ORIGINAL ARTICLE

Early stroke care in Italy—a steep way ahead: an observational study

G Citerio, D Galli, A Pesenti

Emerg Med J 2006;23:608–611. doi: 10.1136/emj.2005.032219

See end of article for authors' affiliations

Correspondence to: Giuseppe Citerio, Dipartimento di Medicina Perioperatoria e Terapie Intensive, Nuovo Ospedale San Gerardo, via Pergolesi, 33, 20052 Monza (MI) Italy; g.citerio@hsgerardo.org

Accepted for publication 17 March 2006

Objectives: To measure the performance of selected Italian emergency medical system (EMS) dispatch centres managing calls for patients suffering from stroke. Data on outcome and on early treatment in the ED were collected.

Methods: Prospective data collection for a trimester from interventions for a suspected stroke in 13 EMS dispatch centres over five Italian regions.

Results: Altogether, 1041 calls for a suspected stroke were analysed. Mean intervals of the sequential phases were 2.3 ± 2 minutes between call and ambulance dispatch, 8.4 ± 5.5 minutes to reach the patient, 14.5 ± 8.5 minutes on the scene, and 40.2 ± 16.2 minutes between call and arrival at the ED. Interventions were performed in 56% of cases by a basic life support (BLS) crew, advanced life support (ALS) crews intervened in 28% of cases, and a combination of ALS and BLS in the remaining 16%. Mean diagnostic interval was 99 ± 85 minutes between emergency system call and the first CT scan. This was performed 71 ± 27 minutes after ED admission. Only 1.6% were admitted to a stroke unit. One month outcome according to GCS was good recovery in 32%, moderate disability in 28%, severe disability in 14%, and death in 25% of the patients.

Conclusions: Mean times show a rapid response of the selected EMS dispatch centres to calls for a suspected stroke. Nevertheless, mean times of the ED phase are still unacceptable according to international guidelines such as Brain Attack Coalition and American Stroke Association guidelines. Efforts should be spent to reduce the time between the arrival and the CT scan and more patients should be admitted to a stroke unit.

Over the past decade, acute stroke has increasingly been accepted as a medical emergency characterised by rapidity of onset,^{1,2} poor prognosis,³ and requirement for prompt intervention. Although for decades stroke has represented an area of therapeutic nihilism, potentially effective treatments are now becoming available. The motto "Time is brain" (http://www.fda.gov/fdac/features/2005/205_stroke.html) summarises the concept of early assessment and treatment. Emergency medical system (EMS) services play a crucial role in this clinical path.^{4,5} As recently published in the European Stroke Initiative Recommendations,⁶ successful care of acute stroke victims depends on a four-step chain: rapid recognition and reaction to stroke warning signs, immediate use of EMS services, priority transport with notification to the receiving hospital, rapid and accurate diagnosis and treatment at the hospital. No data are available in Italy on the early EMS reaction to a call for a suspected stroke. We carried out an extended performance evaluation of EMS services in five Italian regions. This research was funded by the National Minister of Health. Along with other emergency diagnoses, such as ischaemic heart attack, cardiac arrest, and head injury, data on suspected stroke were prospectively collected. This observational study aimed at describing the response of the Italian EMS services to calls for a suspected stroke and the time required for a diagnosis and an early treatment in the emergency department (ED). Data on outcome were also collected but this was not our primary target.

MATERIALS AND METHODS

System configuration

The study was conducted in 13 selected EMS dispatch centres (Monza, Como, Pavia, Cuneo, Biella, Padova, Treviso,

Vicenza, Forlì, Ravenna, Rimini, Frosinone, Rieti) in Italy, named "118" for recalling their phone number, scattered in five Italian regions (Lombardia, Piemonte, Veneto, Emilia Romagna, Lazio). The assisted population of these "118" dispatch centres was about 6.5 million inhabitants and represented more than 12% of the national population. When 118 dispatch centres were activated for a suspected stroke victim, different typologies of ambulance crews were used. Volunteers, trained to perform basic life support (BLS) manoeuvres but not allowed to apply advanced life support (ALS) protocols, composed BLS crews. Advanced care was performed only by ALS crews composed of nurses and emergency physicians. Patients were usually admitted to the nearest hospital. As far as we know, during the study period no protocol was in existence at the admitting hospital for the management of acute stroke.

Data collection

Data collection was carried out prospectively for a trimester, from 5 November 2002 to 5 February 2003. A short training course was organised before the beginning of the data collection to diffuse the aims and the methods of the research and to instruct the participants in the use of a common language and in the application of the Face Arm Speech Test (FAST).⁷ Data were collected by EMS personnel in the prehospital phase and after hospital admittance.

Abbreviations: ALS, advanced life support; ASA, American Stroke Association; BAC, Brain Attack Coalition; BLS, basic life support; CT, computed tomography; ED, emergency department; EMS, emergency medical system; FAST, Face Arm Speech Test; GOS, Glasgow Outcome Scale; r-tPA, recombinant tissue plasminogen activator; SD, standard deviation; SPREAD, Stroke PREvention and Awareness Diffusion

Key messages

- No data are available in Italy on the early EMS reaction to a call for a suspected stroke. This is the first extended performance evaluation of EMS services in five Italian regions.
- EMS presented a quick out of hospital response for stroke victims. Nevertheless, the ED response is not acceptable because of the long delay to obtain a CT scan and to the paucity of patients admitted to a stroke unit.
- The need for developing better in-hospital diagnostic and therapeutic strategies for stroke victims and the need to manage stroke as an emergency is clear.

Design of the database and software interface

The collection form was designed to be used with a computer interface and was composed of different screen layouts covering general data (demography and intervention times), prehospital data (times and treatment), in-hospital data (times and treatment), and data on outcome (at 24 hours and at 1 month).

GC supervised all the development phases, discussing all the details from the ideation to the completion of the data collection with the participating centres. The software was developed using File Maker Pro, version 4 (Claris Corporation, Santa Clara, CA, USA). Anonymised data were sent using the Internet and collected in a database.

Inclusion and exclusion criteria

All suspected stroke, identified by structured telephone interview by dispatch nurses, were included in the data collection. No ethics approval/patient consent was required because of the observational nature of this study according to the national normative.

Outcome tracking

Outcome data collected were death at different time intervals (on the scene, at the ED, at hospital discharge, and at 1 month), and recovery using the Glasgow Outcome Scale (GOS)⁸ at 1 month. Data were collected by the emergency system personnel analysing ambulance and hospital records.

Statistical analysis

The methods used were largely descriptive. All summary data were expressed as mean $\pm$ standard deviation (SD). Means were compared by analysis of variance. Differences in proportions were analysed by the χ^2 test. A level of $p < 0.05$ was considered statistically significant.

RESULTS

Patient characteristics

We collected data on 1041 suspected stroke victims. Data on the studied population are summarised in Table 1. Mean population age was 78 ± 11 years. Subjects were more frequently female (56% (577)). Mean women's age was significantly higher (female 80.5 ± 11.7 v male 74.6 ± 12 years, $p < 0.001$). Calls were more frequent during the morning interval, 6 am to 2 pm (52%), followed by the interval 2 pm to 10 pm (34%), and lower during the night, 10 pm to 6 am (13%). Altogether, 91% of the requests were from home and 87% of the events were witnessed.

Out of hospital intervention times

The system response to the initial call can be summarised in the following intervals.

Table 1 Patients' characteristics on emergency medical system arrival evaluated with the Face Arm Speech Test (FAST)⁷ method

FAST ⁷	Facial droop	Arm drift	Speech
Normal	285 (43.4%)	234 (34%)	170 (22.6%)
Abnormal	372 (56.6%)	456 (66%)	583 (77.4%)

Interval between call and ambulance dispatch was 2.3 ± 2 minutes. This interval describes the time spent in performing the structured interview and the triage for the selection of a crew. Interventions were performed in 56% of cases by BLS crews, ALS crews intervened in 28% of cases, and a combination of ALS and BLS in the remaining 16%.

The interval required to reach the patient was 8.4 ± 5.5 minutes. Time spent on site was 14.5 ± 8.5 minutes. Interval between call and arrival at the hospital ED was 40.2 ± 16.2 minutes.

Early evaluation with the Face Arm Speech Test (FAST)⁷

Data on FAST prehospital scale evaluation were available in 79% of the cohort (804 patients) and are summarised in Table 1. Data were lacking mainly when BLS crews intervened. BLS crews reported the data in 75% of the cases, combined ALS and BLS in 80%, and ALS crews in 87% of the cases.

Only 84 patients (10.4%) did not show, at the EMS evaluation, any deficit at the examination with the FAST whereas 274 (34.1%) presented at least one abnormality, 199 (24.8%) at least two abnormalities, and the remaining 247 (30.7%) three abnormalities.

Physiological data and treatment on site

Mean arterial pressure on emergency crew arrival, available in 766 cases, was 154 ± 33 mmHg. A quarter of the population presented a systolic arterial pressure greater than 180 mmHg. Only 2% of the cohort presented a systolic blood pressure below 90 mmHg. Eight patients (0.7%) required inotropic support.

Mean oxygen saturation, evaluated with a pulse oxymeter in 656 cases, was $94 \pm 6\%$. Seventy patients (10.6%) presented an early desaturation defined as $SpO_2 < 90\%$. Oxygen had been delivered by mask in 62% of the cohort. Less than 2% of the cohort required endotracheal intubation (18 patients, 1.7%).

Physiological data and treatment on hospital arrival

Data on the hospital phase are limited in this research because of the fact that the data were collected by EMS personnel with limited access to hospital records. Mean arterial pressure on ED arrival, available in 952 cases, was 153 ± 31 mmHg. Twenty three per cent of the population presented a systolic arterial pressure greater than 180 mmHg and 1.8% of the cohort presented a systolic blood pressure below 90 mmHg. Mean arterial saturation, available in 626 cases, at arrival was $96 \pm 5\%$. Thirty nine patients (6.2%) presented a desaturation on arrival. None of the desaturated patients was intubated whereas 82.1% received oxygen by mask. In the subgroup in which oxygen saturation was available on site, out of hospital desaturation was reverted in 61% of the cases.

Early blood glucose determination was available only in 249 patients. Mean blood glucose at arrival was 8.7 ± 4.2 mmol/l. Low blood glucose (< 3.3 mmol/l) was present in 2.4% (six cases). Normoglycaemia, ranging from

3.8 to 6.6 mmol/l, was present in 31.7% (six cases). Hyperglycaemia was common: 36.5% (92) presented a value between 6.6 and 10 mmol/l and 29% (73) severe hyperglycaemia (>10 mmol/l). Even if it didn't reach any statistical significance, severe hyperglycaemia was associated with a trend of higher mortality at one month versus normoglycaemia (37% *v* 24%).

Computed tomography (CT) scan time

Data on time of the first neuroradiological evaluation were available only in 524 patients because of the reason cited above—that is, the collection was performed by the EMS. The mean interval between emergency system call and the first CT scan was 99 ± 85 minutes (median 88). First CT scan was performed 71 ± 27 minutes after ED admission. The CT scan findings, available in 680 cases, were compatible with acute ischaemic insult in 79% (534). Haemorrhagic intracranial findings were identified in 17.5% (119 patients) and other intracranial masses were identified in 3.5% (24).

Fibrinolysis

When this data collection was performed, the national legislation on fibrinolysis in stroke was not already available. For this reason, the use of r-tPA in this setting was an “off label” indication. Only two patients enrolled in the data collection received r-tPA.

Hospital admittance

Data were available in 1011 cases. Patient were admitted to 71 hospitals, with heterogeneous cases distribution (1–10 patients: 41 hospitals; 10–20 patients: 12 hospitals; 20–30 patients: 7 hospitals; 30–40 patients: 6 hospitals; 40–50 patients: 3 hospitals; >50 patients: 2 hospitals).

Fifty one patients (5.7%) were discharged from ED. Patients were admitted to hospital mainly to a medical ward (63%, 565). Only 172 (19%) were admitted to a neurological ward and 15 (1.6%) to a stroke unit. Thirty three were admitted to an intensive care unit (3.6%). The remaining cases were transferred to other hospitals.

Outcome

Early outcome was available in 870 patients. After 24 hours from the initial call, 84 patients were at home alive (9.6%). Deaths accounted for 49 cases (5.6%) and the remaining were still in hospital. Mean hospital stay had been 12 ± 11 days.

One month outcome (762 cases), according to the extended GOS, was good recovery in 32% (243), moderate disability in 28% (213), severe disability in 14% (113), and death in 25% (193) of the cases.

DISCUSSION

Following a worldwide trend aimed at improving the treatment of victims of stroke, national guidelines have also been produced in Italy.⁹ The development of the Italian Guidelines on Stroke⁹ has been a coordinated process, involving a multidisciplinary working group, the “SPREAD Collaboration” (Stroke PREvention and Awareness Diffusion), in which 33 different professional organisations and two patients' associations were represented. These guidelines have been widely used in our country and are free accessible from the website (<http://www.spread.it/> (accessed 10 May 2006)).

The aim of our study was to analyse on a large population the early treatment of victims of stroke, mainly in the out of hospital setting, exploring also the ED phase in order to compare the performance of these phases with what is required by the published guidelines.^{6–9–11}

The Italian guidelines⁹ state that “If there is a clinical suspicion of stroke, an urgent transportation to the nearest

emergency room is recommended, using the Emergency Medical System (EMS, 118) to speed transportation.” In our cohort we analysed data on patients that reached the hospital using EMS. We are not aware of the number and of the characteristics of the stroke population that reached the hospital using their own means of transport. Because of this, the study can not be used to estimate any annual incidence of stroke in the geographical area studied.

Data were collected by EMS personnel. This could explain the reason of an expanded amount of information in the prehospital phase and a reduced amount of information collected in the hospital phase.

The EMS responds to the call for a suspected stroke victim promptly. The patient is reached in about 10 minutes predominantly by a BLS crew. In 40 minutes from the EMS call the patient arrives at the hospital. These intervals, even if they could be improved, are acceptable and express the attitude of the EMS to deliver immediate assistance and hospital transport.

SPREAD guidelines⁹ recommend a specific training for EMS ambulance crews on early evaluation and appropriate management of suspected stroke victims. We instructed the participating centres to apply FAST evaluation. We have demonstrated that this simple evaluation instrument could be widely applied. Even if it was not a standard procedure before the observation period, eight out of ten patients have been evaluated with FAST.⁷ Pathological findings were recorded in 90% of the cohort. This shows that this evaluation instrument, for its simplicity, could be applied extensively and could help to identify patients with neurological deficits. The EMS ambulance personnel are also recommended to investigate for coexisting life threatening conditions. Patients were predominantly hypertensive both in the prehospital phase and at hospital arrival. No active treatment for hypertension has been used. Oxygen saturation was normal in the majority of the cohort; about 10% presented an oxygen desaturation even if less than 2% required a tracheal intubation. Oxygen was frequently administered on site and during transport; on admission to the hospital desaturation was present in less than 7%. Acute stroke is a medical emergency that deserves immediate admission to hospital as stated in the Helsingborg Declaration and in several guidelines,^{6–11} including SPREAD.⁹ All patients suffering cerebral vascular events should be admitted to a hospital to undergo a quick and accurate diagnostic work up in order to monitor and to treat possible complications. According to the Brain Attack Coalition (BAC)¹⁰ and American Stroke Association (ASA) guidelines,¹¹ the ED should perform a CT scan within 25 minutes from the admission and, in the absence of exclusion criteria, following the results of recent studies,^{12–20} intravenous or intra-arterial thrombolysis within 3 hours from the onset of stroke should be administered. Neuroimaging studies were obtained in our cohort with a delay compared with guidelines recommendations and, notably, few patients were admitted to a stroke unit. We have to underline that when the data were collected no clear indication for thrombolysis was available and its use was “off label”. For this reason, only two patients received thrombolysis and this could partially explain the long interval for neuroimaging.

CONCLUSIONS

This prospective data collection, performed to analyse the quality of the prehospital and ED treatment of patients suffering from stroke, revealed a quick response of the selected EMS Italian dispatch centres to this kind of emergency. Still, the response of the ED is not acceptable because of the delay to obtain a CT scan and to the paucity of patients admitted to a stroke unit.

ACKNOWLEDGEMENTS

All of the authors were involved in designing the study and collecting data. GC was involved in the statistical analysis. DG was responsible for translation into English. All authors read and approved the final manuscript. We gratefully acknowledge the medical and nurse personnel of the dispatch centres that collaborated on this data collection (118 Monza, Como, Pavia, Cuneo, Biella, Padova, Treviso, Vicenza, Forlì, Ravenna, Rimini, Frosinone, Rieti).

Authors' affiliations

G Citerio, D Galli, Anesthesiologist and Intensivist, NeuroIntensive Care Unit, Department of Perioperative and Intensive Care, Ospedale San Gerardo, Monza, Italy

A Pesenti, Università Milano Bicocca Giuseppe Citerio, Dipartimento di Medicina Perioperatoria e Terapie Intensive, Nuovo Ospedale San Gerardo, Monza, Italy

Funding: This research was funded by the National Minister of Health and by Direzione Generale Sanità-Regione Lombardia.

Competing interests: none declared.

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