

# Intra-arterial Stroke Treatment prior to the Stent-Retriever Era: High Mortality and Lack of Volume–Outcome Association

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*Background:* Mechanical thrombectomy for acute large-vessel occlusive stroke is beneficial when performed with stent-retriever devices; however, little is known about real-world experience with intra-arterial treatment (IAT). We aimed to clarify how hospitals influence outcomes for Medicare thrombectomy patients to inform future delivery of effective mechanical thrombectomy treatment. *Methods:* This is a retrospective cohort study that includes a Medicare fee-for-service patient population. Patients with a primary stroke discharge (ICD-9-CM 433.x1, 434.x1, 436) were included; billing codes were used to identify patients receiving IAT, intravenous thrombolytics (IVT), or a combination of these treatments. Characteristics of treated patients were summarized using descriptive statistics; long-term mortality was summarized via Kaplan–Meier curves; and multilevel logistic regression models with random hospital-level intercept were built to determine hospital influence on outcome and whether a volume–outcome association existed. *Results:* A total of 4557 patients received IAT at 544 hospitals. The mean age of IAT patients was 76 years. IAT patients had longer hospital stay (9.7 versus 6.8 days), longer stay in the ICU (5.5 versus 3.3 days), and greater probability of intubation (36.7% versus 9.5%) compared with IVT patients. Ninety-day mortality was 46% IAT versus 26% IVT. Hospitals had little influence on outcomes (intraclass correlation coefficient, <.01). No association between procedural volume and outcomes was identified. *Conclusions:* IAT for 2007–2010 was associated with higher patient mortality than recent and prior clinical trials. Treated Medicare patients were considerably older than clinical trial populations. Hospitals had little influence on mortality, and increased hospital volume was not associated with lower mortality. Future real-world experience should monitor these parameters as use of stent retrievers disseminates. **Key Words:** Mechanical thrombectomy—stent retrievers—volume–outcome relationships—surgical volume–outcome—endovascular stroke therapy. © 2016 National Stroke Association. Published by Elsevier Inc. All rights reserved.

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## Introduction

Intra-arterial treatment (IAT) using stent retrievers has recently been shown to substantially improve outcomes in patients with large-vessel occlusive stroke.<sup>1-5</sup> Prior to the recent stent-retriever trials, first-generation mechanical thrombectomy devices were in use for some time, although these devices have not been evaluated through randomized clinical trials and little is known about their real-world application and outcomes.<sup>6,7</sup>

Translating an efficacious treatment into an effective real-world treatment is a challenging process.<sup>8,9</sup> Broadly, this process requires ensuring that patient selection and treatment delivery/follow-up in the real world are sufficiently similar to the trial environment to ensure similar outcomes. To identify potential pitfalls in translating the efficacy of stent retrievers into real-world effectiveness, we explored the real-world experience of IAT in Medicare beneficiaries for the period 2007-2010, when patients were largely treated with first-generation devices. To this end, we pursued 3 goals: (1) to characterize real-world long-term mortality in IAT patients to determine if an efficacy-effectiveness gap may exist; (2) to characterize the patient population to inform if patient selection may differ between the real world and in trials; and (3) to determine the influence of hospitals on outcomes, for as with a wide variety of surgical conditions, higher-volume centers have better outcomes.

## Methods

We developed a retrospective cohort study including all Medicare beneficiaries treated for ischemic stroke from 2007 to 2010, thus capturing a large systematic sample of IAT patients at a wide variety of hospitals. As stent retrievers were not approved during this time interval, it is likely that mechanical thrombectomy patients in this population were treated with first-generation devices (e.g., MERCI and Penumbra trials). Patients were classified as receiving IAT only, a combination of IAT and intravenous thrombolytics (IVT), or IVT only.

### *Dataset/Measures*

All primary ischemic stroke discharges (ICD-9-CM 433.x1, 434.x1, 436) from the emergency department or via interhospital transfer were identified using Medicare's Medicare Provider Analysis and Review (MEDPAR) files—a dataset of all hospital discharges for Medicare fee-for-service beneficiaries.<sup>10,11</sup> IVT use was identified using a variety of strategies (DRG 559, MS-DRG 61-63, ICD-9 procedure code 99.10). Identifying IAT was more challenging as prior work has shown that procedure codes are unreliable for identifying IAT.<sup>12</sup> Consequently, we linked MEDPAR files to Medicare Part B (carrier) files—a claims database of all physician payments. This way, we were able to identify the use of IAT CPT Codes (37184-6, 37201,

and 75896) that occurred during the time course of a patient's hospitalization as defined by MEDPAR. This approach does not allow for a reliable differentiation, though, of IAT approaches (i.e., mechanical thrombectomy versus intra-arterial thrombolysis). Similar approaches have been used to identify other procedures that are unreliably recorded in hospital-based claims records.<sup>13</sup> Hospital IAT volume was calculated by summing the number of patients who received IAT only or a combination of IAT and IVT. Patients were identified as receiving combined therapy if the discharge met both IVT and IAT criteria. We determined 90-day and long-term mortality by linking the MEDPAR file to the Medicare Beneficiary Summary File. All patients in the cohort were able to be linked to the Medicare Beneficiary Summary File.

### *Statistical Analysis*

Long-term mortality was characterized using Kaplan-Meier curves stratified by treatment type (IAT versus IVT versus combined). To estimate the influence of hospitals on outcomes, we built multilevel logistic regression models with a random hospital-level intercept predicting each of our 2 primary outcomes of interest (90-day mortality and discharge home). Both models were adjusted for demographics, vascular risk factors, and all individual Charlson comorbidities.<sup>14</sup> The overall effect of hospitals on outcomes was characterized using the interclass correlation coefficient (ICC), which represents the proportion of variance explained by the model at the hospital level. To explore the effects of hospital characteristics, we then added hospital variables identified from claims or the Medicare cost report—IAT volume, stroke volume, number of beds in the hospital, academic status, and whether the was hospital rural or urban.

## Results

A total 4557 patients received IAT at 544 hospitals. In addition, 28,365 patients who received only IVT were also identified. IAT Medicare beneficiaries were on average considerably older than patients in the IAT trials (mean age 76 versus 71 years in the ESCAPE Trial, 69 years in the EXTEND-IA Trial, and 66 years in the MR CLEAN Trial). A majority of IAT patients were females, with a slightly higher representation compared to IAT trials: 56% versus 52% in ESCAPE, 51% in EXTEND-IA, and 42.1% in MR CLEAN trials. IVT patients were significantly more likely to have hypertension, hyperlipidemia, and diabetes than patients in the IAT or combination therapy groups. While stroke severity is not measured in this dataset, IAT patients likely had higher stroke severity than IVT patients, as they had a longer length of stay (9.7 versus 6.8 days), longer length of stay in the intensive care unit (5.5 versus 3.3 days), and a substantially higher probability of intubation (36.7% versus 9.5%). Additional patient characteristics are summarized in [Table 1](#).

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