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Early Outcomes of Routine Delayed Shunting in Carotid Endarterectomy for Asymptomatic Patients

Michele Piazza *, **Marco Zavatta, Margherita Lamaina, Jacopo Taglialavoro, Francesco Squizzato, Franco Grego, Michele Antonello**

Clinic of Vascular and Endovascular Surgery, Padova University School of Medicine, Padua, Italy

WHAT THIS PAPER ADDS

Routine shunting with device insertion just after rapid carotid endarterectomy (CEA) is a valid technique, able to optimise the benefit of continuous cerebral perfusion together with a reduced risk of related complications. This specific method, together with standardisation of the procedure, leads to a neurological complication rate <1%, which can be consistently maintained over time and independently from different operators. In asymptomatic patients with significant carotid stenosis, this approach offers patients the modern reliable CEA low stroke risk rate they expect.

Objective/background: The aim was to evaluate early outcomes of carotid endarterectomy (CEA) in asymptomatic patients using a standardised technique based on routine shunting after rapid plaque removal ("delayed").

Methods: A retrospective review of all asymptomatic patients who underwent CEA during a 10 year single centre experience (January 2007–December 2016) was performed. The technique was based on rapid endarterectomy with distal intimal edge visualisation, followed by routine shunt insertion; subsequent time spent on the manoeuvre and closure were completed under shunting. Primary endpoints were relevant neurological complication rate (RNCR) and death within 30 days. To better identify any difference related to changes in medical therapy, anaesthetic management, and different operators over time, patients were divided into group A (underwent CEA in the first 5 year period) and group B (underwent CEA during the second 5 year period). Univariate analysis of factors associated with RNCR was performed. Operator experience (seniority), expertise (CEA volume per year), and time period were incorporated.

Results: In total, 1745 patients matched the inclusion criteria and were enrolled. Altogether, 147 (8.9%) had contemporary contralateral stenosis ≥70% and 58 (3.5%) had contralateral internal carotid artery chronic occlusion. No patient died peri-operatively; major myocardial infarction occurred in 19 patients (1.1%). Overall, peri-operative RNCR was 0.6% (major stroke: $n = 6$ [0.4%]; minor stroke: $n = 4$ [0.2%]). RNCR distribution was maintained equally comparing group A and B (0.8% vs. 0.4%; $p = 0.17$). No differences were found in RNCR when comparing operator experience ($p = 0.88$) and expertise ($p = 0.93$). Univariable analysis found diabetes as the only clinical factor influencing RNCR (odds ratio 3.79, 95% confidence interval 1.06–13.50; $p = 0.04$); none of the other factors, such as time period, operator experience, and expertise, reached statistical significance.

Conclusions: Routine delayed shunting associated with standardisation of the technique seems to be a safe and effective technique and contributes to maintaining the RNCR < 1% over time and independently from operators and other clinical factors.

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INTRODUCTION

Carotid endarterectomy (CEA) is widely recognised as the gold standard surgical approach to the prevent of major cerebral events in patients with significant carotid stenosis.[1] The results of trials such as the Asymptomatic Carotid Atherosclerosis Study (ACAS)[2] and the Asymptomatic Carotid Surgery Trial (ACST),[3] performed in the 1990s, favoured CEA plus medical therapy over medical therapy alone in the management of asymptomatic patients with significant carotid stenosis.

As emphasised in the literature,[4] these findings hold true only if the cumulative risk of relevant neurological complication rate (RNCR) and peri-operative mortality during surgery is <3%.

* Corresponding author. Clinic of Vascular and Endovascular Surgery, Padova University School of Medicine, Via Giustiniani 2, 35128 Padova (PD), Italy.

E-mail address: mikpia79@hotmail.com (Michele Piazza).

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Despite the fact that CEA has been performed for decades, specific operative techniques remain highly variable, especially techniques for cerebral monitoring and protection.[5] While shunting aims to minimise the cerebral ischaemia time during clamping and therefore to reduce RNCR, on the other side device insertion itself is a delicate manoeuvre that requires operator expertise. Brain embolisation from plaque fragments, intimal lesions with ICA dissection, and shunt malfunctions are some of these aspects. Also, the CEA procedure itself, type of anaesthesia, closure methods, and neurological monitoring have a wide range of approaches depending on operator expertise and preferences. The absence of a standardised procedure is one of the aspects that may be responsible for the wide range in RNCR, depending on the series analysed (from 0.7% to 4%).[6]

The objective of this study was to evaluate early surgical and neurological outcomes (within 30 days of surgery) of CEA in asymptomatic patients with stenosis $\geq$70% using a specific standardised technique based on rapid endarterectomy with accurate assessment of distal intimal break off edge, followed by routine "delayed" shunt insertion.

Also evaluated was whether other factors such as time period or surgeon's experience may influence outcomes in terms of RNCR.

MATERIALS AND METHODS

A retrospective review of all patients admitted to the Clinic of Vascular and Endovascular Surgery of Padua University who underwent CEA between January 2007 and December 2016 was performed. All data were prospectively collected in a dedicated database. Institutional Review Board requirements were waived for this study.

Patient selection

Only asymptomatic patients with $\geq$70% carotid stenosis were enrolled. Patients with significant contralateral carotid stenosis or occlusion were also included.

All symptomatic patients and asymptomatic patients with pre-operative computed tomography (CT) or magnetic resonance imaging (MRI) evidence of recent onset ($<$30 days) ipsilateral ischaemic lesions were excluded. Patients affected by carotid aneurysms, dissections, restenosis, or CEA performed in association with other surgical procedures (coronary artery bypass, common carotid artery stenting at its origin from the arch) were also excluded.

Patients were divided into two groups: those undergoing CEA in the first 5 year time period (2007–11; group A) and those treated during the second 5 year period (2012–16; group B). This was done to better identify any difference in outcomes in relation to improvement in medical therapy, anaesthetic management, and different operators over time.

Treatment and definitions

Demographic baseline characteristics, risk factors, and pre-operative medical therapy were obtained by reviewing all available medical records at the time of operation.

The cardiovascular risk factors considered were hypertension, dyslipidaemia, diabetes, chronic obstructive pulmonary disease, history of coronary artery revascularisation (coronary artery bypass graft or percutaneous transluminal coronary angioplasty [PTCA]). Pre-operative assessment also included information on medical therapy (antiplatelet, anticoagulant, statin therapy). Pre-operative imaging was routinely performed with carotid duplex ultrasound (DUS) followed by CT or MR angiography scan of the supra-aortic and intracranial vessels; a cerebral CT scan was performed to identify any recent ischaemic lesions.

The grade of stenosis was defined based on DUS with the North American Symptomatic Carotid Endarterectomy Trial (NASCET) method;[7] if a stenosis $\geq$70% was identified, a subsequent CT angiogram of the supra-aortic and intracranial vessels was obtained in order to corroborate DUS findings and to evaluate carotid disease extension based on Society for Vascular Surgery (SVS)/European Society for Vascular Surgery (ESVS) guidelines.[8,9]

The definition of asymptomatic was based on SVS/ESVS extracranial carotid disease guidelines (no previous symptoms or no symptoms in the preceding 6 months).[8,9]

Operative factors considered were clamping times, electroencephalogram (EEG) variations during cross clamping, eventual complications during endarterectomy and shunt insertion, type of closure, and additional intra-operative procedures. Technical success was defined as an uneventful endarterectomy without the need for additional procedures during surgery or on waking.

Post-operative transient ischaemic attack (TIA), minor and major stroke were defined according to the current reporting standards.[10] The National Institute of Health Stroke Scale (NIHSS) was used for neurological assessment pre-operatively, at patient awakening, and 6 and 24 h after the procedure. In case of altered NIHSS, the patient was subsequently evaluated by a neurologist for accurate evaluation and management strategy.

All patients with the onset of a new neurological deficit after surgery underwent an urgent carotid DUS and cerebral CT. Eventual subsequent imaging by CT angiogram or any type of interventions, were considered on a case by case basis.

Any other new clinical or neurological findings after discharge and within 30 days were assessed with telephone interviews at 30 days by a dedicated doctor. If a patient referred to any type of symptom, he or she was scheduled for an outpatient clinic visit and eventual additional examinations were required for a precise diagnosis. If a patient developed any acute episode requiring urgent/emergency hospitalisation, the medical records of Padova Hospital Area Intranet System (allowing for visualisation of medical records of all Padova area hospitals and outpatients clinics) were reviewed.

All surgical, cardiac, and neurological complications were categorised in accordance with the SVS reporting standards for carotid interventions.[8]

Primary endpoints were to compare RNCR (minor and major stroke) and related death 30 days after CEA between the two different time periods (groups A and B).

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