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REVIEW

Stroke/Death Rates Following Carotid Artery Stenting and Carotid Endarterectomy in Contemporary Administrative Dataset Registries: A Systematic Review

K.I. Paraskevas [a,*], **E.L. Kalmykov** [b], **A.R. Naylor** [b]

[a] St. George's Vascular Institute, St. George's Healthcare NHS Trust, London, UK
[b] Department of Vascular Surgery, Vascular Research Group, Division of Cardiovascular Sciences, Clinical Sciences Building, Leicester Royal Infirmary, Leicester, UK

WHAT THIS PAPER ADDS

Most contemporary administrative datasets report that CAS was associated with significantly higher stroke/death rates compared with CEA in "average risk for CEA" asymptomatic and symptomatic patients. Stroke/death rates after CAS were often higher than accepted threshold risks recommended by the American Heart Association/American Stroke Association guidelines. There was no evidence of a decline in procedural risks after CAS with time, especially in symptomatic patients.

Background: Randomised trials have reported higher stroke/death rates after carotid artery stenting (CAS) versus carotid endarterectomy (CEA). Despite this, the 2011 American Heart Association (AHA) guidelines expanded CAS indications, partly because of the Carotid Revascularization Endarterectomy versus Stenting Trial, but also because of improving outcomes in industry sponsored CAS Registries. The aim of this systematic review was: (i) to compare stroke/death rates after CAS/CEA in contemporary dataset registries, (ii) to examine whether published stroke/death rates after CAS fall within AHA thresholds, and, (iii) to see if there had been a decline (over time) in procedural risk after CAS/CEA.

Methods: PubMed/Medline, Embase, and Cochrane databases were systematically searched according to the recommendations of the PRISMA statement from January 1, 2008 until February 23, 2015 for administrative dataset registries reporting outcomes after both CEA and CAS.

Results: Twenty-one registries reported outcomes involving more than 1,500,000 procedures. Stroke/death after CAS was significantly higher than after CEA in 11/21 registries (52%) involving "average risk for CEA" asymptomatic patients and in 11/18 registries (61%) involving "average risk for CEA" symptomatic patients. In another five registries, CAS was associated with higher stroke/death rates than CEA for both symptomatic and asymptomatic patients, but formal statistical comparison was not reported. CAS was associated with stroke/death rates that exceeded risk thresholds recommended by the AHA in 9/21 registries (43%) involving "average risk for CEA" asymptomatic patients and in 13/18 registries (72%) involving "average risk for CEA" symptomatic patients. In 5/18 registries (28%), the procedural risk after CAS in "average risk" symptomatic patients exceeded 10%.

Conclusions: Data from contemporary administrative dataset registries suggest that stroke/death rates following CAS remain significantly higher than after CEA and often exceed accepted AHA thresholds. There was no evidence of a sustained decline in procedural risk after CAS.

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* Corresponding author. St. George's Vascular Institute, St. George's Healthcare NHS Trust, Blackshaw Road, London SW17 0QT, UK.
E-mail address: paraskevask@hotmail.com (K.I. Paraskevas).

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INTRODUCTION

Few topics have generated as much controversy as the management of carotid artery disease. Following publication of the 2011 American Heart Association/American

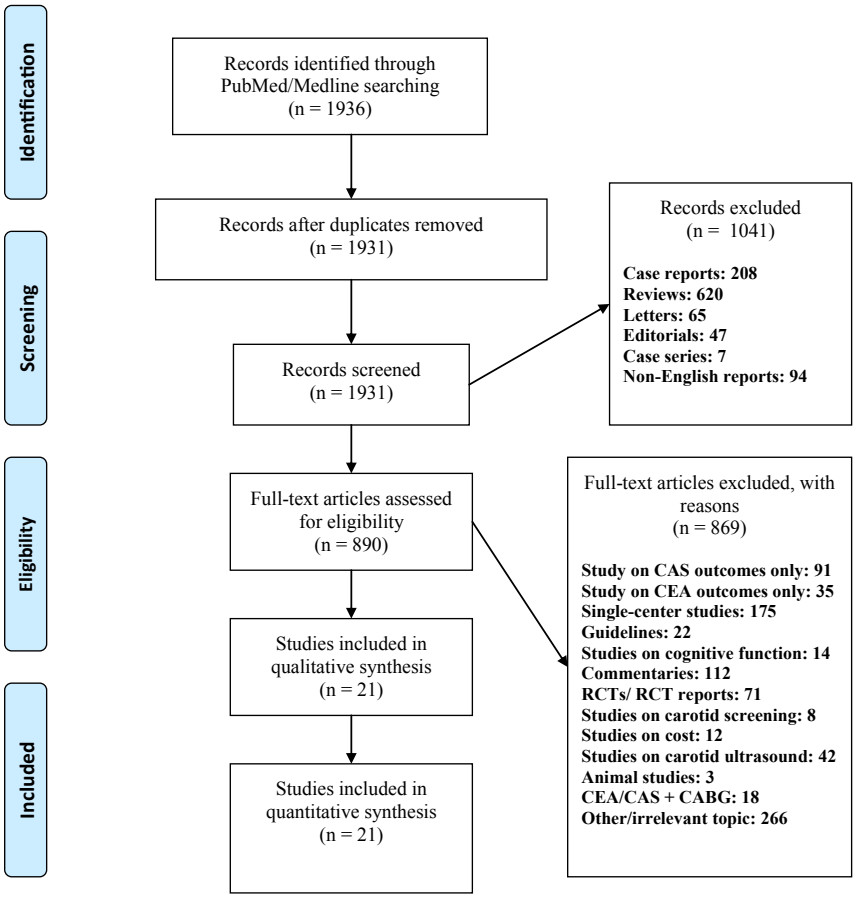

Figure 1. PRISMA Flow Diagram showing the number of studies that were screened, assessed for eligibility and included in/excluded from the systematic review (along with reasons for exclusion). From Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 2009;6(6):e1000097. http://dx.doi.org/10.1371/journal.pmed1000097.

Stroke Association (AHA/ASA) guidelines[1] (updated in 2014),[2] carotid artery stenting (CAS) was considered to be an alternative to carotid endarterectomy (CEA) in selected patients with symptomatic carotid artery stenosis in centres with documented peri-operative stroke/death rates <6% (Class IIa; Level of Evidence: A). The AHA/ASA also advised that CEA (Class IIa; Level of Evidence: A) and CAS (Class IIb; Level of Evidence: B) were appropriate in highly selected (average risk) patients with asymptomatic carotid stenosis, provided the risk of peri-operative stroke/death was <3%.[3]

The AHA/ASA decision to expand CAS indications into "average risk for CEA" patients was primarily based on findings from the North American Carotid Revascularization Endarterectomy versus Stenting Trial (CREST),[4] which showed that a primary composite endpoint of stroke, myocardial infarction, or death during the peri-procedural period and/or ipsilateral stroke within 4 years after randomisation, did not significantly differ among "average risk for CEA" symptomatic and asymptomatic patients undergoing CEA or CAS. In addition, there was evidence from a series of recently published industry-funded registries in "high risk for CEA" patients,[5,6] which suggested that procedural risks after CAS had reduced significantly (compared with older studies) and were now within the risk thresholds recommended by the AHA/ASA.[1–3] A closer inspection of the CREST[4] results, however, revealed that 30 day death/stroke rates in "average risk" symptomatic patients were significantly higher after CAS than CEA (6.0% vs. 3.2%; hazard ratio, 1.89 [95% CI 1.11–3.21]; $p = .02$).

Well designed and properly conducted randomised controlled trials (RCTs) provide Level I evidence for guiding practice. However, most patients undergoing carotid interventions are not randomised within the trials, the quality of reporting may not always be optimal and (most importantly) RCT outcomes may not always reflect practice in the "real world."[7–9]

To test the hypothesis that there had been a parallel improvement in procedural risk following CAS in the real world (as had been observed within the industry sponsored "high risk for CEA" registries), a systematic review was undertaken using outcome data in large, administrative dataset registries. The main aims were to (i) compare stroke/death rates after CAS/CEA in contemporary dataset registries, (ii) examine whether procedural stroke/death rates had fallen within AHA/ASA thresholds,[1–3] and (iii) determine whether there had been a decline (over time) in procedural risk after CEA/CAS.