

Title

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Tenecteplase for Improvement of Hemodialysis Catheter Function: TROPICS 3

Author(s)

J. Tumlin, J. Goldman, D. Spiegel, D. Roer, K. Ntoso, M. Blaney, J. Jacobs, B. Gillespie, S. Begelman, USA

Journal

Clin J Am Soc Nephrol 2010; 5: 631-636

Introduction

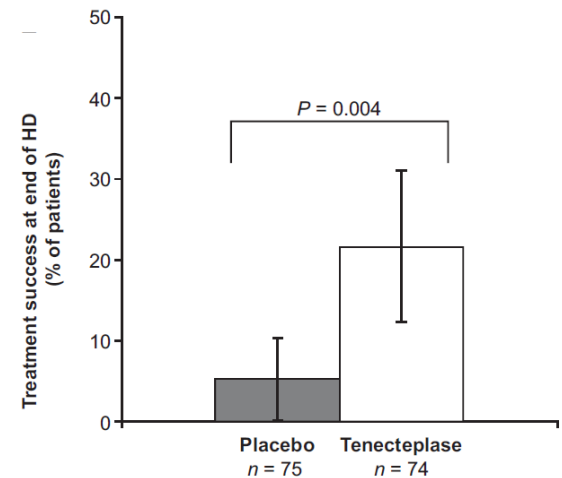
Despite widespread use of tunneled HD catheters, their utility is limited by the development of thrombotic complications. This study investigated whether the thrombolytic agent tenecteplase can restore blood flow rates (BFRs) in dysfunctional HD catheters.

Material and Methods

In this randomized, double-blind study, patients with dysfunctional tunneled HD catheters, defined as a BFR <300 ml/min at 250 mmHg pressure in the arterial line, received 1-hour intracatheter dwell with tenecteplase (2 mg) or placebo. The primary endpoint was the percentage of patients with BFR ≥ 300 ml/min and an increase of ≥ 25 ml/min above baseline 30 minutes before and at the end of HD.

Results and Conclusions

- 74 patients were treated with tenecteplase, 75 with placebo.
- **The figure shows that after a 1-hour dwell, 22% of patients in the tenecteplase group had functional catheters compared with 5% in the placebo group (P= 0.004).**
- At the end of dialysis, mean change in BFR was 47 ml/min in the tenecteplase group and 12 ml/min in the placebo group (P= 0.008).
- Four catheter-related bloodstream infections (one tenecteplase, three placebo) and one thrombosis (tenecteplase) were observed.
- There were no reports of intracranial hemorrhage, major bleeding, embolic events, or catheter-related complications.



Tenecteplase improved HD catheter function and had a favorable safety profile compared with placebo.