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Risk factors associated with in-hospital serious adverse events after stenting of severe symptomatic intracranial stenosis

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ABSTRACT

Objectives: Severe symptomatic intracranial stenosis is an important cause of stroke. Intracranial stenting is alternatively applied to treat intracranial atherosclerotic disease. However, Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis trial (SAMMPRIS) and Vitesse Stent Ischemic Therapy trial (VISSIT) both demonstrated intracranial stenting were inferior to aggressive medical treatment. But careful patient selection probably can improve the outcome of stenting in intracranial artery stenosis. Therefore, the validation of risk factors associated with serious adverse events (SAEs) after intracranial stenting may contribute to identify patients who are at high risk of stenting therapy and benefit patient selection for stenting.

Patients and methods: Patients who underwent intracranial stenting with symptom attributable to severe (>70%) intracranial stenosis were included in our institution. In-hospital SAEs after procedure were reviewed. Risk factors associated with SAEs were analyzed using multivariable logistic regression analysis.

Result: Thirty serious adverse events (5.1%) occurred among a total of 583 patients, with a mean age of 58.1 ± 9.7, including 13 ischemic strokes, 12 brain hemorrhages and 5 deaths. Bivariate analysis and multivariable logistic regression analysis showed age (OR = 0.94, 95% CI:0.900–0.983), history of DM (OR = 2.439, 95% CI:1.107–5.371), preprocedural mRS score (OR = 3.076, 95% CI:1.290–7.336) and lesion site in BA (OR = 9.056, 95% CI:1.147–71.524) were risk factors associated with SAEs.

Conclusion: History of DM and lesion site in BA were risk factors associated with postprocedural in-hospital SAEs after stenting of severe symptomatic intracranial stenosis. But considering of the limitation of this retrospective study, further studies are necessary to confirm our results.

1. Introduction

Intracranial atherosclerotic disease (ICAD) is responsible for approximately 8–10% ischemic stroke in USA [1] and 33% in China [2]. Natural history of ICAD was well-established in the Wafarin-Aspirin Symptomatic Intracranial Disease Trial (WASID), which revealed that severe stenosis >70% resulted in about 19% of stroke in the territory of the symptomatic stenotic artery despite antiplatelet management compared with a lower rate of stroke (8%) in patients with stenosis <70% [3]. Considering that the risk of stroke for asymptomatic intracranial stenosis is <3.5% per year, therefore, patients with severe symptomatic intracranial stenosis is potential population that can benefit from endovascular treatment. The treatment of ICAD included endovascular intervention and aggressive medical management. However, the publication of Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis trial (SAMMPRIS) [4], a multicenter, prospective, randomized controlled trial, which was no longer enrolling patients after 451 patients underwent randomization, have tempered enthusiasm to intracranial stenting, because the 30-day rate of stroke or death was 14.7% in the PTAS group and 5.8% in the medical-management group, and final result established aggressive medical treatment as superior to stenting for severe symptomatic ICAD. Recently, another randomized controlled study that compared the efficacy of stenting to medical therapy in ICAD, Vitesse Stent Ischemic Therapy trial (VISSIT), revealed unsatisfactory outcome of balloon-expandable stent [5]. In spite of the inferior outcome of intracranial stenting compared to medical management for ICAD demonstrated by the two studies, some subgroups of patients who had high risk of stroke despite aggressive medical management may benefit from

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stenting, that is to say, careful patient selection for stenting perhaps improve the outcome of stenting in patients with intracranial artery stenosis. Based on this hypothesis, we conduct this study aiming to analyze risk factors associated with SAEs after intracranial stenting, the data of which may be helpful to patients selection.

2. Patients and methods

2.1. Study population

Between January 2005 and February 2013, the data of patients underwent stenting-assisted angioplasty at our institution with symptom attributable to severe intracranial atherosclerotic stenosis were reviewed. All patients were enrolled for transient ischemic attack or ischemic stroke secondary to >70% stenosis of a major intracranial artery confirmed on digital subtraction angiography (DSA) by NASCET criteria. Patients with nonatherosclerotic, extracranial, or asymptomatic stenosis were excluded. In each case, we assessed demography features, preprocedural modified Rankin Score (mRS), targeted lesion and in-hospital SAEs. Independent neurologists reviewed patients to verify SAEs. SAEs were defined as procedure-related disabling or fatal ischemic stroke, brain hemorrhage or any death after stenting.

2.2. Procedure

Before the procedure, patients were routinely prescribed dual-antiplatelet medication, aspirin 100 mg qd, clopidogrel 75 mg qd and atorvastatin 20 mg qd at least 3 days before intervention. Self-expandable stents and balloon-expandable stents were used at the discretion of neurointerventionalists. The procedure was performed under general anesthesia. A 6F introducer sheath was placed into the femoral artery by Seldinger technique and a 6F guiding catheter advanced to distal carotid artery (CA) or vertebral artery (VA). Repeated angiography was necessary to verify severe intracranial arterial stenosis. Stents used in this study included balloon-expandable stents, like Apollo (Microport, Shanghai), Firebird (Microport, Shanghai), Blue (Cordis Europa N.V.), Endeavor (USA Medtronic, Inc.), Cypher (Cordis Europa N.V.), Coroflex (Braun, Germany) and XIENCE V (Abbott, USA), and self-expandable stents, Wingspan (Boston Scientific Corporation, USA). The balloon-expandable stents were deployed via balloon inflated to the nominal inflation pressure, while the self-expandable stents preloaded in a delivery catheter were deployed across the lesion after the stenotic lesion was predilated by a balloon catheter. Post-dilation was necessary if the stenosis was not improved obviously. Technical success was defined as residual stenosis <20%.

2.3. Postprocedural management

On the completion of intracranial stenting, routine angiography was conducted in each patient. Each patient was administered dual-antiplatelet and atorvastatin as preprocedural treatment, and dual-antiplatelet was converted to mono-antiplatelet, aspirin or clopidogrel alone, after 3 months.

2.4. Statistical methods

In terms of descriptive statistics, continuous variables was presented as Mean ± SD and discrete variables was given as percentage. Bivariate associations between demography features, preprocedural mRS score, targeted lesion site and SAEs were assessed using χ^2 test (for categorical factors) and *t* test or Wilcoxon rank-sum test (for continuous factors). Multivariate logistic regression analysis was done to relate the occurrence of an adverse event to multiple clinical factors. All statistics analyses were performed on SPSS 16.0. A p value <0.05 was assumed to be statistically significant.

Table 1
Baseline characteristics of the patients.

Baseline characteristics	N = 583	Percentage
Age	58.1 ± 9.7	
Time interval (days)	45.6 ± 2.67	
Sex		
Male	499	85.6%
Female	84	14.4%
History of CI	297	50.9%
History of CHD	112	19.2%
History of HT	421	72.2%
History of DM	217	37.2%
History of HLP	64	11.0%
Smoking	254	43.6%
Perivascular disease	6	1.0%
History of cerebrovascular stenting	18	3.0%
Other cerebrovascular stenosis	139	23.8%
Preprocedural mRS score	1.47 ± 0.96	
Lesion site		
Intracranial segment of ICA	72	12.3%
Intracranial segment of VA	226	38.8%
MCA	91	15.6%
BA	194	33.3%
Type of stent		
Balloon-mounted stent	391	67.1%
Self-expandable stent	192	32.9%

Abbreviation: CI, cerebral infarction; CHD, coronary heart disease; HT, hypertension; DM, diabetes mellitus; HLP, hyperlipidemia; mRS, modified Rankin scale; ICA, internal carotid artery; VA, vertebral artery; MCA, middle cerebral artery; BA, basilar artery.

3. Result

A total of 583 patients (male: 499, female: 84) who underwent stenting-assisted angioplasty with symptom attributable to severe intracranial atherosclerotic stenosis were included in this study with procedural success achieved in 99% of the patients. The average age of the population was 58.1 ± 9.7. The average in-hospital time after procedure was 7.4 ± 2.1 days. The average time interval from ictal event to procedure was 30.5 ± 1.92 days in patients with SAEs and 52.7 ± 3.24 days in patients without SAEs (p = 0.723). Baseline characteristics were displayed in Table 1. 5 stents were not deployed successfully and the main reasons was failed lesion access. One technical failure in BA caused brain hemorrhage referable to artery rupture of BA. Thirty in-hospital SAEs (5.1%) occurred including 13 ischemic strokes, 12 brain hemorrhages and 5 deaths. Of those 13 ischemic strokes, 1 occurred in the territory of VA, 2 and 10 in the territory of MCA and BA, respectively. Of those 12 brain hemorrhages, 2 occurred in the territory of ICA, 1, 2 and 8 occurred in the territory of MCA, VA and BA, respectively and 1 was referable to vessel rupture during guiding wire access. Of the 5 deaths, 3 were attributable to artery-to-artery embolization, 2 were referable to thrombogenesis (Table 2), artery-to-artery embolization was referred to as thrombosis from proximal plaque debris after rupure while thrombogenesis was defined as thrombosis developed at the site of lesions or stents. The incidence of SAEs in each period was also presented in Table 3.

Bivariate analysis (Table 4) revealed that history of DM, preprocedural mRS score and lesion site were risk factors associated with SAEs. Bivariate analysis for the preprocedural mRS score showed that preprocedural mRS score ≥ 3 was a risk factor (p = 0.015). In respect of lesion site, Fisher exact test revealed patients whose targeted lesion site located in BA had significant higher rate of SAEs (p = 0.018). The most used stents in this study were balloon-expandable stents. No significant difference in the rate of SAEs were