

The Golden Hour in Acute Stroke

BEST-MSU Sub-Analysis Confirms Benefits of Early Thrombolysis



By Jason S. Mackey, MD

Time is brain but we have struggled to translate that into faster treatment times in clinical practice. Nation-wide only

about 1.5% of patients are treated within 60 minutes of last known normal (LKN) despite various quality improvement initiatives over the years. By reducing time to treatment by 30 minutes on average, MSUs help treat more patients in that so-called golden hour.

That MSUs improve clinical outcomes has now been shown in several large clinical trials, including the BEST-MSU study.

One of the preplanned secondary analyses of BEST-MSU was to evaluate the predictors and outcomes of patients treated in the first 60 minutes after LKN. In our initial report 33% of patients in the MSU arm were treated in the first 60 minutes compared with only 3% in the standard management arm. The secondary analysis looked further at this subgroup and the findings were published in the journal *Stroke* earlier this year.

Overall 941 patients were treated with tPA: 599 in the MSU group and 342 in the standard management group. Of the 206 patients treated in the golden hour, 197 were treated on

the MSU. Treatment on the MSU, older age, male sex, alert via 911, faster arrival on-scene and imaging, more severe stroke, atrial fibrillation, and absence of heart failure and pretreatment antihypertensive treatment were independently associated with golden hour treatment.

Golden hour treatment was associated with almost double the odds of good clinical outcome (modified Rankin 0-1) at 90 days compared with later treatment (OR 1.87 [95% CI, 1.25–2.84]; P=0.003). Nearly a quarter of the patients in BEST-MSU had pre-existing disability and the benefits of golden hour treatment extended to that population as well.

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“Golden hour treatment was associated with almost double the odds of good clinical outcome (modified Rankin 0-1) at 90 days compared with later treatment. ... The key finding was that in the 25-50 minute time window the likelihood of good clinical outcome (modified Rankin 0-1) dropped by 3.5% every 5 minutes that elapsed... ”

Striking Evidence for Mobile Stroke Treatment: No Time to Wait Until Patients Arrive at Hospitals



By Heinrich J. Audebert, MD
President

Traditions have their value - but they can be a major barrier when innovations have been shown to be beneficial compared to what we have been used to.

Over the last year, several groups have published groundbreaking research on Mobile Stroke treatment effects on unselected or specific patients groups as well as MSU cost effectiveness. These and other analyses

have provided deeper insights into stroke pathophysiology and treatment effects during hyperacute stroke within 60 minutes from onset.

When Klaus Fassbender and colleagues published their letter on “Mobile Stroke Unit” for Hyperacute Stroke Treatment 20 years ago,¹ their concept was still based on rather limited data suggesting higher effectiveness of intravenous thrombolysis (IVT) in ischemic stroke when given earlier. Although the rationale was intriguing, many questions had yet to be answered: Was the available technology of CT scanners

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Mobile Stroke Unit News

**Semi-Annual Newsletter
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Note From the Editor

By Robert G. Kowalski, MD, MS



With this year-end issue of the PRESTO group newsletter, we finish out 2023 with a look back at important findings in the world of pre-hospital stroke care in the past year, with a particular focus on important sub-analyses of existing mobile stroke multi-center trials. And we begin to glance forward 2024, anticipating new developments in this gradually maturing field.

On the cover, Jason Mackey, MD, expounds on the results of analysis he and colleagues carried out on the BEST-MSU study sample focusing on patients treated within 60 minutes of last known normal, the so-called Golden Hour in stroke care. As the article notes: “Golden hour treatment was associated with almost double the odds of good clinical outcome (modified Rankin 0-1) at 90 days compared with later treatment.” The authors go on to note that in the 25-50 minute time window the likelihood of good clinical outcome (modified Rankin 0-1) dropped by 3.5% for every 5 minutes that elapsed.

Also on the front page, in his departing letter as PRESTO President, Heinrich Audebert, Professor of Neurology at Charité Universitätsmedizin, Berlin, Germany, anthologizes the robust body of evidence now established regarding the mobile stroke paradigm of care, since the advent of the concept two decades ago.

Bianca Oana Pirlog, MD and James Grotta, MD, in a sub-analysis of the BEST-MSU data, compared outcomes of acute stroke patients with a pre-existing disability treated with mobile stroke vs. standard ambulance management. Their work found patients with premorbid disabilities had better, but not statistically significant, outcome at 90 days, and more (56% vs.

44%) returned to at least their baseline mRS.

Babak B. Navi, MD, MS explores the complicated question of outcomes in averted stroke. This analysis of the BEST-MSU data included 159 patients (16%) with a tissue-defined averted stroke and 276 patients (27%) with a stroke with early symptom resolution. The authors conclude: “...in optimized stroke systems where more than 50% of patients receive thrombolysis within 90 minutes, approximately one in four will fully recover within 24 hours and one in six will have no demonstrable brain injury on imaging.”

Research studies in the Pre-hospital and mobile stroke paradigm continue to generate prolific conference presentations and journal publications. A selection of papers published in this field during 2023 is found on page 8. Meantime, the field of mobile stroke continues to expand as is depicted in the updated world map of existing and planned MSU centers on page 7 of this newsletter issue.

We are grateful for the articles contributed to the newsletter by authors on these important research developments in mobile stroke. The newsletter will continue to monitor these studies, and those in the pipeline, in the field of mobile stroke and airborne pre-hospital stroke care, we welcome any ideas and contributions for future issues of the Mobile Stroke Unit News.

Robert G. Kowalski, MD, MS is Clinical Research Instructor at the University of Colorado School of Medicine, Departments of Neurology and Neurosurgery, and is leading research on the university's Mobile Stroke Unit.



**International Stroke
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BEST-MSU Trial Sub-analysis

Disabled patients managed with a Mobile Stroke Unit

By *Bianca Oana Pirlog, MD*
and *James Grotta, MD*

In early 2021, my husband got accepted to a Fulbright fellowship in Houston, USA. Since we decided to travel together, my former supervisor, Prof. Dr. Amarencio Pierre, recommended I contact Dr. James Grotta, who accepted me for a research fellowship of 7 months at the Mobile Stroke Unit Department, Memorial Hermann Hospital, Houston, Texas.

My work there was focused on a sub-analysis regarding the outcomes of patients with pre-existing disability (PD) managed by mobile stroke units (MSU), compared to those managed by the EMS (emergency medical services) as well as those without disability (ND). We presented the results at the International Stroke Conference held in February 2023 in Dallas and later this year we published a paper in the International Journal of Stroke. We focused on this subject because there are little data on acute management for patients with PD.

In the BEST-MSU multicenter study, we observed that patients treated faster with tPA had a better clinical outcome at 90 days; of 1047 tPA-eligible patients included in the primary trial, 254 (24%) had mRS ≥ 2 (PD). We observed that patients with PD compared to those without PD were older, had higher NIHSS, more comorbidities, less often lived at home, were treated slower, and had less thrombectomy.



Bianca Oana Pirlog, MD



James Grotta, MD

As expected, ND patients had a better outcome at 90 days (uw-mRS) than PD patients. There was no difference between PD and ND patients in the rate of symptomatic intracerebral hemorrhage or stroke mimics. More than half (52%) of PD patients returned to at least their baseline mRS and those treated within the first hour had a better clinical outcome at 90 days than those treated later.

In the PD patient sub-group, those treated by MSU vs. EMS received tPA bolus faster,

and 24% of them were treated in the first “golden hour”. Furthermore, they had a better outcome at 90 days, however not statistically significant ($p=0.09$), and more (56% vs 44%) returned to at least their baseline mRS (Fig 1).

In conclusion, we observed that a patient’s baseline functional status did not interfere with the benefit of the MSU paradigm. Our data supports the earliest treatment for acute ischemic stroke for patients with a mRS ≥ 2 .

Bianca Oana Pirlog, MD, is a physician in the Department of Neurology, County Emergency Hospital Cluj-Napoca, Romania.

James Grotta MD is Director of Stroke Research, Clinical Institute for Research and Innovation, Memorial Hermann - Texas Medical Center

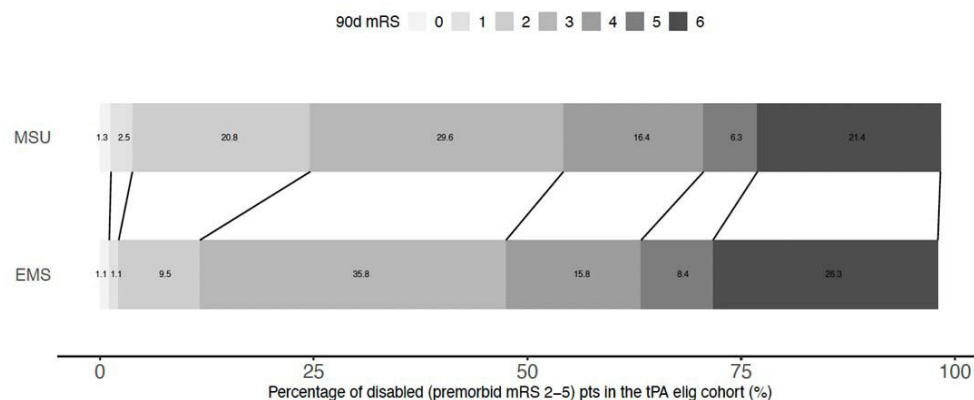


Fig.1 Distribution of 90-day mRS for PD (Disabled) tPA-eligible patients in the MSU (mobile stroke unit) and EMS (emergency medical services) groups.

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Favorable Outcomes Linked by Minutes to Speed of Stroke Care

Continued from Mackey, p. 1

More than two-thirds of patients treated in the first 60 minutes either returned to normal or to their baseline functional status.

Such a large cohort of patients treated in the golden hour also allowed for cubic spline analyses. The key finding was that in the 25-50 minute time window the likelihood of good clinical outcome (modified Rankin 0-1) dropped by 3.5% every 5 minutes that elapsed, while the drop was less precipitous in the 50-120 minute window at 1.3% every 5 minutes. Beyond 120 minutes the drop was only 0.1% every 5 minutes.

Faster treatment could prompt concern about additional harm. Reassuringly golden hour treatment was not associated with increased risk of asymptomatic or symptomatic intracerebral hemorrhage or with increased mortality at 90 days. Golden hour treatment was associated with reduced risk of treating neurovascular mimics as well.

The findings of this work underscore how time-sensitive acute stroke is and provide support for including MSUs as part of stroke delivery systems of care to improve outcomes.

Mackey J, Yamal JM, Parker SA, Silnes K, Rajan SS, Jacob AP, Wang M, Singh N, Jones WJ, Spokoyny I, Navi BB, Saver JL, Grotta JC; BEST-MSU Study Group. Golden Hour Treatment With tPA (Tissue-Type Plasminogen Activator) in the BEST-MSU Study. Stroke. 2023 Feb;54(2):415-425.

doi: 10.1161/STROKEAHA.122.039821. Epub 2023 Jan 23. PMID: 36689579.

Jason S. Mackey, MD, MS, is Associate Professor of Neurology at the Indiana University School of Medicine. He also serves as the director of the IU Mobile Stroke Unit.

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Averted Strokes Common in Optimized Stroke Systems

Full recovery Observed in One-Fourth of MSU Patients

By Babak B. Navi, MD, MS



While ultimately the goal of intravenous thrombolysis and other acute stroke reperfusion therapies, few data exist on the rate and predictors of averted stroke in optimized stroke systems

Therefore, we performed a secondary analysis of the BEST-MSU trial to determine the frequency and clinical factors associated with averted stroke in a large, controlled trial evaluating mobile stroke units (MSUs). The main study outcome was a tissue-based averted stroke, defined as a final diagnosis of stroke with resolution of presenting symptoms and signs by 24 hours attributed to thrombolysis and no infarction or hemorrhage on follow-up imaging. A secondary outcome was stroke with early symptom resolution, defined as a final diagnosis of stroke with resolution of presenting symptoms and signs by 24 hours attributed to thrombolysis, regardless of the presence of infarction or hemorrhage on follow-up imaging. This secondary outcome was meant to represent a time-based definition for averted stroke.

The primary analytical cohort included 1,009 suspected stroke patients treated with intravenous thrombolysis, including 644 assigned MSU care and 365 assigned standard management. Patient characteristics were similar between groups except the MSU group was slightly older and had lower rates of large vessel occlusions and thrombectomy.

The median last known well-to-thrombolysis times were 87 minutes for the overall cohort, 110 minutes for

“...this analysis demonstrated that in optimized stroke systems where more than 50% of patients receive thrombolysis within 90 minutes, approximately one in four will fully recover within 24 hours and one in six will have no demonstrable brain injury on imaging.”

patients assigned standard management, and 73 minutes for patients assigned MSU care. Importantly, 21.8% of the MSU group were treated within the golden hour.

There were 159 patients (16%) with a tissue-defined averted stroke, including 118 (18%) treated by MSU and 41 (11%) treated by standard management. In multivariable analysis, MSU care was associated with an estimated 82% increased odds for a tissue-defined stroke. Other associated factors included hyperlipidemia, female gender, lower NIHSS, lower blood pressure, and not having a large vessel occlusion. There was also a nonsignificant trend for more averted stroke with earlier thrombolysis.

Meanwhile, there were 276 patients (27%) with a stroke with early symptom resolution, including 200 (31%) treated by MSU and 76 (21%) treated by standard management. All patients diagnosed with tissue-defined averted stroke also met criteria for stroke with early symptom resolution. In multivariable analysis, MSU care was associated with an estimated 74% increased odds for a stroke with early symptom resolution. Other associated factors included earlier thrombolysis, normal prestroke functional status, younger age, hyperlipidemia, female gender, lower NIHSS, lower blood pressure,

lower glucose, and not having a large vessel occlusion.

Study findings were robust across multiple secondary analyses, including restricting the cohort to patients with confirmed large vessel occlusion, excluding patients with prior stroke, using secondarily adjudicated final diagnosis data, and excluding patients deemed ineligible for thrombolysis after expert review.

In conclusion, this analysis demonstrated that in optimized stroke systems where more than 50% of patients receive thrombolysis within 90 minutes, approximately one in four will fully recover within 24 hours and one in six will have no demonstrable brain injury on imaging. MSUs, which expedite thrombolysis by about 30 minutes, further increase the odds of averting stroke compared to standard management.

Earlier treatment time, particularly within the first 45 minutes, appears to be an important determinant of averted/early recovered strokes, although this relationship appears complex and likely varies according to individual patient factors. Future studies should investigate novel strategies to avert stroke, including neuroprotectants and newer generation thrombolytics. Additionally, stroke leaders and other stakeholders should consider the investment and implementation of MSUs to facilitate the rapid delivery of intravenous thrombolysis to appropriate patients with acute ischemic stroke.

Babak B. Navi, MD, MS is Associate Professor of Neurology, and Chief, Stroke and Hospital Neurology, Weill Cornell Medical College.

Robust Evidence Now Established in Mobile Stroke Paradigm of Care

Continued from *Audebert*, p. 1

robust enough for mobile use in ambulances? Was it safe to treat patients with IVT at the scene and to transport them on sometimes bumpy roads to the hospital? Were there enough medical professionals willing to staff such specialized ambulances? Would the association of earlier treatment and better outcomes hold during the hyperacute phase stroke or would it be outweighed by possible harms in non-stroke patients or treating just too many TIA patients? Would the incremental costs be justified and accepted in our societies?

With the increasing evidence of 'time is brain' not only for IVT but also for endovascular treatment (EVT) and the first proof of concept studies, the MSU movement picked up pace and the first studies showed remarkable time savings.^{2, 3} Over the last 10 years, we have seen stepwise answers to the above listed questions. Even after the publication of the large clinical studies showing substantial outcome improvements in patients who were eligible for IVT, it remained unclear whether specific subgroups such as hemorrhagic stroke patients or patients with pre-existing disabilities would benefit. While ischemic stroke patients with pre-existing disability obviously benefit as much as patients with the same subtype but no pre-stroke disability,^{4, 5} we had to learn that aggressive prehospital blood pressure lowering in hemorrhagic stroke patients was not associated with better outcomes.⁶ It is even more reassuring that in both recent large studies, the MSU effects remain clearly beneficial when not only ischemic stroke patients but all stroke and TIA patients are considered.^{7, 8} The additional number patients with favorable outcome after MSU dispatch was higher in the total cohort of the B_PROUD study (i.e. 114

patients) than in the primary population (only patients with no contraindication for IVT or EVT, 89 patients). These studies suggest that there may be beneficial effects of MSU care beyond IVT.⁸

MSUs can be considered cost-effective when using internationally recommended thresholds when operating MSUs in metropolitan areas.⁹

To better delineate the effects of mobile stroke treatment, it is very helpful to understand the effects of IVT in the ultra-early phase, hence in the first 60 minutes or 'Golden Hour' after symptom onset. Jason Mackey summarized the results of his groundbreaking research¹⁰ in this newsletter showing the time dependence curve is extremely steep during the first hour after stroke and then flattening to the shape we already knew from the pooled analyses of randomized controlled IVT trials.

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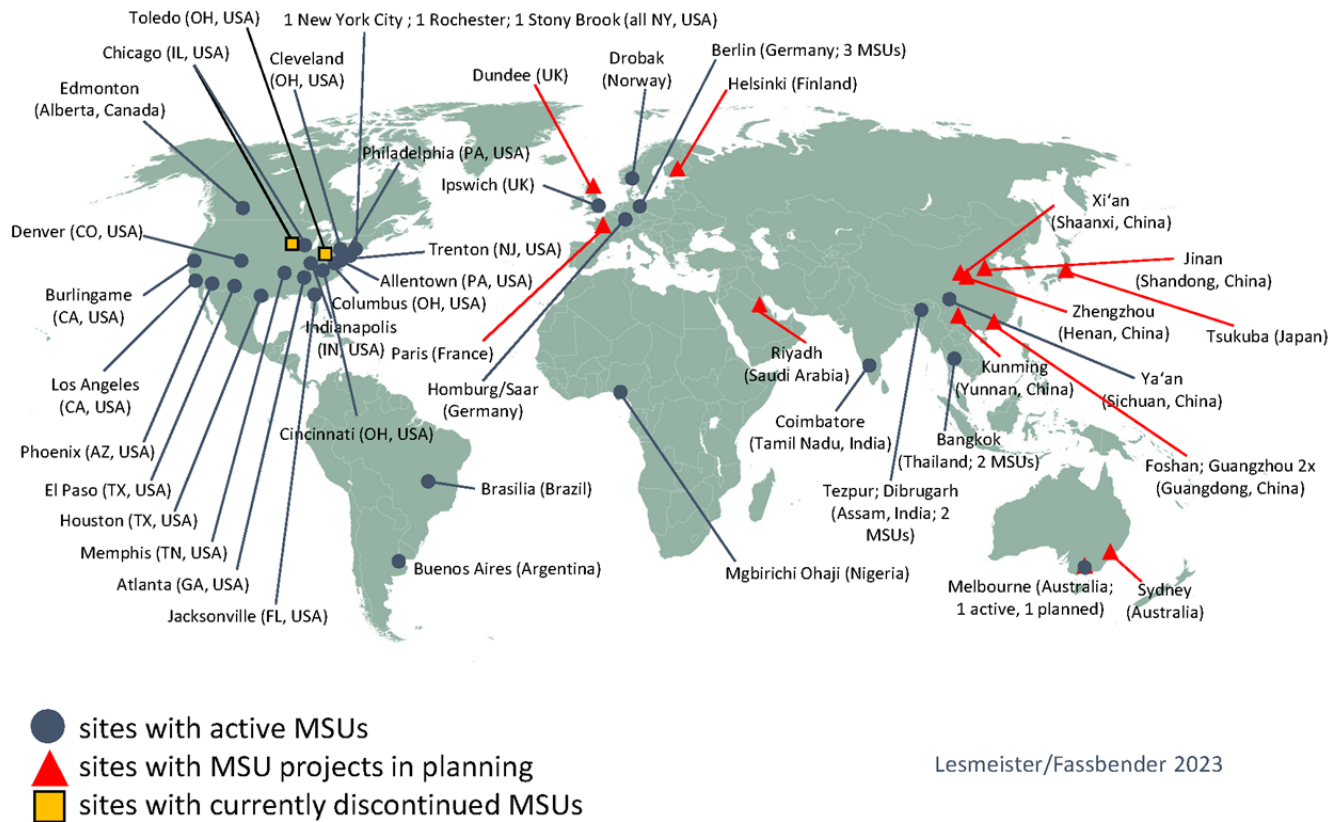
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Treating patients within this ultra-early time window not only improves functional outcome in general but makes total symptom remission and avoidance of imaging defined tissue damage much more likely.¹¹ And prehospital treatment may not only prevent the brain from immediate ischemic damage but also ameliorate the inflammatory cascade after stroke. The recent biomarker research by Robert Kowalski and colleagues convincingly illustrate that inflammatory processes are activated within 36 to 133 minutes after stroke and progress rapidly over time.¹²

With this increasing body of evidence and first recommendations for MSU care in international guidelines,¹³ it is time for a transition of MSU projects to become part of regular care.

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Evolving Landscape of Mobile Stroke Centers



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Select Mobile Stroke Publications 2023

Effect of Mobile Stroke Unit Dispatch in all Patients with Acute Stroke or TIA.

Rohmann JL, Piccininni M, Ebinger M, Wendt M, Weber JE, Schwabauer E, Geisler F, Freitag E, Harmel P, Lorenz-Meyer I, Rohrpasser-Napierkowski I, Nolte CH, Nabavi DG, Schmehl I, Ekkernkamp A, Endres M, Audebert HJ. Effect of Mobile Stroke Unit Dispatch in all Patients with Acute Stroke or TIA. *Ann Neurol*. 2023 Jan;93(1):50-63. doi: 10.1002/ana.26541. Epub 2022 Nov 24. PMID: 36309933.

Interdisciplinary interactions, social systems and technical infrastructure required for successful implementation of mobile stroke units: A qualitative process evaluation.

Bagot KL, Purvis T, Hancock S, Zhao H, Coote S, Easton D, Campbell BCV, Davis SM, Donnan GA, Foster S, Langenberg F, Smith K, Stephenson M, Bernard S, McGowan S, Yan B, Mitchell P, Middleton S, Cadilhac DA. Interdisciplinary interactions, social systems and technical infrastructure required for successful implementation of mobile stroke units: A qualitative process evaluation. *J Eval Clin Pract*. 2023 Apr;29(3):495-512. doi: 10.1111/jep.13803. Epub 2023 Jan 17. PMID: 36648226.

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Rapid Activation of Neuroinflammation in Stroke: Plasma and Extracellular Vesicles Obtained on a Mobile Stroke Unit.

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