Spotlight

Is carotid artery stenting without protection safe? A single-center experience: Case series

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Abstract
Introduction: Carotid artery stenosis is one of the main causes of ischemic stroke in the Iranian population. Carotid artery stenting (CAS) is a method for treating carotid artery disease in order to prevent stroke. Dispersion of the embolus is a significant risk for carotid angioplasty which can be prevented by using protective devices. However, previous studies have shown that the use of these protective devices is not safe and can result in side effects such as vascular spasm and dissection.

Methods: Thirty-six patients, who underwent unprotected carotid artery angioplasty from April 2018 to August 2019 in Shahid Madani hospital, were retrospectively entered to this study. Hospital records were studied for data collection. Patients were followed by phone interviews. Major adverse cardiovascular and cerebral events (MACCE) was defined as a composite of the occurrence of MI, stroke, bleeding, and all-cause mortality in the long term. The mean length of our follow-up was 6 months.

Results: During the in-hospital course, an 82 years old woman with a history of cerebrovascular accident (CVA), hypertension, diabetes and a significant stenosis in her contralateral internal carotid artery (ICA) had an episode of stroke, which was fatal. Also, there was a 46 years old woman without any risk factors, who had developed intracranial hemorrhage (ICH). Twenty-two patients were followed. No MI, stroke, or death occurred in any of the patients. There were only 2 cases of bleeding.

Conclusion: CAS without protection may be is a safe method of carotid revascularization. Further prospective studies and clinical trials are needed.

Introduction
Carotid artery stenosis is one of the main causes of ischemic stroke in the Iranian population. In comparison with carotid artery endarterectomy, carotid artery stenting (CAS) is a less-invasive method to prevent stroke, with shorter hospitalization and recovery period for treating carotid artery disease.

One of the most important problems related to carotid angioplasty procedure is the spread of embolism to the cerebral circulation, which can be primarily prevented by using protective devices. However, previous studies have shown that the use of these protective devices is not safe and can result in side effects such as vascular spasm and dissection.

This study aims to investigate the in-hospital course and long-term outcomes of unprotected CAS procedures which were performed on 36 patients in Shahid Madani hospital, Tabriz, Iran, between April 2018 and August 2019.

Methods
All patients who underwent unprotected carotid artery angioplasty from April 2018 to August 2019 in Shahid Madani hospital were retrospectively entered to this study. Cerebrovascular risk factors including hypertension, diabetes mellitus, hyperlipidemia, coronary artery disease, and cigarette smoking were recorded using the patients' medical history or direct evaluation: Hypertension (initial blood pressure over 140/90 mm Hg), diabetes mellitus (Fasting blood glucose > 120 mg/dL, HbA1c >6.5%,...
or current administration of oral antidiabetic agents or insulin), hyperlipidemia (fasting serum cholesterol levels over 220 mg/dL or current statin medication), smoking (current or within the previous year), coronary artery disease (history of myocardial infarction, angina, percutaneous transluminal angioplasty, or open surgery). Cerebrovascular accidents, including stroke and transient ischemic attack, were also recorded. Details of CAS procedure and early events after the procedure and before patients’ discharge were noted in prepared checklists.

All CAS procedures were performed using the standard femoral approach and under local anesthesia, without using cerebral protection devices. Predilatation with a balloon was done just for some cases who had very tight and calcified stenosis precluding stent delivery. Then, an appropriate stent was deployed in the lesion and post-dilatated by a balloon. Control intracranial angiogram was performed on procedure completion to exclude distal embolization, and the patient was sent to the recovery room to be monitored.

Major adverse cardiovascular and cerebral events (MACCE) was defined as a composite of the occurrence of MI, stroke, bleeding, and all-cause mortality in the long term. The mean length of our follow-up was six months.

Statistical analysis
The continuous variables were reported as mean ± SD and the nominal variables as counts and percentages. The χ² test was used for comparing nominal variables, and the independent-samples t test was used for continuous values. The statistical analyses were performed using the SPSS version 16 software (SPSS, Chicago, IL, USA).

Results
A total of 36 cases were enrolled in our study. The mean age of the population was 64.9 ± 10.8. Twenty patients (55.6%) were male. Stent implantation in 24 cases (66.7%) was in the right internal carotid artery (ICA) and in 12 cases (33.3%) was in the left ICA. Six patients (13.9%) had significant stenosis in their contralateral ICA. Nine patients (25%) had 50-70% stenosis, and 27 patients (75%) had 70-99% stenosis in their ICA. Also, there was a single case of hyperacute stent thrombosis. Other procedural information is shown in Table 1.

Risk factor assessment revealed hypertension in 23 cases (61.1%), diabetes mellitus in 5 cases (13.9%), hyperlipidemia in 3 cases (8.3%), coronary artery disease in 4 cases (11.1%) and cigarette smoking in 3 cases (8.3%). Also, 27 patients were symptomatic, which means they recently had experienced an episode of cerebrovascular accident (CVA).

One patient experienced stroke after CAS and before discharge. She was 82 years old with a history of CVA, hypertension, diabetes, and she had a significant stenosis in her contralateral ICA. She Unfortunately expired. Also, there was a 46 years old woman without any risk factors, who had developed intracranial hemorrhage (ICH), and she was recovered within a few days.

We were able to follow 22 patients. Mean duration of our long-term follow-up was 6 months. During this period, no MI, stroke, or death occurred in any of the patients. There were only 2 cases of bleeding, which, according to the guidelines of International Society on Thrombosis and Hemostasis (ISTH) classification, one of them was major bleeding, and one of them was minor bleeding.12,13

Discussion
As it was mentioned in previous studies, ICH, stroke, and death are the most serious long-term complications of CAS.14,16 In long-term follow up of this study (during 6 months), bleeding complications just had happened in 2 patients. One of them had a major bleeding, which was a 72 years old man with a history of hypertension and a significant stenosis in contralateral ICA. The other one was a 56 years old man without any cardiovascular risk factor who had a minor bleeding.

As it is shown in Table 2, our analysis results do not show any significant correlation between cardiovascular risk factors and long-term complications. This may be due to the low sample size of our study. Also, shorter follow-up duration could be another reason for this. Further prospective studies with larger population size are needed to find the predictors of CAS procedure complications.

Conclusion
CAS without protection may be a safe method of carotid
Unprotected carotid artery stenting. Further prospective studies and clinical trials are needed.

Conflict of Interest
None declared.

Ethical Approval
The present study was conducted in accordance with the ethical standards of the Declaration of Helsinki and approved by the institutional review board and Human Ethics Committee of Tabriz University of Medical Sciences. Informed consent was obtained from all patients.

Authors’ Contributions
Authors contribute to patient selection, procedure planning, data collection and writing of this article.

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