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Early decompressive surgery after combined intra-venous thrombolysis and endovascular stroke treatment

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ABSTRACT

Background and purpose: The prognosis of malignant middle cerebral artery infarctions (MCA) is poor. The poor prognosis is attributable to the severe cerebral edema that causes a brain herniation and death. Decompressive surgery reduces mortality and may further improve patient outcomes. However, the safety and effectiveness of decompressive surgery in patients who underwent combined intravenous (IV) thrombolysis and endovascular stroke treatment are not certain. Moreover, the evidence on the timing of decompressive surgery is lacking.
Methods: The purpose of the open, prospective and non-randomized study was to compare the outcome and complication rates of patients with malignant MCA strokes who underwent early decompressive surgery after combined intravenous thrombolysis and endovascular treatment with those of decompressive surgery patients without prior recanalization treatment strategy. All patients underwent decompressive surgery within 24 h of symptom onset.
Results: Thirty patients were included in the study. Twelve of the 30 patients were treated with combined IV thrombolysis and endovascular approach and 18 patients received standard treatment. The proportion of patients with a modified Rankin score ≤ 3 at the sixth month follow-up was 33% in the standard group and 44% in the combined treatment group ($p = 0.712$). Mortality, and major and minor complications including symptomatic intracerebral hemorrhage after decompressive surgery did not differ between the two groups ($p > 0.05$).
Conclusion: Early decompressive surgery can be safely performed in patients who received combined IV thrombolysis and endovascular treatment and there was no difference in outcome of these patients compared with patients who did receive the standard medical treatment before early decompressive surgery.

1. Introduction

Between 1% and 10% of supratentorial ischemic infarctions are associated with severe brain edema which usually manifests itself between the second and fifth day after stroke onset [1–3]. The prognosis of malignant middle cerebral artery infarctions (MCA) is poor [1]. A pooled analysis of the three randomized controlled trials included patients with malignant MCA stroke who were randomized to decompressive surgery or medical treatment within 48 h of symptom onset, showed that decompressive surgery reduces mortality and increases the chance of a favorable outcome [4]. However, the safety and effectiveness of decompressive surgery in patients who underwent combined stroke treatment including intravenous (IV) thrombolysis and endovascular stroke approach is not certain. In addition, the optimal time window for decompressive surgery after malignant MCA stroke is unknown. In this study, we aimed to compare the outcome and complication rates of patients with malignant MCA strokes who underwent early decompressive surgery after combined intravenous IV-rtPA and endovascular treatment with decompressive surgery patients without prior recanalization treatment strategy.

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2. Materials and methods

This study was a single center, nonrandomized, prospective study comparing the outcome of malignant MCA patients who underwent decompressive surgery after intravenous thrombolysis and endovascular stroke treatment versus decompressive surgery patients without prior acute stroke recanalization treatment. Patients with malignant MCA infarction between 18 and 65 years of age who were treated with decompressive surgery within the 24 h after stroke onset were included in the study from January 2011 to January 2013. Written confirmation from Eskisehir Clinical Research Ethics Committee was received for this study.

Patients with MCA strokes were considered as malignant in the presence of complete MCA infarction (including at least 50% of the territory MCA on CT with or without additional ipsilateral anterior cerebral artery) and clinical signs of infarction of the MCA territory with an NIHSS score >18 for lesions of the non-dominant hemisphere and >20 for lesions of the dominant and these patients underwent decompressive surgery. In combined acute stroke treatment group CT was obtained at baseline, after acute stroke recanalization treatment for the decision of decompressive surgery and after decompressive surgery. Patients who did not receive recanalization therapy, CT was done baseline and after the decompressive surgery. Hemorrhagic transformations were classified according to radiological and clinical criteria [5]. Hemorrhagic infarction 1 (HI1) was defined as small petechiae along the margins of the infarct; HI2, as confluent petechiae within the infarcted area but no space occupying effect. Parenchymal hematoma 1 (PH1) was defined as blood clots in ≤30% of the infarcted area with some slight space-occupying effect; and PH2, as blood clots in >30% of the infarcted area with a substantial space occupying effect. Decompressive surgery was not performed in patients with space-occupying hemorrhagic transformation (parenchymal hemorrhage 1 and 2). Patients with known coagulopathy or systemic bleeding disorder, pre-stroke score on the mRS ≥ 2, contralateral ischemia or other brain lesion and another serious illness that could affect the outcome were excluded from the analysis.

Symptomatic intracerebral hemorrhage was defined as local or remote PH2 on the 24 h post-decompressive surgery CT scan combined with an increase of ≥4 NIHSS points from baseline or leading death [6]. Worsening of pre-existing petechial intracranial hemorrhage on the post-decompressive surgery CT scan with neurological deterioration (an increase of ≥4 NIHSS points from baseline) was also considered symptomatic intracerebral hemorrhage. Symptomatic intracranial bleeding, life-threatening infections and pulmonary embolism after decompressive surgery were considered major complications. Asymptomatic hemorrhagic transformations, hydrocephalus, the sinking flap syndrome or non-life-threatening infections, non-life threatening deep vein thrombosis and seizures, were considered minor complications.

Outcome was assessed 6 months after stroke using the modified Rankin scale (mRS). mRS scores of 0–3 were considered "favorable", and mRS scores of 4–6 were considered "poor" outcomes.

Briefly early decompressive surgery consisted of a large flap removal and a duroplasty. A bone flap diameter was at least 12 cm (always including the frontal, temporal and parietal bones). In surviving patients, cranioplasty was performed after 6 months with acrylate.

≈0.6 mg/kg (60 mg max) intravenous (IV) tissue plasminogen activator (rt-PA) was administered within 3 h of symptom over 40 minutes followed by endovascular treatment [7]. All endovascular procedures were performed under conscious sedation within 6 h of symptom onset. A heparinized saline solution was continuously perfused through the catheter during the procedure. Mechanical thrombectomy with stent retrievers or thromboaspiration with penumbra system and/or intra-arterial thrombolysis was performed as an endovascular treatment. TREVO (Stryker Neurovascular) or REVİVE (Cordis) stent retrievers were used as a mechanical thrombectomy device. Patients who did not receive combined acute stroke treatment were routinely given 300 mg of aspirin. Apart from decompressive surgery, standard medical treatment was based on published guidelines for the early management of patients with ischemic stroke in both groups [8].

Stroke type was determined using the Trial of Org 10172 in Acute Stroke Treatment (TOAST) trial criteria after the diagnostic work-up was completed [9].

Fisher exact test, independent t test and Mann–Whitney *U*-test were done to compare the outcome, baseline characteristics and complications of ultra-early DC in patients who received IV rt-PA and endovascular stroke treatment with patients without prior recanalization therapy. A two-sided p value <0.05 was considered statistically significant.

3. Results

30 consecutive patients were assessed. Of these patients, 12 (40%) patients were treated with a combined IV rt-PA and endovascular approach and 18 patients received standard treatment before early decompressive surgery. Ten patients underwent mechanical thrombectomy or thromboaspiration. Two of 10 patients were treated with penumbra thromboaspiration system, and 8 were with stent retrievers. Only two patients underwent intra-arterial thrombolysis without mechanical thrombectomy or thromboaspiration. One patient with a tandem occlusion of the proximal internal carotid artery underwent carotid angioplasty before distal mechanical thrombectomy. The mean age was 46.2 ± 13.5 years in standard treatment group and 52.9 ± 11 in multimodal acute stroke treatment group ($p < 0.05$). There were no clinically relevant differences in baseline demographic and clinical characteristics between multimodal acute stroke treatment group and standard treatment group (Table 1). Stroke etiologies did not differ between two groups (Table 1). Mean time from symptom onset to decompressive surgery did not differ between two groups (Table 1). Two of 12 patients (%) in combined stroke treatment group and two of 18 patients (%) in standard treatment group revealed signs of uncal herniation prior to decompressive surgery ($p > 0.05$). The ischemic stroke affected the dominant hemisphere in 7 (%67) patients in combined stroke treatment group versus 12 patients (%58) in standard treatment group ($p = 0.712$). Five patients (42%) had an additional anterior cerebral infarction in combined stroke treatment group and 7 patients (39%) in standard treatment group ($p > 0.05$). Malignant MCA infarction was observed in three of the 12 patients despite complete recanalization of occluded MCA in the multimodal acute stroke treatment group.

The proportion of patients with an mRS ≤ 3 at the 3-month follow-up was 33% in the standard group and 42% in the combined stroke treatment group ($p = 0.712$) (Table 1). Mortality did not differ between two groups ($p > 0.05$). In the combined stroke treatment group, one of three patients died because of symptomatic ICH. Two patients died due to progressive swelling of the infarct. Three patients in the standard treatment group died due to the ischemic edema. Major complications after decompressive surgery did not differ between two groups ($p > 0.05$). One patient in the standard group and one patient in the combined acute stroke treatment group had symptomatic PH2. Both patients had pre-existing hemorrhagic infarction type 2 that was detected by cerebral CT prior to decompressive surgery. One patient in combined stroke treatment group and two patients in the standard group experienced brain abscess. Minor complications were not statistically different between these two groups ($p = 0.458$) (Table 1). In the combined