Aortic Transgraft Hemorrhage after Intravenous Tissue Plasminogen Activator Therapy in Patients with Acute Ischemic Stroke

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Background: The safety of intravenous recombinant tissue plasminogen activator (IV tPA) therapy for patients with an aortic aneurysm or undergoing aortic graft replacement has not been established. We evaluated the incidence, bleeding site, coagulation factors, and clinical outcomes of patients treated with IV tPA for acute stroke. *Methods:* Between October 2005 and May 2013, 394 ischemic stroke patients were treated in our stroke center with IV tPA. Among these patients, we investigated those who had a history of aortic aneurysm with or without aortic graft replacement before IV tPA therapy and underwent computed tomography imaging. We compared the levels of D-dimer and hemoglobin (Hb) around IV tPA therapy between the patients with and without tPA-associated periaortic bleeding. *Results:* Seven patients with a history of aortic aneurysm (3 men; mean age: 80.4 years) were examined; 3 had undergone aortic graft replacement, and 2 had experienced tPA-associated bleeding around vascular grafts. The serum D-dimer levels in those with bleeding were only slightly higher before tPA than in those without (median: 10.5 vs. 1.5 μg/mL) but were elevated 1 day after tPA (107.4 vs. 8.6 μg/mL). The Hb levels 2 days after tPA were comparable with those before tPA (11.9 vs. 11.8 g/dL) but were lower in the patients with bleeding than in those without (8.5 vs. 11.7 g/dL). Surgical intervention was not required, although 1 patient required blood transfusion. *Conclusions:* Our analysis provides reassurance regarding the risk of IV tPA therapy in patients undergoing aortic graft replacement. **Key Words:** Intravenous thrombolysis—IV tPA therapy—acute ischemic stroke—aortic aneurysm—aortic graft replacement—aortic transgraft hemorrhage.
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Intravenous recombinant tissue plasminogen activator (IV tPA) therapy improves functional neurologic outcome and reduces mortality in acute ischemic stroke.[1] In August 2012, the indication of IV tPA therapy for acute ischemic stroke was extended in Japan to 4.5 hours after stroke onset.[2] Because the benefit of IV tPA therapy rapidly declines over time from the initial symptom onset,[3] it is important to identify patients who are suitable for IV tPA therapy as early as possible. However, given that IV tPA therapy increases the risk of major bleeding, particularly in the brain, patients should be carefully selected for IV tPA therapy using valid eligibility criteria.

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Patients with stroke have been associated with a higher incidence of abdominal aortic aneurysm.[4] According to the Japanese guidelines for administering IV tPA therapy, patients with an aortic aneurysm require "careful administration" of tPA for acute ischemic stroke.[2] However, the safety of IV tPA therapy for patients with an aortic aneurysm or undergoing aortic graft replacement has not been established. Few studies have examined whether periprosthetic graft hemorrhages are associated with thrombolysis.[5-10] In those studies, the indications for thrombolysis were limb ischemia or myocardial infarction, and the thrombolytic agents used included tPA, streptokinase, or urokinase. There are no reports on IV tPA therapy for acute ischemic stroke in patients with a history of aortic aneurysm when the coagulation and fibrinolytic systems were sufficiently monitored.

In the present study, we evaluated the incidence, bleeding site, coagulation/fibrinolysis markers, and the clinical outcomes of consecutive patients treated with IV tPA for acute ischemic stroke who had a history of aortic aneurysm with or without aortic graft replacement.

Methods

Patients were selected from a prospective clinical registry of patients with acute ischemic stroke treated in our stroke center with IV tPA between October 2005 and May 2013. The study was approved by Medical Ethics Committee of National Cerebral and Cardiovascular Center, Japan. Inclusion and exclusion criteria for IV tPA (.6 mg/kg) therapy were used in accordance with the Japanese guidelines for administering IV tPA (alteplase) therapy. Based on these Japanese guidelines, the patients with acute ischemic stroke were treated with IV tPA within 3 hours of stroke onset between October 2005 and August 2012, and within 4.5 hours of stroke onset after August 2012.[2]

Patients meeting the following inclusion criteria were included in the study: (1) history of aortic aneurysm with or without aortic graft replacement before IV tPA therapy and (2) at least 1 body examination with computed tomography (CT) imaging (Aquilion TM, Toshiba Medical Systems Co., Ltd., Tokyo, Japan) during hospitalization for acute stroke.

An aortic aneurysm was defined by the Japanese guidelines for the diagnosis and treatment of aortic aneurysm and aortic dissection, which included a circumferential or local enlargement of part of the aortic wall that exceeded 45 mm in diameter in the thoracic region or 30 mm in the abdominal region in a fusiform manner.[11]

The baseline characteristics, stroke severity on admission and discharge, onset-to-needle time, risk factors, subtype of ischemic stroke, body CT images, blood examination including coagulation markers, and modified Rankin scale (mRS) score on discharge were collected for each patient.

The original Trial of ORG 10172 in Acute Stroke Treatment criteria were used to determine the subtype of ischemic stroke.[12] Symptomatic intracranial hemorrhage was defined as extravascular blood present in the brain or cranium that was associated with clinical deterioration and was accompanied by at least a 4-point increase in the National Institutes of Health Stroke Scale (NIHSS) score. Hemorrhagic transformations occurring within 36 hours of IV tPA therapy were classified according to the European Cooperative Acute Stroke Study (ECASS) morphologic definitions into the following 5 categories: no hemorrhagic transformation, hemorrhagic infarction (HI) types 1 and 2, and parenchymal hematoma types 1 and 2.[13] Body CT images were reviewed by an experienced radiologist (M.H.). Statistical analysis was not performed because only a small number of patients were examined.

Results

Between October 2005 and May 2013, 394 patients were treated in our hospital with IV tPA for acute stroke. During this period, 9 patients presented with a history of aortic aneurysm who were treated with IV tPA. Two of these patients, however, were not examined by body CT imaging during their hospitalization for acute stroke. Therefore, 7 patients (3 men and 4 women; mean age: 80.4 years) met the inclusion criteria and were enrolled in the study.

The clinical characteristics of these 7 patients are summarized in Table 1. The subtypes of ischemic stroke included 2 cases (28.6%) of large artery atherosclerosis and 5 cases (71.4%) of cardioembolism. The onset-to-needle time, which indicates the period between symptom onset and treatment initiation, ranged between 68-186 minutes with a median of 158 minutes.

Three patients (2 men and 1 woman; mean age, 80.3 years) had undergone an aortic aneurysm repair (Table 2). One patient had received a prosthetic graft for an abdominal aortic aneurysm with an InterGard graft (InterVascular, La Ciotat, France), and one patient had received a prosthetic graft for a thoracic aneurysm with a Gelweave graft (Vascutek Ltd, Renfrewshire, Scotland, United Kingdom). Another patient had received 2 prosthetic grafts, which included a thoracic aortic aneurysm with a UBE J-graft (Junken Medical Co, Ltd, Tokyo, Japan) and an abdominal aortic aneurysm with the InterGard graft. All 4 prosthetic grafts used Dacron grafts. In all 3 patients, the period between the operation and IV tPA therapy was at least 4 months, and according to their medical records, their postoperative courses were uneventful. Four patients (1 man and 3 women; mean age, 80.5 years) had a history of thoracic aortic aneurysm without surgical repair. The mean maximum diameter of thoracic aortic aneurysm was 46.5 mm (range, 45-48 mm).

Body CT examinations were performed between 1-24 days after tPA infusion, with a median of 5 days. Bleeding in a body cavity associated with IV tPA therapy was present in only 2 of the 7 patients. The basic clinical characteristics of bleeders and nonbleeders are presented

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