

Report

□ **Stroke care policy and management in Italy**

S. FERRO, R. FACCHINI, M. MARCHETTA, G. PAGOTO, M. VIZIOLI

Servizio Presidi Ospedalieri, Direzione Generale Sanità e Politiche Sociali, Regione Emilia-Romagna, Italy

□ **INTRODUCTION**

The Organisation for Economic Co-operation and Development (OECD) and the European Commission's "Health at a Glance: Europe 2012" presents key indicators of health status, determinants of health, health care resources and activities, quality of care, health expenditure and financing in 35 European countries. According to this report, cardiovascular diseases are the main cause of mortality in almost all European Union (EU) member states, accounting for 36% of all deaths in the region in 2010.

Cardiovascular diseases encompass a wide range of illnesses involving the circulatory system, including Ischaemic Heart Disease (IHD, or heart attack) and cerebrovascular disease (or stroke). Together, IHD and stroke comprise 60% of all cardiovascular deaths, and caused more than one fifth of all deaths in EU member states in 2010. Thus, in Europe, stroke and other cerebrovascular diseases account for around 9% of all deaths and are the third most common cause of mortality. Stroke is also a major cause of adult disability, with around one third of all incident strokes leading to permanent sequelae and dependency.

As with IHD, there are large variations in stroke mortality rates across countries, and lower mortality in both can be at least partially attributed to a reduction in modifiable risk factors, namely tobacco smoking and hypertension. Improvements in medical treatment for stroke have also increased survival rates.

Treatment for ischaemic stroke has advanced dramatically over recent decades. Indeed, since the 1990s, clinical trials have consistently demonstrated the clear benefits of thrombolytic treatment in both European and non-European countries. Better survival with respect to the usual modes of care has also been ensured by the introduction of dedicated stroke units in many countries, as these facilitate timely and aggressive diagnosis and therapy for ischaemic and haemorrhagic stroke victims. However, whilst international data on stroke unit access is limited, there are some indications that access varies across and within countries.

As stroke survival reflects the *quality* of acute care, which involves treatment methods of proven effectiveness such as thrombolysis, it also serves as an indicator of the promptness and adequacy of care delivery. Consequently, stroke case-fatality rates have been used for hospital benchmarking within and between OECD countries.

While the standardised case-fatality rate for ischaemic stroke was about 5.4% on average across EU member states in 2009, the average standardised rate for haemorrhagic stroke is 20.2%, about four times greater than the rate for ischaemic stroke, reflecting the more severe effects of intracranial bleeding. Between 2000 and 2009, case-fatality rates for ischaemic stroke declined by over 20% across EU member states. These reductions suggest overall improvements in the quality of care for stroke patients, although this is not true for all countries. Indeed, the overall reduction in case-fatality rates can be at least partially attributed to

the high level of access to dedicated stroke units in countries such as Norway, Denmark and Sweden⁽¹¹⁾. Italy is one of the countries with the most rapidly increasing growth in the elderly population. In this country the reported prevalence of stroke in people aged over 65 years is 6.5%, and about 200,000 new stroke cases are expected each year. Given the significant impact on public health that this entails, improving adherence to evidence-based care is of primary importance, and offers great potential for reducing the burden of stroke on both the afflicted and the public health care budget⁽¹²⁾.

□ STROKE CARE POLICY IN ITALY

In Italy, rather than being nationally defined, stroke care programmes are planned by the regional health authorities in accordance with the “*Guidelines for the definition of stroke patient care strategies*” (Registered Act n. 2195), approved on 3rd February 2005 at the State/Regional Healthcare Conference, drafted on the basis of the scientific literature of the time. In addition to outlining recommended treatment strategies, these guidelines also state the importance of research, continual staff training, raising awareness among patients, people at risk, their families, caregivers and the general public in addition to improving health care catering for such patients⁽¹²⁾. The way stroke patients are treated has also been influenced by the Ministry of Health decree “*Modification of the authorization for the commercialization of ‘Actilyse’ medicines for human use*” (issued on 24th July 2003, and published in the Official Gazette n. 190 on 18th August 2003), which extended the therapeutic indications relative to fibrinolytic treatment of ischaemic stroke to within 3 hours of symptom onset, and the more recent report by the Agenzia Italiana del Farmaco (AIFA), the Italian Medicines Agency, (issued on 16th November 2007, and published in the Official Gazette n. 278 on 29th November 2007) entitled “*Implementation of SITS-ISTR: continuation of postmarketing surveillance SITS-MOST (Deliberation n. 1/AE)*”, through which certain regional Italian centres were authorized to administer thrombolytic therapy within 3 hours of stroke symptom onset, in accordance with the Safe Implementation of Thrombolysis in Stroke - Monitoring Study (SITS-MOST) protocol^(1,9).

Recent studies extend the therapeutic indications of fibrinolytic treatment to within 4.5 hours of symptom onset in patients of any age⁽¹⁴⁾. In 2004 the Italian

Ministry of Health set up the National Research Programme “*How to guarantee adherence to effective interventions in stroke care*” in 13 Italian regions. The programme, which was coordinated by the Emilia-Romagna Regional Council, was in essence a comparative analysis of the regional legislation governing stroke care. The results of this analysis, which are still applicable today, highlighted the fact that there is great discrepancy between regions in stroke care legislation and how stroke patients are cared for before, during and after hospitalization. It also emerged that the relative legislation was also less than uniform in terms of its specificity and phase of operation/performance^(2,5). These findings prompted the Ministry of Health to publish two reports (Quaderni del Ministero della Salute) on the subject, entitled, respectively, “*Stroke care organization: Stroke Units*”⁽¹⁰⁾ and “*Structural, technological and clinical criteria suitable for the prevention, diagnosis and treatment of cerebrovascular pathologies*”⁽⁷⁾ with a view to promoting quality stroke care and the diffusion of Stroke Units throughout Italy. Finally, the Ministry of Health also commissioned the National Outcome Evaluation Programme (PNE), coordinated by the National Agency for Regional Health Services (Agenzia Nazionale per i Servizi sanitari regionali: AgeNAS), to analyse the mortality within 30 days of onset, in addition to re-admission rates due to ischaemic stroke in each region, and in each treatment centre.

As regards publicly funded research into stroke, the Ministry of Health has allocated roughly 5 million euro to targeted research programmes over the last decade^(3,8).

□ STROKE CARE POLICY AND MANAGEMENT IN EMILIA-ROMAGNA

In 2007, the Emilia-Romagna Regional Council officially adopted the “*Guidelines for the organization of integrated care for stroke patients - Stroke Care Programme*”, which instructs the local healthcare authorities in the creation of a regional network for treating stroke patients⁽⁶⁾. The aim of this document was to present the evidence of the efficacy of the selected stroke care model, identifying those elements that would be necessary to implement the model in a local context. However, it was left up to the individual local health authorities to decide upon an organizational model that best met their individual needs⁽⁶⁾.

This document prompted the local health authorities in the region to interpret and implement the guidelines contained therein. They identified the relevant healthcare strategies and their various phases (pre-admission, hospitalization and post-discharge), defined the Operative Units licensed to dispense thrombolytic therapy in acute ischaemic stroke (10 Neurology and 3 Emergency Medicine), laid out the dedicated inpatient facilities (4-20 Stroke Unit bed), mainly within the Neurology Operative Units but a few located in Internal Medicine, Geriatric Medicine or Cardiology Departments, and tasked internal and external departments with intensive/extensive rehabilitation of these patients. Local implementation of the Emilia-Romagna Guidelines was also encouraged by the Regional Council via the definition of specific targets for the chief executive officers of the local health authorities. Moreover, to monitor the implementation process, the Council also set up a technical and scientific committee to oversee the regional “*Stroke Care Programme*.” This committee had the task of conducting regular audits and ensuring that the regional guidelines were put into practice throughout the regional healthcare network, with particular focus on thrombolytic therapy, stroke units, rehabilitation, and community care.

An audit was also performed in Emilia-Romagna as part of the national Strategic Stroke Programme, a research programme commissioned by the Ministry of Health, to measure the diffusion of Stroke Units in acute medicine facilities, and to assess the quality of care received by stroke patients in the region. This “*Organisational and Clinical Audit*”, conducted in 2009, involved the collection and reporting of data through questionnaires designed to collect information on the structures themselves and quality markers⁽¹³⁾. The audit was carried out in two phases as follows:

- *Phase 1, an Organisational Audit*, involved 30 acute hospitals in the Emilia-Romagna region that possessed an Emergency Department/Unit and more than 50 discharges/year with a primary diagnosis of stroke. The local health authorities were charged with conducting on-site interviews and compiling an exhaustive 9-section questionnaire with healthcare team members (managers, clinicians, nurses and physiotherapists).
- *Phase 2, a Clinical Audit*, was designed to collect retrospective data from a sample of 1245 clinical records of consecutive patients with a principal diagnosis of acute ischaemic stroke (International Classification of Diseases: ICD-9 codes 433 and 434) discharged from the 30 hospitals of the region

in the year 2009. This was achieved by means of a questionnaire gathering both demographic and clinical information. Clinical Audit data were anonymously collected by trained staff, and sent to the Emilia-Romagna Regional Health Authority for analysis through a web-based data collection tool.

Preliminary results identified in the Organizational Audit show that almost all hospitals have a local emergency service (118) that applies protocols/algorithms for the rapid transport of stroke patients to the hospital. CT brain scan is available in all of the facilities considered. However, fewer than half of these facilities are licensed to administer thrombolytic therapy (SITS - International Stroke Treatment Registry: ISTR study). Indeed, only 40% of the 30 hospitals have a dedicated Stroke Unit (n = 13), all of which can administer thrombolytic therapy. In 77% of Emilia-Romagna hospitals, the multidisciplinary Stroke Care team meets at least once a week.

Preliminary results identified in the Clinical Audit show that only 27.6% of stroke patients are hospitalized in Stroke Units, accounting for 58% of the total daily bed use and indicating that Stroke Unit beds are assigned on the basis of patient age, comorbidities, and/or factors that may jeopardize acute treatments and/or the possibility of rehabilitation. As far as diagnosis and treatment are concerned, almost all patients are scanned using CT within the first 24 hours, and only a very slim minority are not given antiaggregant therapy (aspirin) within 48 hours. However, fewer than 50% of patients are assessed for deglutition disorders, admitted for early rehabilitation, or evaluated for cognitive disturbances within 24 hours of hospital admission. 10% of acute ischaemic stroke patients are received in intensive rehabilitation wards (code 56), 25.6 % in a long-stay post-acute extensive rehabilitation ward (code 60), and 8.9% in another rehabilitation setting. Where a patient is admitted for treatment is strongly conditioned by the policy of the particular healthcare structure.

□ CONCLUSIONS

Strong evidence indicates that patients' outcome(s) can be improved by implementing dedicated stroke care, which must entail: timely referral to a dedicated ward, rapid access to diagnostic imaging, prompt rehabilitation, early supported discharge, and appropriate care. In order to promote this model and reduce the variability of care across the Italian regions, and

therefore to improve the overall quality of care for stroke patients, it would be advisable for a national/regional clinical-organizational audit or stroke registry to be set up. Indeed, audits are an essential tool for monitoring care strategies and outcomes, enabling their improvement and maximizing the efficiency and efficacy of the former over time. Indeed, this tool enables not only the criteria by which a stroke care facility can be accredited to be defined, but also ensures that appropriate treatment programmes and strategies are in fact being adhered to in the various facilities (including the Stroke Units) that share the burden of continuous care for stroke patients. Although clinical databases are more useful tools for monitoring the quality of care, they are far more expensive and difficult to roll out on a national scale. Hence, regular regional and national auditing of performance markers and variables related to stroke severity and patient disability is vital for healthcare facilities and therefore the patients themselves. Indeed, until scientific research provides us with other markers, it is only through implementation of such measures that wide-scale improvements in healthcare organization and quality can be brought about.

□ REFERENCES

1. Agenzia Italiana del Farmaco (Italy). Determina per l'implementazione del SITS-ISTR: proseguimento dello studio post-marketing Surveillance SITS-MOST. (Determinazione n. 1/AE). Determinazione del 16 novembre 2007. GU n. 278 on 29th November 2007.
2. Biocca M, Ferro S, Pasquali D. (a cura di). Agenzia Sanitaria e Sociale Regionale dell'Emilia-Romagna. Dossier n. 155/2007 - La formazione e la comunicazione nell'assistenza allo stroke [cited 2013, April 24]. Available from: assr.regione.emilia-romagna.it/it/servizi/pubblicazioni/dossier/doss155
3. Centro nazionale per la prevenzione e il Controllo delle Malattie (CCM). I programmi e i progetti del CCM [cited 2013, April 24]. Available from: www.ccm-network.it/pagina.jsp?id=programmi
4. Di Carlo A, Baldereschi M, Gandolfo C, Candelise L, Ghetti A, Maggi S et al. Stroke in an elderly population: incidence and impact on survival and daily function. The Italian longitudinal study on aging. *Cerebrovasc Dis* 2003; 16 (2): 141-150.
5. Ferro S, Pallazzoni P, Bellan M, Facchini R, Nonino F, Agenzia sanitaria e sociale regionale dell'Emilia-Romagna. Dossier n. 166/2008 - Assistenza all'ictus. Modelli organizzativi regionali [cited 2013, April 24]. Available from: assr.regione.emilia-romagna.it/it/servizi/pubblicazioni/dossier/doss166
6. Giunta della Regione Emilia-Romagna (Italy). Approvazione linee di indirizzo per l'organizzazione dell'assistenza integrata al paziente con ictus - Programma Stroke Care (deliberazione n. 1720 del 16th November 2007) [cited 2013, April 24]. Available from: www.saluter.it/documentazione/leggi/regionali/delibere/programmazione-provvedimenti-regionali-del-2007/dgr.-1720-2007/view
7. Ministero della Salute (Italian Republic). Criteri di appropriatezza strutturale, tecnologica e clinica nella prevenzione, diagnosi e cura della patologia cerebrovascolare. Quaderni del Ministero della Salute n. 14, March-April 2012 [cited 2013, April 24]. Available from: www.quadernidellasalute.it/archivio-quaderni/14-marzo-aprile-2012.php
8. Ministero della Salute (Italian Republic): Direzione generale della ricerca sanitaria e biomedica e della vigilanza sugli enti. Ricerca finalizzata. Progetti finanziati 2000-2007 [cited 2013, April 24]. Available from: www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=764&&area=Ricercasanitaria&menu=finalizzata
9. Ministero della Salute (Italian Republic). Modificazione dell'autorizzazione all'immissione in commercio della specialità medicinale per uso umano "Actilyse". Decreto 24 luglio 2003. GU n. 190 del 18-8-2003.
10. Ministero della Salute (Italian Republic). Organizzazione dell'assistenza all'ictus: le Stroke Unit. Quaderni del Ministero della Salute n. 2, March-April 2010 [cited 2013, April 24]. Available from: <http://www.quadernidellasalute.it/archivio-quaderni/2-marzo-aprile-2010.php>
11. Organisation for Economic Co-operation and Development (OECD) Health at a Glance: Europe 2012. OECD Publishing, Paris (France), 2012 [cited 2013, April 24]. Available from: www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe-2012_9789264183896-en
12. Presidenza del Consiglio dei Ministri (Italy). Accordo, ai sensi dell'articolo 4 del decreto legislativo 28 agosto 1997, n. 281, tra il Ministro della salute, le Regioni e le Province autonome di Trento e di Bolzano, concernente "Linee di indirizzo per la definizione del percorso assistenziale ai pazienti con ictus cerebrale". Repertorio n. 2195 del 3 febbraio 2005 [cited 2013, April 24]. Available from: www.statoregioni.it/DettaglioDocGOV.asp?IDDoc=24489
13. Regione Emilia Romagna (Italy). Progetto Stroke Care. Un programma regionale di audit clinico-organizzativo. Risultati preliminari [cited 2013, April 24]. Available from: www.stroke-er.it/sites/default/files/Progetto_Stroke_Care_.pdf
14. Stroke Prevention and Educational Awareness Diffusion (SPREAD), 7th edition. Ictus cerebrale: linee guida italiane di prevenzione e trattamento. Stesura del 14 marzo 2012. Raccomandazioni e sintesi. Pierrel Research Italy, Milan, 2012 [cited 2013, April 24]. Available from: www.siapav.it/pdf/SPREAD%202012.pdf