Vascular Access Outcomes Reported in Maintenance Hemodialysis Trials: A Systematic Review

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Background: Many randomized controlled trials have been performed with the goal of improving outcomes related to hemodialysis vascular access. If the reported outcomes are relevant and measured consistently to allow comparison of interventions across trials, such trials can inform decision making. This study aimed to assess the scope and consistency of vascular access outcomes reported in contemporary hemodialysis trials.

Study Design: Systematic review.

Setting & Population: Adults requiring maintenance hemodialysis.

Selection Criteria: All randomized controlled trials and trial protocols reporting vascular access outcomes identified from ClinicalTrials.gov, Embase, MEDLINE, and the Cochrane Kidney and Transplant Specialized Register from January 2011 to June 2016.

Interventions: Any hemodialysis-related intervention.

Outcomes: The frequency and characteristics of vascular access outcome measures were analyzed and classified.

Results: From 168 relevant trials, 1,426 access-related outcome measures were extracted and classified into 23 different outcomes. The 3 most common outcomes were function (136 [81%] trials), infection (63 [38%]), and maturation (31 [18%]). Function was measured in 489 different ways, but most frequently reported as "mean access blood flow (mL/min)" (37 [27%] trials) and "number of thromboses" (30 [22%]). Infection was assessed in 136 different ways, with "number of access-related infections" being the most common measure. Maturation was assessed in 44 different ways at 15 different time points and most commonly characterized by vein diameter and blood flow. Patient-reported outcomes, including pain (19 [11%]) and quality of life (5 [3%]), were reported infrequently. Only a minority of trials used previously standardized outcome definitions.

Limitations: Restricted sampling frame for feasibility and focus on contemporary trials.

Conclusions: The reporting of access outcomes in hemodialysis trials is very heterogeneous, with limited patient-reported outcomes and infrequent use of standardized outcome measures. Efforts to standardize outcome reporting for vascular access are critical to optimizing the comparability, reliability, and value of trial evidence to improve outcomes for patients requiring hemodialysis.

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A reliably functioning vascular access is associated with improved health outcomes and overall well-being of patients treated by maintenance hemodialysis, but establishing and maintaining such a vascular access without major complications and the need for recurrent interventions remains challenging.[1-3] Vascular access–related complications account for ~20% of hospital admissions of patients with end-stage kidney disease annually and are associated with increased morbidity, mortality, and health care costs.[4,5] As such, vascular access is often referred to as both the "lifeline" and "Achilles' heel" of hemodialysis.[6] From a patient's perspective, the experience and anticipation of vascular access surgery and complications, particularly pain during cannulation, bleeding, and access failure, are key sources of stress and anxiety.[7,8] Improving vascular access outcomes is a high priority for patients, their caregivers, and health professionals.[9,10]

During the last 2 decades, numerous interventions have been trialed in an attempt to improve vascular access outcomes, with little success.[11-13] This is in the context of increasing recognition across many health conditions that outcomes used in clinical trials are measured inconsistently and may not be relevant to end-users, including patients, caregivers, and health professionals.[2,7,8,14,15] In addition, reporting bias due to selective publication of outcomes with favorable results makes interpretation and comparison of research output unreliable.[16,17] The lack of consensus on outcome selection (ie, what to measure, such as "infection" or "pain") and outcome measures (ie, how and when to measure the outcome, such as "number of access interventions within 12 months of access creation") has been identified as an additional source of research waste.[18-21] The comparability, value, and reliability of trial evidence are compromised by the selection of outcomes with limited clinical or policy relevance, under-reporting of patient-centered outcomes, and inconsistent use of outcome measures. There have been efforts to standardize outcome definitions for vascular access by various working

groups, with the most recent publication released in 2011.[22-25] However, these may not have been widely adopted.

This study aimed to describe the scope and consistency of vascular access outcomes and outcome measures used in contemporary hemodialysis trials and assess the use of previously published standardized outcome definitions. A secondary longer-term aim is to underpin strategies to prioritize outcomes, improve outcome reporting for vascular access complications, increase the value of future trials to inform evidence-based practice, and ultimately, help improve patient outcomes.

Methods

Selection Criteria

An electronic search using Embase, the Cochrane Kidney and Transplant Specialized Register, and MEDLINE databases without language restriction was conducted using search strategies developed in collaboration with a specialist information manager to identify trials reporting on vascular access outcomes in adult (aged ≥ 18 years) patients requiring maintenance hemodialysis (Table S1). Trials in patients with acute kidney injury undergoing temporary hemodialysis were excluded. All randomized controlled trials including protocols and post hoc analyses of randomized controlled trials published between January 1, 2011, and June 16, 2016, were included. This time frame was chosen to provide an assessment of contemporary outcome measures of recently published and ongoing trials allowing for implementation of previously published standardized outcome measures.[22-25] Systematic reviews and meta-analyses were screened to identify additional randomized controlled trials published within the same time frame. In addition, the ClinicalTrials.gov registry was searched for unpublished protocols of randomized controlled trials using the same inclusion criteria to ensure that current and ongoing trials were included. Trials of registered protocols that had completed recruitment before January 2011; terminated recruitment due to poor enrollment; been withdrawn, suspended, or published; or not yet started recruitment were excluded. Research ethics committee approval was not required for this study.

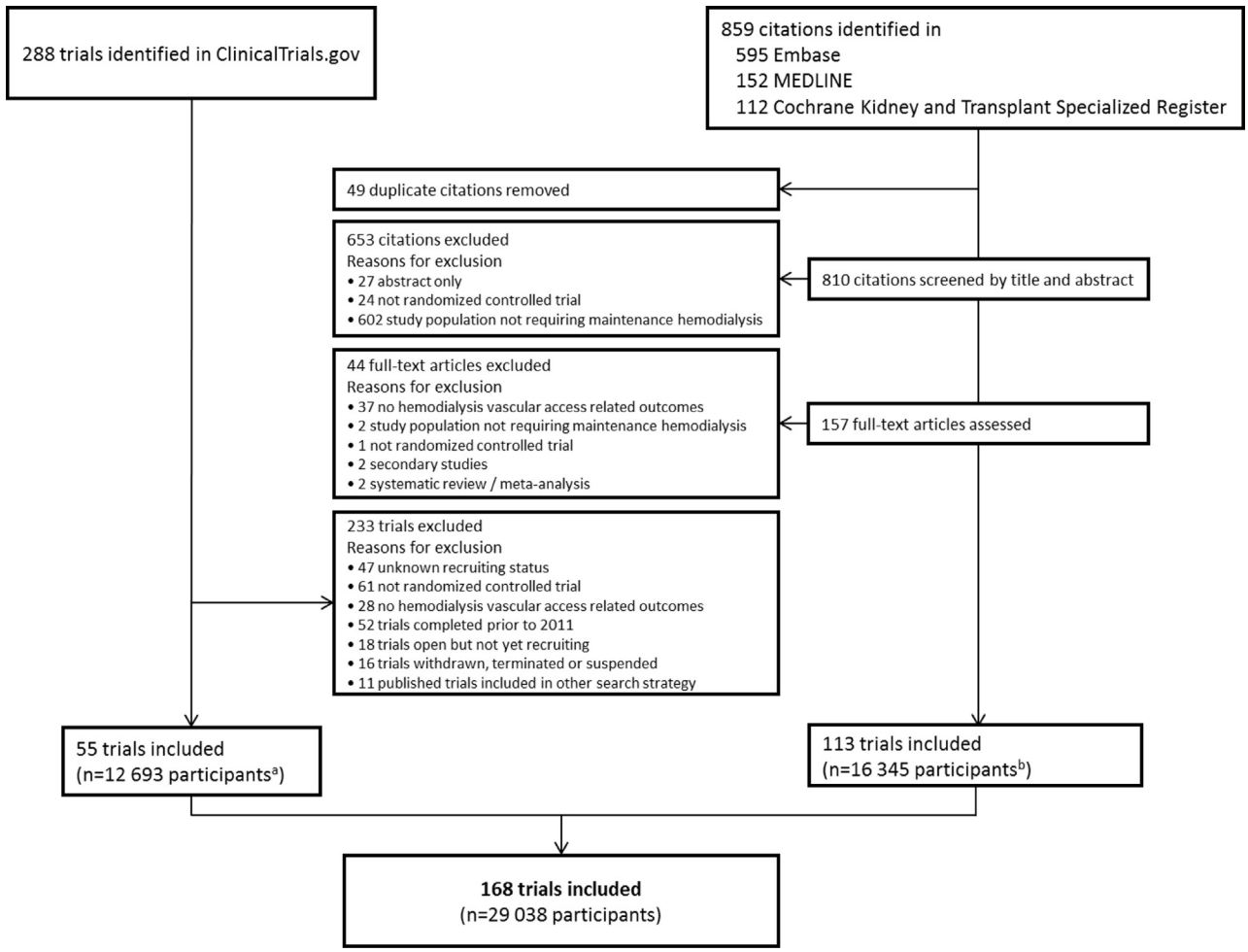

Figure 1. Search results. [a]Estimated number of enrollment. [b]Sample size unknown in 4 trials.