In the era of large randomized control trials for carotid artery disease, do real-world data offer additional information?

Andreas M. Lazaris1, Konstantinos Moulakakis1, George Sfyroeras1, Vangelis Alexiou1, George Tsivgoulis2, George Geroulakos4

1Vascular Surgery Department, Attikon Teaching Hospital, National and Kapodistrian University of Athens, Athens, Greece
22nd Neurology Department, Attikon Teaching Hospital, National and Kapodistrian University of Athens, Athens, Greece

The study of Nana et al.1 presents real-world data regarding carotid endarterectomy (CEA) and carotid artery stenting (CAS) of a single center experience. According to the authors, CEA and CAS can have excellent short, medium and long-term results when performed in properly selected patients by an experienced surgical and anesthesiological team that follow a well-established standardized practice protocol. No significant difference exists between CEA and CAS as it concerns the 30-day stroke/death rate, either in the total cohort of patients (0.9% for CEA vs. 2% for CAS), or separately in symptomatic (1.6% for CEA vs. 4.4% for CAS) and asymptomatic patients (0% for CEA vs. 1.1% for CAS). Similarly, no differences are noticed in the long-term (15-year) follow-up, both in freedom from an ipsilateral stroke (100% in each group), or from any stroke (88.4 for CEA vs. 90% for CAS).

Following the 2011 American Heart Association / American Stroke Association (AHA/ASA) Guidelines, CAS was considered an alternative to CEA. This was based mainly on the results of CREST trial,1 and suggested that CEA or CAS can be performed in symptomatic and asymptomatic patients as long as the accepted rates of perioperative death/stroke are met (6% in symptomatic and 3% in asymptomatic ones). This was replicated in the 2017 ESVS guidelines.4 However, registries and audits from various vascular societies throughout the world representing real-world data, report worse death and stroke rates than in the randomized controlled trials (RCTs). In a systematic review of large administrative dataset registries of patients who had CEA or CAS, almost three quarters of registries reported procedural risks after CAS well in excess of the 6% recommended risk threshold in symptomatic patients.5

Nevertheless, single centers with high-level of expertise of both surgical and anesthesiological teams seem to offer exceptional results in properly selected patients. It is known that increased experience improves results after CAS.6 On the contrary, poor exposure is related to inferior results for both CEA and CAS. Definitely, a high-selection in favor of low-risk patients which may be the practice of a specific surgical team or a medical center can offer better results with a reduced stroke rate, despite the fact that this may not be translated in saving more patients from a recurrent stroke. Time to intervene after a TIA or minor stroke is a factor that can contribute to this paradigm. In a meta-analysis of population-based studies, Giles et al observed that the risk of stroke at 2 days after a TIA was 6.7% and at seven days 10.4%.7 On top of that, Rothwell et al,8 based on their predicting scoring system, supported that in case of elderly (more than 60 years of age), hypertensive population, a TIA or minor stroke presenting with unilateral weakness of more than 60 minutes duration incurs a risk of recurrent stroke at seven days of 31.4%. Interestingly, the model was replicated by Tsivgoulis et al,9 who noticed that the risk of stroke in this group of patients may be up to 31.3% at 30 days after a TIA. These observations indicate that the first few days (less than 14) after the index event are those that are the most crucial for a recurrent episode. Unfortunately, these are the days that is most possible to have an undesired cerebrovascular event, after a revascularization attempt, either open or endovascular. Nevertheless, it seems that performing CEA or CAS within the first 14 days after the stroke event with a 10% procedural risk will actually prevent more strokes at 5 years than waiting 4 weeks and then intervening with a 0% procedure risk.10 Thus, time of intervention after the ischemic event is crucial in symptomatic carotid artery disease management, and it should be documented. In the current study by Nana et al, although a large percentage of patients were symptomatic, larger than what is described in most of RCTs comparing CEA with CAS, no specific data regarding the time-interval from the event to intervention are presented.

Definitely, results from population-based studies add to the current knowledge of carotid artery disease management as long as data recording follows certain rules. This can become a reality when adapting specifically designed audits and registries in the current medical practice. Uniform registries that report the catholic practice with a unique way of documentation will provide us with all the necessary information to assess the medical practice compliance to the guidelines, this leading to reducing mistakes and improving outcomes. Based
on the current practice in most of the modern health systems, the Hellenic Society of Vascular and Endovascular Surgery has endorsed the creation of HEVAR (Hellenic Vascular Registry).\textsuperscript{11} HEVAR will hopefully become the mean of data collection of, among others, CEA and CAS. When results of large number of patients treated with either CAS or CEA from Greek hospitals are obtained, then an established overall conclusion regarding the current vascular practice on carotids could be made. Hopefully, this may the beginning of a new era, with a plethora of data regarding among all and the carotid artery disease.

REFERENCES


