that has been shown to be effective in reducing the risk of CRBSIs in HPS patients.

The aim of this study was to evaluate the efficacy and safety of the taurolidine-citrate-heparin CLS compared with heparin 100 IE/mL in high-risk HPS patients. The primary endpoint was the occurrence of CRBSIs. Secondary endpoints included CVC removal rates, costs, and quality of life.

This study was a randomized, double-blinded, placebo-controlled trial. Patients were randomly assigned to receive either the taurolidine-citrate-heparin CLS or heparin 100 IE/mL. The trial was conducted in a tertiary HPS unit. The results of the trial are presented in this abstract.

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