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A Propensity Matched Comparison for Open and Endovascular Treatment of Post-carotid Endarterectomy Restenosis

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WHAT THIS PAPER ADDS

This study showed that CAS in post-CEA restenosis is as effective as redo CEA in equivalent subgroups of patients from the clinical and anatomical point of view. Moreover, CAS may be preferred over CEA in patients with respect to secondary restenosis and re-interventions. This suggests a primary role for an endovascular strategy in such conditions.

Objectives: To compare results of open and endovascular management of post-carotid endarterectomy (CEA) restenosis.

Methods: This was a retrospective single centre matched case control study. From 2005 to 2015, 148 consecutive interventions for post-CEA restenosis were performed: 80 cases received carotid artery stenting (CAS) and 68 cases received redo CEA. Propensity score based matching was performed in a 1:1 ratio to compare outcomes. Coronary artery disease, degree of the carotid restenosis, timing of the re-intervention with respect to the primary intervention (greater or less than 24 months) and the presence of ipsilateral brain lesions were the covariates included in the matching. Peri-operative outcomes were analysed with χ^2 tests, while late results were estimated by Kaplan–Meier methods.

Results: After propensity matching, 32 CAS interventions were matched with 32 redo CEAs. There were no peri-operative deaths or strokes. Cranial nerve palsy occurred in seven patients in the redo CEA group. Median duration of follow-up was 36 months (interquartile range 24–60; range 6–120). The estimated 5 year survival rate was 94% in the CAS group and 72% in the redo CEA group (p=.1, log rank 2.4). There were no significant differences between the groups in terms of stroke free survival. In the CAS group, no severe restenosis were found, while in the redo CEA group eight patients had severe restenosis or occlusion of the operated carotid artery. Freedom from secondary restenosis at 4 years was 100% in the CAS group and 72.5% in the redo CEA group (p=.005, log rank 7.9). The corresponding figures in terms of freedom from secondary re-intervention were 100% and 83%, respectively (p=.02, log rank 4.8).

Conclusions: CAS and redo CEA in patients with post-CEA restenosis provided similar peri-operative results in a sample of equivalent patients. CAS patients had better follow-up results in terms of secondary restenosis and re-interventions. Further analysis is required with a larger number of patients and a longer follow-up time.

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INTRODUCTION

The optimal management of post-carotid endarterectomy (CEA) restenosis is still controversial. There are no randomised studies comparing the outcomes of open and endovascular treatment in this field. The current evidence is derived from retrospective non-randomised registries and studies, and contemporary practice guidelines do not provide specific advice on how these patients should be managed. While best medical treatment (BMT) seems to be reserved for stable severe asymptomatic and for mild symptomatic lesions, the most recent guidelines suggest that in patients needing re-intervention both open and endovascular interventions are effective, provided that a multidisciplinary decision including surgeon preference and patient choice is taken.[1] Carotid artery stenting (CAS) is considered by several authors to be the treatment of choice because of its reduced invasiveness in comparison with the challenges associated with repeat CEA (redo CEA)

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procedures.[2] On the other hand, several studies and meta-analyses have shown similar rates of peri-operative complications with these techniques,[3,4] while the risk of neurological complications and development of secondary restenosis during follow-up varies widely among the published data.[5,6] One possible explanation for these inconsistent results is that most published studies include heterogeneous patients in terms of demographic, clinical, and anatomical characteristics. Moreover, the duration of follow-up often varies between CAS and redo CEA. Finally, there is a general trend to treat late *de novo* atherosclerotic plaques with open surgery, while patients with early (<24 post-operative months) hyperplastic restenosis are more frequently treated by CAS.[7]

The aim of the present paper was to retrospectively compare open and endovascular treatment of post-CEA restenosis, in terms of peri-operative and late outcomes, among a homogenous population. To this end, a single centre matched case control study design was employed.

MATERIALS AND METHODS

Patient population, pre-operative workup, indications for surgery, and surgical strategy

From January 2005 to December 2015, 3112 consecutive CEAs were performed at the study institution. In the same period of time, 140 consecutive CAS procedures were performed. Data on these interventions were prospectively collected in a dedicated database, the characteristics of which have been reported previously.[8]

A retrospective analysis of this database was performed, and 155 interventions carried out for post-CEA restenosis were identified. CAS was performed in 80 cases and redo CEA in 68. Seven patients underwent a common to internal carotid artery bypass and were excluded from the study. Informed consent for the treatment of personal data was obtained from each patient before the insertion of their data in the prospective registry. The retrospective analysis of the data did not require approval of the institutional review board. The present study included all the patients from a prior study,[7] plus those who were operated on between January 2012 and December 2015, namely 49 new interventions.

All of the patients underwent both duplex scanning of the extracranial vessels and computed tomography angiography (CT) scans of the intra- and extra-cranial vessels and the cerebral parenchyma. The degree of carotid stenosis was measured using the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria. The duplex criteria employed for the definition of post CEA carotid restenosis were those indicated in the national guidelines: namely, a peak systolic velocity (PSV) greater than 180 cm/s indicated the presence of a >70% restenosis, while a PSV greater than 225 cm/s was used to define a >80% restenosis.[9] During the pre-operative workup, a phoniatrist conducted an otolaryngological evaluation of the motility of the vocal cords and damage to the cranial nerves.

The indications for re-intervention were the presence of symptomatic stenosis >50% or asymptomatic stenosis >80% in progression despite optimal medical management (antiplatelets drugs, statins). Patients were considered to be symptomatic in the presence of ipsilateral neurological events (transient ischemic attack [TIA], or stroke) in the previous 6 months.

The selection of either open or endovascular treatment was not randomised; it was made at the surgeon's discretion on the basis of clinical and anatomical considerations, including the characteristics of the neck and the previous surgical wound, the site of the lesion (distal lesions beyond the angle of the jaw), the presence of past cranial nerve injuries, and the duplex appearance of the lesion. In addition, the time from the primary interventions was taken into account: in patients with early (<24 months) restenosis an endovascular approach was preferred, while in patients with late recurrent disease a new open surgical intervention was generally carried out. Technical details of open and endovascular interventions were as described previously.[7] In CAS patients, a double antiplatelet regimen (aspirin and clopidogrel) was adopted in all patients for at least 6 months and, after that, ASA was administered indefinitely. In all redo CEA patients, post-operative medical treatment consisted of single antiplatelet therapy. Patients in both groups were treated with statins indefinitely.

Peri-operative and follow-up evaluation

A neurological evaluation was independently performed by an experienced neurologist at discharge and within 30 post-operative days, to determine the presence of minor or major strokes. A minor stroke was defined as any post-operative neurological event of more than 24 h duration followed by a recovery in the subsequent weeks or months either without impairment or with minimal residual functional impairment. A major stroke was defined as any post-operative neurological event of more than 24 h duration with residual functional impairment. An otolaryngological evaluation was also performed within the first peri-operative month. Patients with cranial nerve injuries at the first post-operative evaluation were further followed up every 6 months.

Follow-up was performed at 1, 6, and 12 months, and yearly thereafter, with a clinical examination and a duplex scan. All the follow-up visits were performed by a vascular surgeon; the patients were asked to report their clinical history during the index period, with particular interest paid to the occurrence of neurological events and their time of appearance, as well as major cardiovascular events. The collaboration of a neurologist was sought in cases where the clinical history suggested the occurrence of a new neurological symptom. DUS studies were performed by two vascular surgeons (W.D., R. P.), certified as institutional national tutors by the Italian Society for Vascular Investigation, using an Acuson Sequoia 512 Ultrasound System (Acuson Corporation, Mountain View, Ca, USA). During DUS examination, the patency of the operated vessel and the status of the contralateral internal carotid artery were assessed. Criteria for secondary restenosis were the same as primary in the redo CEA group, while in CAS patients

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