Clinical trials and observational studies demonstrate that patients with acute stroke have better outcomes when cared for at designated acute stroke centers. Consequently, national guidelines from emergency medical service (EMS) organizations and from the American Stroke Association have recommended that EMS systems preferentially route patients with acute stroke to certified acute stroke centers known to be capable of rapidly and reliably delivering systematic stroke care. By the end of 2010, in the United States, 17 states and several additional counties, covering 53% of the national population, had legislation or regulation requiring EMS to set up regional systems of acute stroke care with preferential routing of patients with early stroke to stroke center facilities.

Methods

Data were obtained from the National Institute of Health Field Administration of Stroke Therapy-Magnesium (FAST-MAG) clinical trial. The study aimed to evaluate the impact of preferential routing of patients to stroke centers on sites of care, prehospital transport times, and research recruitment in the most populous county in the United States.

Results

There were 863 subjects enrolled before and 764 after emergency medical service preferential routing, with implementation leading to an increase in the proportion cared for at an ASC from 10% to 91% (P<0.0001), with a slight decrease in paramedic on-scene to emergency department arrival time (34.5 [SD, 9.1] minutes versus 33.5 [SD, 10.3] minutes; P=0.045). The effects of routing were immediate and included an increase in proportion of receiving ASC care (from 17% to 88%; P<0.001) and a greater number of enrollments (18.6% increase) when comparing 12 months before and after regional stroke system implementation.

Conclusions

The establishment of a regionalized emergency medical services system of acute stroke care dramatically increased the proportion of patients with acute stroke cared for at ASCs, from 1 in 10 to >9 in 10, with no clinically significant increase in prehospital care times and enhanced recruitment of patients into a prehospital treatment trial.

Clinical Trial Registration


(Stroke. 2015;46:2886-2890. DOI: 10.1161/STROKEAHA.115.010264.)

Key Words: emergency medical services ◼ emergency service, hospital ◼ prehospital emergency care ◼ stroke ◼ triage

However, during the rapid expansion of regionalized stroke care systems, formal studies of the effect on increasing access to stroke center care have been sparse. In addition, previous studies have not investigated the impact of regionalized routing on recruitment of patients into prehospital stroke treatment trials. We studied the impact of preferential routing of patients to stroke centers on sites of care, prehospital transport times, and research recruitment in the most populous county in the United States.

Methods

Data were obtained from the National Institute of Health Field Administration of Stroke Therapy-Magnesium (FAST-MAG) clinical trial.
trial,1 a phase 3 clinical trial of prehospital initiation of magnesium versus placebo for likely patients with stroke presenting within 2 hours from last known well time (LKWT). The detailed methods of the FAST-MAG trial have been published.4,5 Patients with likely stroke indicated by a positive Los Angeles Prehospital Stroke Screen and paramedic and physician-confirmed LKWT of within 2 hours were offered enrollment in the trial. The trial was conducted in Los Angeles County from 2005 to 2012 and in Orange County from 2010 to 2012. Cases entered into this study were confined to Los Angeles County. Los Angeles County has a population of 10 million racially and ethnically diverse inhabitants. The Los Angeles County EMS system is the largest in the United States, with 31 provider agencies, 238 paramedic ambulances, >2200 paramedics, and 69 adult emergency department (ED)—receiving hospitals.

In response to national6 and state7 recommendations, the deliberations of the Los Angeles County Stroke Task Force, and public stakeholder forums, the Los Angeles EMS Agency implemented a countywide stroke regional system of care on November 16, 2009. This regional policy was developed independently of the clinical trial and will continue to be implemented indefinitely. Before this date, paramedics transported patients with presumptive stroke to the nearest adult ED. After this date, EMS preferentially routed patients with presumptive stroke within 2 hours of LKWT directly to the nearest approved stroke center (ASC). However, if paramedic ambulance transport time was >30 minutes, the patient was medically unstable, or the patient requested a preferred non-ASC facility, they were transported to the nearest or preferred medical facility, whether or not it was an ASC. To be designated as ASCs, receiving hospitals had to (1) be certified as primary stroke center (PSC) by The Joint Commission (TJC; or equivalent national body), (2) sign a letter of understanding indicating that they would follow the policies required by Los Angeles EMS for ASCs, and (3) share prespecified data on individual cases transported to their facility with Los Angeles EMS.

The implementation of the Los Angeles County EMS Regional Stroke System during the period of performance of the FAST-MAG clinical trial afforded a unique opportunity to analyze data collected before and after policy enactment. FAST-MAG was a phase 3, National Institutes of Health–funded, randomized clinical trial assessing magnesium sulfate or placebo initiated by paramedics in the field within 2 hours of stroke onset being conducted throughout Los Angeles County.11 Entry criteria for FAST-MAG and selection criteria for routing to ASCs strongly overlapped. Both required patients to be identified as likely having acute stroke on a modified version of the Los Angeles Prehospital Stroke Screen and to be within 2 hours of LKWT.11,12 However, appropriate to a research trial, FAST-MAG had additional selection criteria, including the absence of severe renal failure, absence of prestroke disability, and systolic blood pressure between 90 and 220.14

Data collected prospectively in FAST-MAG analyzed for this report included date of enrollment, destination hospital, LKWT, time of paramedic arrival on-scene, time of ED arrival, and final diagnosis (ischemic stroke, transient ischemic attack, intracranial hemorrhage, and other). Neurological deficit severity at the time of paramedic encounter was rated on the Los Angeles Motor Scale.13 In addition, ASC or non-ASC status of destination hospitals on enrollment dates was determined for all enrolled patients from January 2005 to December 2012. Launch of the EMS routing policy occurred in the middle of this period, on November 16, 2009. During the prerouting period, 41 of the 69 adult ED receiving facilities in the county participated in the FAST-MAG trial, including all the medium and large stroke volume hospitals. At the initiation of the routing policy, 9 of the 67 adult ED receiving facilities (2 facilities closed) in the county were approved ASCs. By December 2011, the number of ASCs increased to 24, and by trial end in December 2012, the number of ASCs increased to 29. Patients were considered brought to a non-ASC if they were transported to a hospital that never became an ASC or were transported to a hospital that eventually became an ASC but before it acquired ASC status. Patients were considered brought to an ASC if they were transported to an ASC facility after it had acquired ASC status. All ASC hospitals in this study were certified as PSCs by TJC. Although every certified PSC hospital eventually sought approval as an ASC, the dates of certification (by TJC) and designation (as an ASC) may have differed. For the purposes of these analyses, we considered the date of ASC designation and not of PSC certification; however, there were no study cases presenting to a hospital achieving PSC certification but not ASC approval, and thus the terms ASC and PSC are used interchangeably in this study.

The impact of routing policy implementation on the proportion of patients accessing ASCs was analyzed over the entire 8-year study period. In addition, to minimize the effects of secular changes in care processes, the effect of routing policy on the use of tissue-type plasminogen activator and trial enrollment rate was examined in the narrower time band of the year before and 1 year after field triage policy start.

Results

From January 2005 to December 2012, there were 1627 enrollments in Los Angeles County, 863 (53%) before and 764 (47%) after adoption of the countywide EMS routing protocol. In the immediate periadoption period, during the 1 year before routing, 215 patients were enrolled, and during the 1 year after routing, 255 patients were enrolled. Clinical characteristics of patients enrolled before and after EMS routing are shown in the Table, and did not differ.

Figure 1 shows the number of enrolled acute likely patients with stroke receiving care at PSC/ASCs throughout the course of the study. Overall, in the ≈5 years before EMS routing, 90 of 863 (10%) patients were transported to a PSC. In contrast, in the slightly >3 years after EMS routing, 698 of 764 (91%) patients were transported to a PSC (P<0.001). Before introduction of routing, in the years 2005 to 2008, there was minimal or no increase in the proportion of patients treated at PSCs. The start of routing in 2009 had a substantial immediate effect, with further increases in the PSC care proportion throughout 2010 to 2012 as more facilities became designated stroke centers. By the final year of the study, 2012, 201 of 207 (97%) patients received initial care at a certified PSC. Over the entire study period, the introduction of preferential routing was not associated with an increase in the time interval from paramedic arrival on-scene to ED arrival (scene-to-door time). Scene-to-door time actually slightly decreased from the predetermination to the diversion period, 34.5 minutes (SD, 9.1 minutes) versus 33.5 minutes (SD, 10.3 minutes), P=0.045.

Figure 2 shows data from the focused analysis of the year immediately before and the year immediately after implementation of the EMS routing policy. During the baseline year, under the policy of transport to the nearest ED regardless of stroke center status, 215 subjects were enrolled in the field and transported to 44 receiving hospitals. In the postintervention year, under the destination policy of preferential routing to stroke centers, 255 subjects were enrolled in the field and transported to 27 receiving hospitals. The percentage of subjects transported to TJC-certified PSCs increased from 17% in the period before implementation to 88% after PSC diversion (P<0.0001; Figure 1). The mean monthly enrollment rate increased from 17.9 before to 21.2 after stroke center diversion. Time intervals from paramedic arrival on-scene to patient arrival at the ED (scene-to-door times) during the before and after stroke center routing periods were similar, 33.6 (SD, 9.7 minutes) before versus 34.8 (SD, 10.6 minutes) after, P=0.221, in the focused 2-year analyses. The number of patients who received intravenous tissue-type plasminogen activator after ED...
arrival increased from 49 to 60, an increase of 22%, although the rates of tissue-type plasminogen activator use among enrolled patients with ischemic stroke did not differ (23% versus 24%) in the 2-year period encompassing policy change.

Discussion

Our findings demonstrate that regionalized systems of stroke care can have an immediate and profound effect on acute stroke care processes. Implementation of a prehospital routing system to ASCs in the most populous county in the United States resulted in an immediate and dramatic increase in the proportion of patients with acute stroke cared for at certified PSCs. In the first year of implementation, the percentage of patients with hyperacute stroke (LKWT under 2 hours) cared for at TJC-certified PSCs quintupled, from <20% to ≈90% of eligible patients. The substantial increase

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall FAST-MAG Study Population</th>
<th>1 y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before (n=863)</td>
<td>After (n=764)</td>
</tr>
<tr>
<td></td>
<td>Before (n=215)</td>
<td>After (n=255)</td>
</tr>
<tr>
<td>Age, y, mean (SD)</td>
<td>69 (14)</td>
<td>70 (14)</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>366 (42%)</td>
<td>325 (43%)</td>
</tr>
<tr>
<td>Race</td>
<td>0.016</td>
<td>0.485</td>
</tr>
<tr>
<td>White</td>
<td>692 (80%)</td>
<td>568 (74%)</td>
</tr>
<tr>
<td>Black</td>
<td>95 (11%)</td>
<td>123 (16%)</td>
</tr>
<tr>
<td>Asian</td>
<td>67 (8%)</td>
<td>64 (8%)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (1%)</td>
<td>9 (1%)</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>200 (23%)</td>
<td>191 (25%)</td>
</tr>
<tr>
<td>LAMS score, median (IQR)</td>
<td>3 (2–5)</td>
<td>3 (1–5)</td>
</tr>
<tr>
<td>Final diagnosis</td>
<td>0.193</td>
<td>0.197</td>
</tr>
<tr>
<td>Cerebral ischemia</td>
<td>628 (73%)</td>
<td>563 (74%)</td>
</tr>
<tr>
<td>ICH</td>
<td>207 (24%)</td>
<td>165 (22%)</td>
</tr>
<tr>
<td>Other (ie, stroke mimic)</td>
<td>28 (3%)</td>
<td>36 (5%)</td>
</tr>
<tr>
<td>Time from 911 call to paramedic on-scene, min, mean (SD)</td>
<td>6.4 (3.1)</td>
<td>7.4 (3.9)</td>
</tr>
<tr>
<td>Time on-scene to ED arrival, min, median (IQR)</td>
<td>33 (28–40)</td>
<td>32 (27–39)</td>
</tr>
<tr>
<td>Intravenous tPA administered (% of cerebral ischemia, no. of treated/no. of cerebral ischemia)</td>
<td>29% (178/624)</td>
<td>42% (230/547)</td>
</tr>
<tr>
<td>Transported to an approved stroke center</td>
<td>10% (90/863)</td>
<td>91% (698/764)</td>
</tr>
</tbody>
</table>

FAST-MAG indicates Field Administration of Stroke Therapy-Magnesium; ICH, intracranial hemorrhage; IQR, interquartile range; LAMS, Los Angeles Motor Scale; LKW, last known well; and tPA, tissue-type plasminogen activator.

Figure 1. Yearly count of subjects enrolled by destination hospital without (No) or with (Yes) primary stroke center (PSC) certification.
in the proportion of patients cared for at certified PSCs is expected to have beneficial effects on clinical outcome based on previous clinical trials and observational studies. The systematic medical and nursing care provided at PSCs has been shown to improve outcomes for patients with hemorrhagia and for patients with ischemic stroke treated with lytics and treated with supportive care.2,3,17

In addition to improving access to stroke center care, implementation of EMS routing also drove a substantial increase in recruitment of patients into an National Institutes of Health trial of a potential prehospital neuroprotective agent for stroke. In the 1-year preintervention period, the FAST-MAG trial was active at 50 of the 69 receiving facilities in the County, accounting for >80% of patient transports in the county. However, patients being transported to the remaining 19 smaller hospitals could not be offered trial enrollment. Because all ASCs in the county were also active trial sites, after system implementation, more patients had trial facilities as their destination hospitals and could be offered trial enrollment. The Los Angeles experience is one of the first to demonstrate that regional systems of acute stroke can increase patient enrollment in studies of promising new therapies, an often envisaged potential benefit of care regionalization.18 Fewer destination hospitals receiving a greater share of patients with acute stroke can lead to more efficiency in clinical trial planning and better focus of resources.

This study’s findings confirm and extend previous reports of implementation of stroke centers in US urban regions. The pioneering system implementations in Houston and in 2 New York City boroughs were both associated with rapid and substantial increases in the proportion of patients cared for at designated facilities.19,20 The current study demonstrates this effect in a larger EMS system using TJC-certified, not locally certified, stroke centers and also uniquely shows a beneficial impact on research recruitment.

This study has limitations. The population recruited into FAST-MAG is a subset of patients covered by the regional routing policy, rather than all patients. However, none of the exclusion criteria, such as renal failure, absence of a consent provider, or patient declaration on trial participation, appear likely to confound analysis of routing impact. The study analyzed effects in the first 3 years after system implementation. At the end of this period, 29 hospitals had become ASCs and joined the regional system. In subsequent years, several additional facilities have joined, as the regional system continued to mature. With more facilities, a few additional geographic pockets in our system with no available ASC were filled in, likely allowing even a greater proportion of patients to be transported to an ASC and further decreasing field transport times.

We conclude that the impact of EMS regional stroke care organization is immediate and profound, has the potential to improve patient outcomes, and can substantially enhance patient recruitment into prehospital clinical trials.

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Disclosures
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Routing Ambulances to Designated Centers Increases Access to Stroke Center Care and Enrollment in Prehospital Research
FAST-MAG Investigators and Coordinators

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