# Benefits of Stroke Treatment Using a Mobile Stroke Unit Compared With Standard Management

## The BEST-MSU Study Run-In Phase

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***Background and Purpose***—Faster treatment with intravenous tissue-type plasminogen activator (tPA) is likely to improve outcomes. Optimizing prehospital triage by mobile stroke units (MSUs) may speed treatment times. The Benefits of Stroke Treatment Delivered Using a Mobile Stroke Unit (BEST-MSU) study was launched in May 2014 using the first MSU in the United States to compare stroke management using an MSU versus standard management (SM). Herein, we describe the results of the prespecified, nonrandomized run-in phase designed to obtain preliminary data on study logistics.

***Methods***—The run-in phase consisted of 8 MSU weeks when all-patient care occurred on the MSU and 2 SM weeks when the MSU nurse met personnel on scene or at the emergency department to ensure comparability with MSU patients. Telemedicine was independently performed in 9 MSU cases.

***Results***—Of 130 alerts, 24 MSU and 2 SM patients were enrolled. Twelve of 24 MSU patients received tPA on board; 4 were treated within 60 minutes of last seen normal, and 4 went on to endovascular treatment. There were no hemorrhagic complications. Four had primary intracerebral hemorrhage. Agreement on tPA eligibility between the onsite and telemedicine physician was 90%.

***Conclusions***—The run-in phase provided a tPA treatment rate of 1.5 patients per week, assured us that treatment within 60 minutes of onset is possible, and enabled enrollment of patients on SM weeks. We also recognized the opportunity to assess the effect of the MSU on endovascular treatment and intracerebral hemorrhage. Challenges include the need to control biased patient selection on MSU versus SM weeks and establish inter-rater agreement for tPA treatment using telemedicine. **(*Stroke*. 2015;46:3370-3374. DOI: 10.1161/STROKEAHA.115.011093.)**

**Key Words:** ambulances ■ emergency medical services ■ stroke ■ telemedicine ■ tissue-type plasminogen activator



The relationship of treatment success with time from stroke symptom onset to initiation of treatment with tissue-type plasminogen activator (tPA) has been confidently established by clinical trials and pooled analyses.[1–6] One way to speed treatment may be by optimizing prehospital triage systems of stroke care, so that tPA can be administered within the first 60 minutes after symptom onset when it is likely to have its greatest effect. However, despite efforts to streamline these systems, most patients are treated beyond 2 hours.[7] The establishment of the first mobile stroke units (MSUs) in Germany and the United States has made earlier identification and treatment of ischemic stroke a reality and provides the potential to substantially improve outcomes.[8,9] The process and logistics of establishing the first MSU in the United States in Houston, TX, and initiating the Benefits of Stroke Treatment Delivered Using a Mobile Stroke Unit (BEST-MSU) study compared with standard management by emergency medical services (EMS) study have been published previously.[10]

Herein, we describe the results of the prespecified, nonrandomized run-in phase of the study and summarize the initial lessons learned during this implementation phase. Given that ours was the first MSU to be established in the United States, we had no experience using such a paradigm of delivering stroke care. The purpose of the run-in phase was thus to test and finalize the system of communication with EMS to coordinate dispatch of the MSU, determine the expected enrollment rate and demographics of patients to be enrolled into the randomized phase, establish the logistics of simultaneous independent on site and remote telemedicine patient assessment, and test EMS response to having standard management (SM) weeks when the MSU was not deployed. These data were intended to help prepare for and finalize the logistics of the randomized phase of the BEST-MSU study when

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weeks would be randomized to those when the MSU would be deployed and used for evaluation, treatment, and transport (MSU weeks) versus those when we would be alerted to evaluate the patient without the MSU with patients receiving current SM by EMS and the emergency department (ED; SM weeks).

## Methods

The details and processes of organizing and establishing the first MSU in the United States have been published previously in detail.[10] This study was approved by the University of Texas Committee on the Protection of Human Subjects, and informed consent was obtained from all patients. On May 14, 2014, the run-in phase began with calls to the MSU team from the EMS dispatch center and first responders. We created 3 sequential steps for patient inclusion into the study (Table 1). The first was alerting the MSU team by EMS. The second occurred once the MSU vascular neurologist (VN) or registered nurse (RN) first evaluated the patient on site and, after initial assessment, decided that the patient probably had a stroke and possibly would qualify for tPA once further evaluation occurred. This was the point of study enrollment, and the determination was mainly based on history on time from symptom onset and evidence consistent with acute stroke on screening neurological examination. The third step was final determination of tPA eligibility based on all data on completion of computed tomography (CT), baseline laboratories, and re-evaluation of history and examination. On MSU weeks, the team was notified of the patient location and met EMS either on scene or by rendezvous en route to the destination ED. On SM weeks, the RN was notified of the patient location and met EMS either on scene or at the destination ED. On MSU weeks, the MSU was staffed from 8 AM to 6 PM by a CT tech, a VN, a RN skilled in stroke management, 1 of 5 off-duty Houston EMS paramedics, and for 9 cases a remote VN via telemedicine. On MSU weeks, the VN and RN decided about enrollment and tPA eligibility, and once the patient was enrolled in the study, all further care took place on the MSU. On SM weeks, the RN met EMS on scene or at the same EDs and during the same hours as on MSU weeks to determine whether they should be enrolled in the study and were tPA eligible. More MSU weeks than SM weeks were planned because MSU weeks required assessment of the logistics of MSU dispatch, travel times, en route and on-scene communication and coordination with EMS, and on-board patient management, whereas patient management on SM weeks proceeded along SM pathways already in place.

## Results

During the 10-week run-in phase, the MSU was dispatched on 130 occasions or roughly 2.7 per day and called off en route to the scene on 41 of these calls after the first responders deemed the patients as ineligible for the study once they arrived on scene. On 65 other occasions, the MSU team on arrival determined the patient to be ineligible for the study.

Twenty-four patients met criteria for enrollment during the 57 MSU days (8 weeks) and 2 during the 14 SM days (2 weeks; Table 2). During the MSU days, 13 of the 24 patients were deemed tPA eligible; 12 were treated with tPA on the MSU, and 1 was not treated until arrival in the ED because of malfunction of the MSU i-STAT international normalized ratio device (Abbott Point of Care Inc., Princeton, NJ). On the SM days, 1 of the 2 patients was deemed tPA eligible who received tPA in the ED. Of the 14 MSU+SM tPA eligible patients, 4 had baseline modified Rankin Scale (mRS) score of >1.

Four of the 26 enrolled patients were found to have primary intracerebral hemorrhage after CT scanning on the MSU, all of whom had their blood pressure treated on board. One had an acute subdural hemorrhage. Three patients had seizures on board the MSU, which were thought to be the cause of their presentation and were treated with antiepileptic medications on board the MSU. Two patients had complete resolution of symptoms before tPA was started, and 1 patient was deemed ineligible for tPA because of uncertainty about his/her time of symptom onset. One enrolled SM patient was not tPA eligible once further evaluation uncovered a history of previous trauma.

Of the 12 patients treated with tPA on the MSU (Table 3), 4 (33%) were treated between 0 and 60 minutes of symptom onset, 4 between 61 and 80 minutes from onset, and 4 between 81 and 270 minutes of onset. The average time from EMS activation by a 911 call to tPA bolus was 47 minutes (range, 37–60 minutes). Average baseline National Institutes of Health Stroke Scale score was 10, and average on-scene time from MSU arrival to tPA bolus was 25 minutes (range,

**Table 1. Algorithm for Patient Selection**

| | |
|---|---|
| (1) Criteria to alert MSU team (by either a, b, c, or d, and meeting all criteria i–iv) | (a) HFD, Bellaire or West University EMS dispatch center identifies a possible stroke 911 call |
| | (b) EMT or paramedic on scene recognizes a possible stroke |
| | (c) MSU team identifies a possible stroke by monitoring EMS communications |
| | (d) EMS base station is notified by EMTs about a stroke patient en route to one of the CSCs |
| | (i) LSN on the same day as 911 call to EMS dispatch, and after awakening |
| | (ii) EMS decision to transport the patient to one of the CSCs within predesignated catchment area |
| | (iii) Call to dispatch within pre-established hours of availability |
| | (iv) >18 y old |
| (2) Criteria for MSU team to enroll patients into study | (i) LSN possibly within 4 h 30 min |
| | (ii) History and physical/neurological examination consistent with acute stroke |
| | (iii) No definite tPA exclusions per guidelines,[11] before CT scan or baseline laboratories |
| | (iv) Informed consent obtained from patient or legal representative. Prehospital management and treatment, including IV tPA, not delayed for consent; consent must eventually be obtained for data to be retained for analysis |
| (3) Criteria for tPA eligibility | (i) Meeting all inclusion/exclusion criteria according to current AHA guidelines[11] |

AHA indicates American Heart Association; CSC, Comprehensive Stroke Center; CT, computed tomography; EMS, Emergency Medical Services; EMT, Emergency Medical Technician; HFD, Houston Fire Department; IV, intravenous; LSN, last seen normal; MSU, mobile stroke unit; and tPA, tissue-type plasminogen activator.

**Table 2. Baseline Characteristics of Enrolled Patients During the Run-In Phase**

| All patients (n=26) | |
|---|---|
| Age, y, mean | 64 |
| Sex, male/female, n | 13/13 |
| Hypertension, n | 16 |
| Diabetes mellitus, n | 4 |
| Hyperlipidemia, n | 9 |
| Atrial fibrillation, n | 5 |
| Baseline NIHSS, mean (range) | 11 (3–25) |
| Baseline mRS, n (%) | |
| 0 | 15 (57) |
| 1 | 1 (4) |
| 2 | 2 (8) |
| 3 | 3 (11) |
| 4 | 4 (15) |
| 5 | 1 (4) |
| Final diagnosis, n | |
| Acute ischemic stroke | 11 |
| TIA | 1 |
| ICH | 4 |
| Seizure | 4 |
| Other | 6 |

ICH indicates intracerebral hemorrhage; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and TIA, transient ischemic attack.

17–42 minutes). There were no hemorrhagic or other clinical complications and no technical malfunctions of the CT scanner or the MSU ambulance. The intravenous infusion pump malfunctioned on 1 patient, and the i-STAT device malfunctioned on 1 occasion when it was exposed to temperatures above 85°F outside the MSU. Telemedicine assessment of the patient was attempted in 9 cases. There were no telemedicine malfunctions and 90% agreement (ie, 8 of 9 patients) between the remote and on-site VN for tPA eligibility and disagreement in 1 case. Four of the 12 MSU tPA patients had endovascular treatment with an average symptom onset to groin puncture time of 175 minutes (range, 140–224 minutes). Ninety-day mRS score was 0 or 1 in 4 of the 12 tPA-treated MSU patients and was within 1 point of baseline mRS in 3 who had baseline mRS score of >1. Of the 12 patients, 1 patient died because of causes unrelated to cerebrovascular pathology and 1 was lost to follow-up.

## Discussion

The run-in phase of the BEST-MSU study provided us with the following important information. First, we treated about 1 patient with tPA for every 10 alerts of the MSU, averaging ≈1.5 treatments per week, with 33% treated within the first hour. These data have helped us plan how long we will have to carry out the randomized phase of the BEST-MSU study to reach our desired sample size and also suggested that our hypothesis (that we could treat relatively large numbers of patients more quickly than with SM) was worth pursuing in a larger trial. Our average door-to-needle time of 25 minutes on the MSU where all diagnostic equipment, medications, and skilled treatment team are located in 1 dedicated space and immediately available is comparable with the fastest ED door-to-needle times reported in the literature.[12]

Second, we learned that we were able to enroll patients into the study and determine tPA eligibility on SM weeks. This was not surprising because SM management did not require any change in current management pathways other than alerting the MSU team and meeting EMS and the patient on site or at the ED. However, we also found that enrollment was slower on SM weeks than on weeks when the MSU is deployed, which will affect our power calculations. One reason is that first responders were more reluctant to notify us once they found that the MSU would not be responding. This has prompted us to institute a second level of MSU team alert from the central telemetry center. It is a Houston Fire Department requirement that EMS squads notify this center when en route to an ED with a stroke or any other major emergency on either MSU or SM weeks. We also realized that because allocation of MSU versus SM weeks is not blinded, we would have to adjudicate all treatments by another investigator blinded to MSU versus SM group allocation to assure comparability of the groups.

Third, we realized that in the real world, ≈30% of patients who qualify for treatment with tPA have pre-existing disability. These patients have been excluded from most randomized trials to date because the most common outcome used to measure success has been the mRS dichotomized to achieving a

**Table 3. Characteristics of Patients Receiving tPA on the MSU (n=12)**

| | |
|---|---|
| Distance from base station, miles, mean | 6.7 |
| MSU on scene to tPA time, min, mean (range) | 25 (18–42) |
| LSN to tPA time, min, mean (range) | 98 (47–265) |
| Baseline NIHSS, mean (range) | 10 (3–19) |
| Baseline mRS, n (%) | |
| 0 | 7 (58) |
| 1 | 1 (8) |
| 2 | 0 (0) |
| 3 | 2 (17) |
| 4 | 2 (17) |
| 5 | 0 (0) |
| 90-day mRS, n (%) | |
| 0 | 2 (18) |
| 1 | 2 (18) |
| 2 | 1 (9) |
| 3 | 1 (9) |
| 4 | 2 (18) |
| 5 | 2 (18) |
| 6 | 1 (9) |
| Total endovascular interventions | 4 |
| LSN to groin puncture time, min, mean (range) | 175 (140–224) |
| Door to groin puncture time, min, mean (range) | 101 (77–124) |

LSN indicates last seen normal; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; MSU, mobile stroke unit; and tPA, tissue-type plasminogen activator.

score at 90 days of <1 versus higher.[13] Therefore, we have little data on expected 90-day mRS outcomes in patients with pre-existing disability. We will need to obtain such data because patients with pre-existing disability, advanced age, and comorbidities will be an important component of those served by any MSU. Furthermore, we need to consider using an outcome measure such as the utility weighted mRS that will be more sensitive to improvements in outcomes in this subset of patients.[14]

Fourth, we are reassured that remote telemedicine assessment independent of the decision being made by the on-site VN is possible. Recently, we demonstrated the feasibility and accuracy of telemedicine assessment of actors stimulating patients with stroke in ambulances using existing technology.[15] Our telemedicine success rate (100%) and agreement on tPA eligibility (90%) in this run-in phase suggest that telemedicine might be a reliable way to replace the on-site VN even in a rushed, crowded MSU, although this needs confirmation in a much larger sample. Also, in reviewing the literature, there are no data on the inter-rater agreement between ≥2 VNs evaluating the same patient in person in the ED. Such a study is needed to interpret if the remote versus on-site VN agreement on the MSU is comparable.

Fifth, earlier evaluation soon after symptom onset may result in a larger number of stroke mimic patients being treated with tPA on board the MSU. Ebinger et al[9] did not find this to be the case, but our preliminary data suggest otherwise, despite having experienced personnel making the neurological assessment. The incidence and type of stroke mimics and transient ischemic attack patients treated with tPA on the MSU in comparison with SM and the rate of treatment complications will be an important component of the overall evaluation of the MSU concept.

Sixth, we learned that the MSU and its equipment are reliable for daily use but that the CT scanner requires daily tube warm-up, calibration, cleaning, and trouble-shooting each morning and that the point-of-care i-STAT cannot be moved out of the MSU into ambient hot or cold temperatures. Not having backup equipment is a potential problem on the MSU. Although some of our equipment, such as infusion pumps, are backed up with replacements, backing up all equipment would be cost prohibitive and so far has not been necessary. Like our other equipment on board, such as the CT scanner, monitors, and telemedicine cameras, when used properly, our i-STAT is reliable and concordant with data obtained in the hospital.

Seventh, it will be important to have protocols in place for managing blood pressure in patients with intracerebral hemorrhage (4 of the 24 MSU patients had an intracerebral hemorrhage). The implementation of the MSU has made the management of hemorrhagic stroke faster, with earlier blood pressure reduction based on the most recent guidelines.[16] Having intravenous antihypertensive medications on board the MSU with experienced medical personnel familiar with their use and titration makes the hyperacute management of hemorrhagic stroke potentially more effective. Because hemorrhage enlargement occurs more frequently early in the course of intracerebral hemorrhage,[17–19] the MSU might be a useful venue for testing out new therapies to limit bleeding.

Finally, given recent evidence from clinical trials showing the efficacy of endovascular therapies for large-vessel strokes,[20–24] it is vital for triage processes in acute stroke care to be modified in a manner that promotes efficient transitions from the prehospital to the inpatient setting to reduce onset- and door-to-recanalization times. The identification of patients with large-vessel occlusions in the MSU can potentially save time by bypassing unnecessary triage delays in the ED. To date, we have not been carrying out CT angiography on board our MSU. Although doing the CT angiography on board may not save time in most cases, it may be of particular value in helping direct questionable cases to a comprehensive stroke center with endovascular capability rather than to a primary stroke center.

Conclusions from this run-in phase are limited by the small number of patients and shortness of the study period. However, the purpose was not to reach any conclusions about outcome but rather to gain familiarity with the BEST-MSU study processes to identify problem areas and unforeseen obstacles or opportunities. The BEST-MSU study randomizing MSU versus SM weeks will be sufficiently powered to address the specific aims of whether tPA eligible patients managed on MSU weeks have better patient-centered outcomes than those managed on SM weeks, whether telemedicine assessment on the MSU is reliable and accurate, and a formal cost–benefit analysis of MSU versus SM management.

## Conclusions

The run-in phase of the BEST-MSU study has provided important information that has helped in the final design and execution of the randomized study. Important lessons learned include the need to reduce bias because of the lack of concealment of treatment allocation, using an end point that will allow assessment of outcome in patients with baseline disability, the need to determine the normal rate of agreement among experts pertaining to tPA treatment, the need to carefully asses the rate and outcome of stroke mimics that will probably occur with substantially earlier treatment on the MSU, and the potential for MSU management to have a positive effect on endovascular success.

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## Disclosures

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