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Invited Commentary

Commentary to 'Outcome After 7 Years of Carotid Artery Stenting and Endarterectomy in Sweden – Single Centre and National Results'

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Equipoise

'Equipoise' is a situation described as a "doubt as to which of two clinical interventions is more beneficial for the patient." In practice, equipoise mandates that patients may be assigned to different treatment options as long as there is a professional uncertainty about which treatment is superior.[1] For carotid revascularisation, uncertainty does not exist while numerous randomised trials have demonstrated the inferiority of carotid artery stenting (CAS) versus carotid endarterectomy (CEA) for stroke prevention in symptomatic patients, especially in patients older than 70 years. Although asymptomatic patients are still under trial, CAS in asymptomatic patients has been associated with approximately double the peri-procedural rate of death/stroke compared with CEA.

The American College of Surgeons stated that it is "essential that the value and safety of a new procedure is established before it is widely used on patients."[2] Nowadays, the introduction of new surgical devices is mostly driven by commercial enterprise, and most innovative surgical procedures enter practice without regulatory oversight.[1] The article by Lindstrom et al. in fact demonstrates the potential detrimental impact on patients when a new surgical procedure is widely introduced at a time of not knowing its safety and efficacy.[3] The authors compared the periprocedural outcome in a consecutive series of CAS and CEA from a single high-volume centre (SÖS) with data from low-volume centres derived from the Swedvasc national database. The authors conclude, "although not as safe as CEA, a single centre can achieve acceptable results with CAS."

The fact that a single hospital has acceptable outcomes with 208 CAS cases over a 7-year time frame does not convince us that CAS can be recommended as the first line of therapy. Moreover, besides not supporting the further application of CAS, this analysis far more indicates what can happen when CAS is applied outside the strict borders of randomised trials, considering the extraordinary result within Swedvasc of a 10.9% (11/101) stroke and death rate after CAS for asymptomatic patients.

The three key messages of this report are:

1. Observed, acceptable, single-centre results when applying CAS to a 'selected' group of patients deemed 'high risk'. However, approximately half of patients in both compared groups were asymptomatic. It should be clear that asymptomatic patients, by definition, can never be at high risk for stroke.
2. Reported and unacceptably high periprocedural death/stroke rate in asymptomatic patients related to CAS in Swedvasc. If this article should influence clinical practice, the death/stroke rate is astonishingly quite alarming and unacceptable for elective treatment of carotid stenosis in any patient by any revascularisation technique.
3. Observed large difficulties in comparing single-centre results with Swedvasc registry data. This may warrant a revision of the standardised data gathered in Swedvasc to make future comparisons more worthwhile and may be an important lesson for other countries planning to start national registries.

In the past, we have been shown that procedural risk may be much higher in 'routine clinical practice' than within the confines of a randomised trial. The present article confirms these observations and does not add to the safety qualification of CAS but far more should add to the discussion of what happens with broad implementation of a new technique, especially when applied to a subgroup of patients that should not receive any type of revascularisation in general. True, depending on certain but still ill-defined patient characteristics, one procedure might have an advantage over the other, leaving space for application of CAS in highly selected cases.[4] However, 15% of patients in SÖS were included for a non-specified reason, and the indications for selecting CAS nationally could not be provided at all!

The overall aim of an analysis, such as performed by Lindstrom et al., should be an internal vascular centre quality control measure, and every vascular centre should be encouraged to regularly do so. These measures should include an adequate feedback mechanism and ideally lead to an adjustment in revascularisation policy, where necessary, to support the ongoing attempt to make carotid revascularisation a safer process. Ethical acceptability mandates that the potential benefits of an intervention outweigh any inherent risk of harm. This cannot be the case with coverage for CAS to routine practice management of asymptomatic or low-risk patients.

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