O R I G I N A L

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Stroke Unit care in Italy. Results from PROSIT (Project on Stroke Services in Italy). A nationwide study

Abstract The future challenge for improving stroke patients' outcome will be to implement new Stroke Units (SUs) worldwide. However the best SU model remains uncertain. The aim of this study was to evaluate the number of SUs and the quality characteristics of acute stroke care in Italy. We conducted a SU survey in Italy, interviewing the directors of the hospital wards that discharged at least 50 acute stroke patients a year. A SU was defined as an acute ward area with stroke-dedicated beds and staff. To compare the quality of care provided in SUs with that in general wards (GWs) we investigated the characteristics of five domains: hospital setting, unit setting, staffing, process of care and diagnostic investigations. We identified 68 SUs and 677 GWs. Multivariate logistic regression analyses demonstrated that SUs compared to GWs had higher quality scores in unit setting (ROC area=0.9721), staffing (ROC area=0.8760) and care organisation (ROC area=0.7984). The hospital setting (ROC area=0.7033) and the availability of rapid diagnostic investigations (ROC area=0.7164) had lower power in discriminating SU from GW. In Italy in 2003/04 only 9% of the hospital services had organised SU care. The study demonstrated that SUs admitted more than 100 patients per year, had more monitoring equipment and staffing time, and practised multidisciplinary meetings and early mobilisation. The utility of these structural and performance characteristics needs validation from outcome studies.

Key words Stroke Unit • Stroke services • Quality of health care • Stroke care • Stroke outcome

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Introduction

Clinical trials and meta-analysis have consistently demonstrated the effectiveness of Stroke Unit (SU) services for hospitalised stroke patients [1]. Despite these results and derived recommendations [2], the percentage of stroke patients admitted to a SU bed remains very low in many countries [3]. Many stroke physicians claim that these delays in SU implementation are due to a shortage of adequate resources. But the general uncertainty about the best SU model is also a contributor to this delay. In fact, despite the meta-analysis providing evidence in favour of the comprehensive SU model, SUs currently implemented vary significantly in structure and organisation [4–7]. Randomised clinical trials and other research have been used to evaluate the efficacy of the individual elements of care that would improve stroke patient outcomes [4, 8–12]. But clear evidence of the relative efficacy for different models combining different structural and performance characteristics is very poor [10]. New SU research is still necessary to identify well defined and measurable quality indicators, evaluating both structural and performance parameters, for outcome studies.

The Project on Stroke Services in Italy (PROSIT) was undertaken with the goal of counting the number of SUs and measuring the quality of stroke care delivery across the country.

Methods

Definitions (see Appendix 1)

The definition of a Stroke Unit (SU) was an acute ward area with stroke-dedicated beds (at least 80% of admitted patients were stroke patients) and dedicated teams (at least one full-time physician and nurse were caring exclusively for acute stroke patients). A conventional General Ward (GW) was a ward (neurology, internal medicine, cardiology or other) admitting stroke patients in the same wards with others patients and without dedicated beds and teams. The *hospital setting* quality indicators were the presence in the same hospital of emergency, intensive care, neurosurgery, vascular surgery, cardiology, rehabilitation and neuroradiology departments. The quality indicators of *unit setting* included neurological management, the number of admissions per year, the number of sets of monitoring equipment per bed and the presence of stroke outpatient service. We measured the quality of *unit staffing* counting the numbers of full-time dedicated staff. We estimated the total number of operators in the ward per patient, separately for each health professional category. We did not calculate the person time per patient during a 24-h period because it varies according to the local shift organisation. The quality indicators of *process of care* were the declared use of physician and nurse protocols, the number of multidisciplinary meetings and the practice of early mobilisation. The quality of *diagnostic investigations* was determined by the availability over 24 h, seven days a week of brain CT scan, brain MRI scan, echocardiography, ultrasound and cerebral catheter angiography.

Data source

PROSIT is a study implemented from 1999 in Italy in order to evaluate the provision and the quality of stroke care. For the present study conducted on all 21 national regions we used the same standard methodology of the previous survey on seven regions [13, 14]. A list of all patients hospitalised during 2001 for acute stroke (DRG 14) together with the code of the hospital ward where they were admitted was obtained from the national Minister of Health facilities. Wards that discharged more than 50 DRG14 patients per year were identified. From May 2003 to April 2004 telephone interviews were performed with the medical directors of each ward. A few days before the telephone call they received a copy of the form (Appendix 1) to be used during the interview. Trained interviewers filled the forms during the telephone call. For the propriety of the information collected, all the data were supervised in collaboration with the regional clinical supervisor. A random sample of 44 interviews was performed twice. The second time a different interviewer went to the hospital site and interviewed the ward director face to face. There was complete agreement between telephone and face-to-face interviews for SU identification.

Statistical analysis

We conducted separate multiple logistic regression analysis for the five domains (hospital setting, unit setting, staffing, process of care and diagnostic investigations). The dependent variable was SU/GW condition. The quality indicators of each domain were the independent variables. The multiple logistic regression odds ratio (OR) and the 95% confidence intervals for each variable were calculated. The statistical significance of the overall effect of each domain in differentiating SU from GW was evaluated with the logistic regression x^2 statistics. We estimated the accuracy of the logistic model predictive value by measuring the area under the receiver operating characteristic (ROC) curve using the STATA 8.0 software.

Results

We identified 785 hospital wards that discharged at least 50 acute stroke patients per year. Thirty-three wards had been closed or merged with others since the interviews were performed, and seven interviews were refused. Thus, this study presents the results of 745 interviews of the ward directors from May 2003 to April 2004. Sixty-eight SUs were identified, all admitting only acute stroke patients and with at least one full-time physician and nurse. In the remaining 677 GWs, the stroke patients were managed together with other neurological or internal medicine patients. The 58 wards with only dedicated beds and the six with only dedicated staff (stroke team) were included in the GW group. Nationwide, 68 (9%) of the wards were SUs. The rates were lower in the central (10%) and southern (6%) regions than in the northern Italian regions (13%) (Fig. 1).
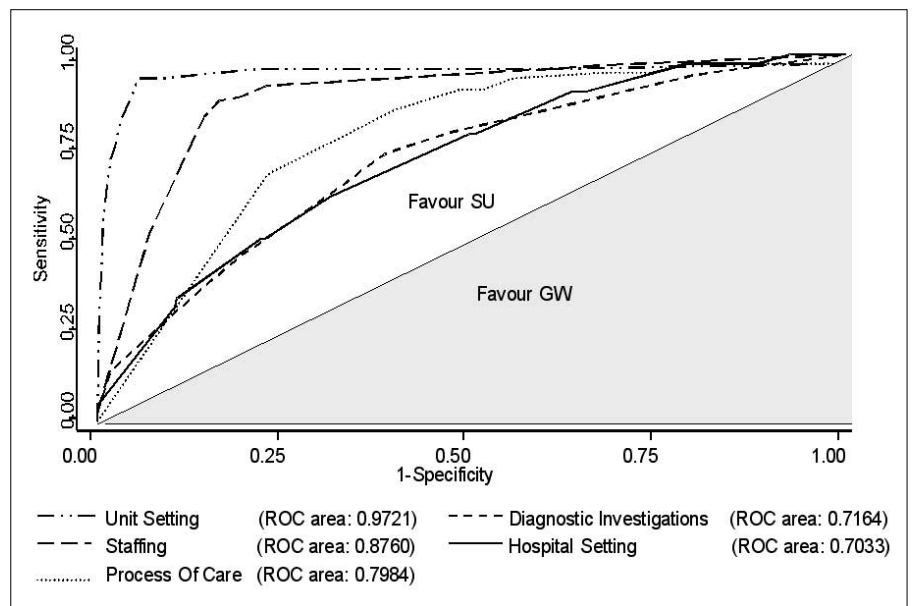
Hospital setting quality

The contribution of the hospital indicators in differentiating SU from GW services was very low (ROC area=0.7033) (Fig. 2). The only statistically significant differences for hospitals hosting a SU compared to the ones with a GW were the presence in the same hospital of a coronary unit and a neuroradiology department (Table 1). The ORs below 1 for intensive care and neurosurgery department were the result of a multiple regression model adjustment.

Unit setting quality

The structural characteristic of the ward was the more important factor for differentiating SUs from GWs (ROC area=0.9721) (Fig. 2). Seventy-five percent of SUs and 45%
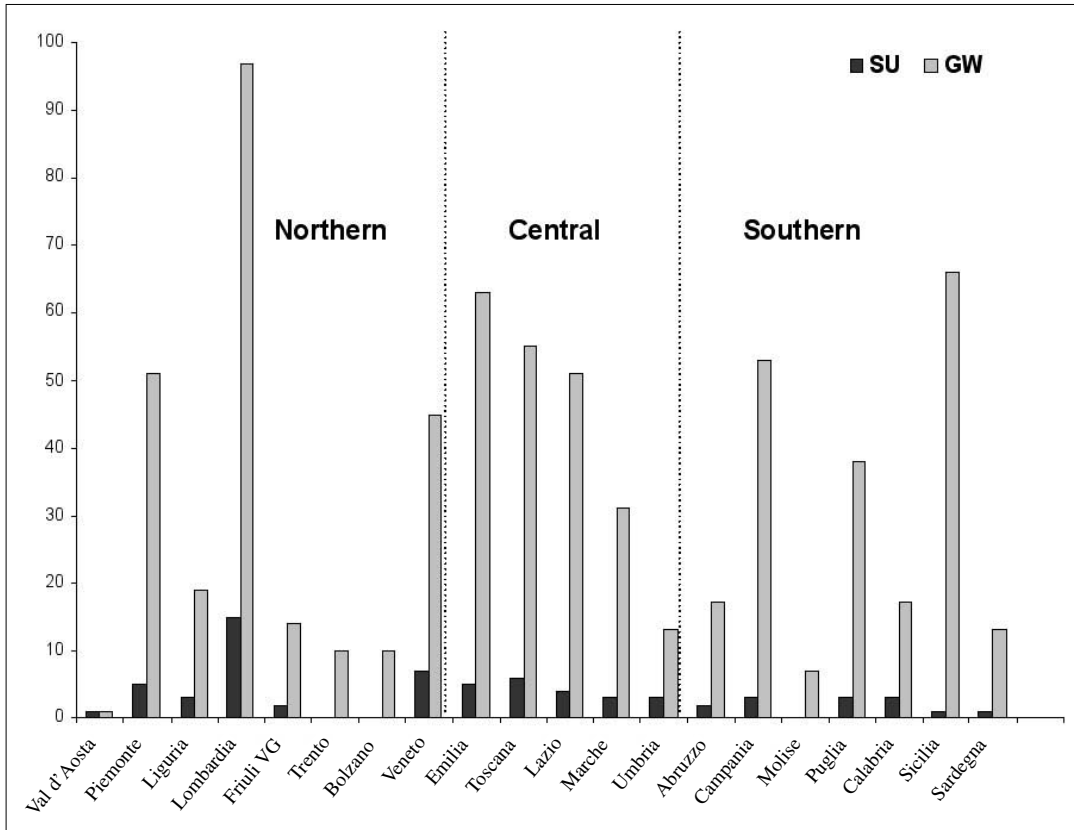
Fig. 1 Number of stroke units (*SU*) and conventional general wards (*GW*) by Italian regions

Fig. 2 Association of hospital setting, unit setting, staffing, process of care and access to diagnostic investigation domains with stroke unit (*SU*) or conventional general ward (*GW*). Results of multiple logistic regression analyses

of GWs admitted more than 100 patients per year, and 87% of SUs and 7% of GWs had at least two sets of monitoring equipment for ten beds. Patient elevators (lifting equipment) at least one in every ten beds were available for 69% of SUs *vs*. 4% of GWs. Stroke outpatient clinics were activated by 78% of SUs and by only 26% of GWs. The odds ratios (OR) for these unit setting parameters were in favour of SUs and all statistically significantly different from GWs (Table 1).

Unit staffing

The overall number of dedicated health operators was higher in SUs compared to GWs (ROC area=0.8760) (Fig. 2). Ninety-one percent of the SUs had more than two dedicated medical staff per ten patients, 88% had more than 0.5 physiotherapists and 57% had more than 0.25 speech therapists. The OR for these variables was statistically significant (Table 1).

Table 1 Quality indicators associated with stroke unit (SU) care compared with conventional general ward (GW) care

	SU (n=68)	GW (n=677)	Multiple logistic regression OR	95% Confidence interval
Hospital setting				
Located in northern regions	33 (48%)	247 (36%)	1.59	0.93–2.70
Intensive care	60 (88%)	509 (75%)	0.58	0.21–1.61
Neurosurgery dept	28 (41%)	183 (27%)	0.68	0.35–1.33
Vascular surgery dept	47 (69%)	300 (44%)	1.53	0.75–3.15
Coronary unit	64 (95%)	512 (76%)	4.42	1.26–15.52
Rehabilitation dept	43 (63%)	314 (46%)	1.20	0.68–2.12
Brain MRI in the hospital	51 (75%)	360 (53%)	1.24	0.59–2.56
Neuroradiology dept	40 (59%)	220 (32%)	2.38	1.23–4.63
Contribution to likelihood ratio		x^2=34.78	df=8	$p<0.0000$
Unit setting				
Neurological management	50 (75%)	147 (22%)	1.02	0.35–2.98
>100 pt/year	51 (75%)	306 (45%)	5.40	1.74–16.76
>2 monitors for 10 beds	59 (87%)	47 (7%)	47.60	18.09–125.24
>1 elevator for 10 beds	47 (69%)	28 (4%)	19.13	7.45–49.12
Stroke outpatient clinic	53 (78%)	175 (26%)	5.17	1.97–13.61
Contribution to likelihood ratio		x^2=302.84	df=5	$p<0.0000$
Staffing				
>2 physicians for 10 pts	62 (91%)	452 (67%)	3.41	1.34–8.64
>5 nurses for 10 pts	53 (78%)	430 (63%)	1.32	0.66–2.64
>0.5 physiotherapists for 10 pts	60 (88%)	131 (19%)	20.43	8.95–46.65
>0.25 speech therapists for 10 pts	39 (57%)	91 (13%)	1.93	1.03–3.61
>0.25 social workers for 10 pts	31 (45%)	133 (20%)	1.11	0.60–2.04
Contribution to likelihood ratio		x^2=150.08	df=5	$p<0.0000$
Process of care				
Diagnostic/therapeutics protocols	66 (97%)	545 (80%)	2.44	0.52–11.34
Nurses protocols	66 (97%)	505 (75%)	4.24	0.93–19.43
Early mobilisation	66 (97%)	528 (78%)	6.26	1.49–26.39
Multidisciplinary meetings	61 (90%)	378 (56%)	4.03	1.77–9.13
Outcome monitoring	55 (81%)	317 (47%)	3.51	1.85–6.65
Contribution to likelihood ratio		x^2=150.08	df=5	$p<0.0000$
Diagnostic exams 24 h/7 days				
CT scan	67 (98%)	608 (90%)	4.48	0.59–33.94
Brain MRI scan	38 (56%)	220 (32%)	1.67	0.91–3.05
Ultrasounds	40 (59%)	195 (29%)	3.33	1.85–6.00
Echocardiography	36 (51%)	366 (51%)	0.48	0.27–0.85
Angiography	35 (51%)	194 (29%)	1.46	0.78–2.70
Contribution to likelihood ratio		x^2=40.42	df=5	$p<0.0000$

Processes of care

SUs also provided a better care organisation than GWs (ROC area=0.7984) (Fig. 2). Early mobilisation was reported to be a common practice in SUs and less used in GWs. Multidisciplinary staff meetings were held in 90% of SUs and 56% of GWs. Outcome monitoring was applied in 81% of SUs and 47% of GWs. All these modalities of care delivery were statistically significantly different between the two types of units (Table 1).

Diagnostic investigations

Overall the availability of diagnostic examinations 24 h a day, seven days a week, was less useful in differentiating SU from GW care (ROC area=0.7164) (Fig. 2). Nevertheless, the opportunity to get a rapid ultrasound investigation was higher for SU wards (Table 1).

Discussion

This study is the first systematic survey of stroke hospital services nationwide that includes all Italian regions. The study demonstrates that all regions except three had at least one SU (Fig. 1) and that nationwide 9% of acute stroke wards were SUs. The SUs admitted more than 100 acute stroke patients per year, had more than one set of monitoring equipment per five beds, and had about four full-time physicians and one physiotherapist per 20 patients. All SUs reported that they have multidisciplinary

meetings and practice early rehabilitation. These findings, compared with our previous survey [13, 14], show the tendency in Italy to increase the number and the quality of structures dedicated to stroke care. Nevertheless, the study demonstrated an overall shortage of stroke unit beds, which was clearer in the central and southern parts of the country. This geographic disparity, documented also by others [15, 16], is not related to the variation of the population needs, because the stroke incidence in the south is similar to that of the northern regions [17]. A shortage of acute SU beds is also evident in many European countries where the percent of stroke patients hospitalised in a SU bed ranged from 5% to 40%. Access to SUs is quite good in Norway [18], Sweden [19], Germany [20], Austria [21] and Scotland [22], but is still patchy in France [23], Hungary [24], Italy [13, 14], Poland [25] and Portugal [26]. In Australia only 23% of hospitals had a SU [27]. In Ontario hospitals, a SU existed in only 4% of acute institutions [28]. In the United States many hospitals do not have the necessary infrastructure and organisation for acute stroke care [29–31]. Thus, there is an urgent need to implement new SUs worldwide [32, 33].

Our study evaluated also the quality of stroke care provided in SUs and GWs. We considered the structural indicators (setting and staffing) as well as the performance indicators (process of care and diagnostic availability) because both types of parameters could influence the patient's outcome [34, 35]. Adherence to a process of care was evaluated in SUs with respect to stroke teams in single unit trials [36] and in SUs with respect to mobile teams or conventional care in a multicentre cohort study [8]. These two studies demonstrated that a closer adherence to a well defined process of care explains the effectiveness of SU hospitalisation. But whether the structural indicators had an influence on stroke outcomes has not been investigated in great detail. Only a few preliminary studies have been published, which indicated that monitored beds in the unit could improve acute stroke outcome [37, 38]. The present study has documented that the quality of unit structure and the number of dedicated persons, together with a good care organisation, clearly differentiated SUs from GWs. Nevertheless, further studies underway in Italy are necessary to fully demonstrate if a higher intensity of SU setting and staffing could significantly improve the stroke outcome.

The method used for conducting the present survey has several advantages. We used a standard identification of the wards that resulted in being unbiased and that provided a good description of clinical reality. Complete responses were obtained by limiting the length of the interview, including only questions that the respondents could readily address. The telephone interview reduced the cost and the time compared to a site visit interview. The standardisation of the questionnaire and the experience of the inter-

viewers permitted us to obtain reliable results. We documented this by conducting a reproducibility study comparing the telephone and the face-to-face modalities. However, this type of study also has limitations. Reported availability of some facilities might differ from those actually used. This may be particularly true for the process of care parameters.

Despite these inherent limitations, the present study provides unique and important data reflecting distribution of the nationwide availability of stroke units and the quality of stroke care in Italy. We hope that these results produce a rapid broad-scale implementation of a well defined model of SU care. Furthermore, repeating this type of study periodically will provide a measure of effectiveness of efforts to improve the number of SUs and to maintain the quality of acute stroke care provision.

Sommario Per migliorare la prognosi dei pazienti con ictus cerebrale occorrerebbe aumentare il numero di Stroke Unit (SU) a livello mondiale. Resta ancora da chiarire, tuttavia, quale sia il modello migliore di SU. Lo scopo dello studio è di valutare il numero di SU e la qualità dei servizi di cura per ictus acuto in Italia. Abbiamo condotto un censimento delle SU intervistando i direttori dei reparti che ricoverano almeno 50 pazienti all'anno con ictus cerebrale acuto. Per SU si intende un reparto con letti e personale dedicato. Per valutare la qualità di cura nelle SU rispetto ai servizi misti (SMs) sono stati esaminati 5 domini: le caratteristiche dell'ospedale, dell'unità, del personale, del processo di cura e l'accesso alle indagini diagnostiche. Sono stati identificati 68 SUs e 677 SMs. All'analisi multivariata le SUs si differenziano dai SMs per una migliore qualità nelle caratteristiche dell'unità (ROC area=0.9721), del personale (ROC area=0.8760) nell'organizzazione del processo di cura (ROC area=0.7984). Le caratteristiche dell'ospedale (ROC area=0.7033) e il rapido accesso alle indagini diagnostiche (ROC area=0.7164) hanno basso potere nel discriminare le SU dai SM. Nel 2003/4 solo il 9% dei servizi ospedalieri in Italia possiede una SU. I risultati del nostro studio dimostrano che le SUs ricoverano più di 100 pazienti all'anno, hanno una maggior strumentazione di monitoraggio e personale dedicato, organizzano riunioni multidisciplinari e praticano la mobilizzazione precoce. L'efficacia di queste caratteristiche strutturali e del processo di cura deve essere confermata da studi di outcome.

Appendix 1 Stroke Unit/General Ward survey – Italy 2003/04

	Yes	No	Number
Identification of stroke unit			
Discrete ward area used solely for patients with stroke (at least 80% of admissions)			
Physicians and nurses (at least one of each) working solely for patients with stroke (at least 80% of the working time)			
Is this ward therefore a stroke unit (yes to both the previous questions)?			
Hospital setting			
Emergency department in the hospital			
Intensive care department in the hospital			
Neurosurgery department in the hospital			
Vascular surgery department in the hospital			
Cardiology department in the hospital			
Coronary unit in the hospital			
Rehabilitation department in the hospital			
Brain MRI in the hospital			
Neuroradiology department in the hospital			
Unit setting			
Neurological management			
No. admissions per year			
No. ECG and BP monitors			
No. digital oxymeters			
No. temperature monitors			
No. defibrillators			
No. artificial ventilators			
No. patient elevators			
Stroke clinic (outpatient service)			
Number of dedicated staff*			
No. physicians			
No. fellows or graduate students			
No. nurses			
No. assistant nurses			
No. physiotherapists			
No. speech therapists			
No. social workers			
No. administrative workers			
Process of care			
Diagnostic/therapeutic physician protocol**			
Nursing care protocol**			
Early mobilisation (within 48 h of admission)			
Multidisciplinary meetings (physician, nurse, physiotherapist, caregiver)			
No. multidisciplinary meetings/month			
Process for outcome monitoring			
Diagnostic investigations over 24 h/7 days			
Brain CT scan			
Brain MRI scan			
Ultrasounds (carotid/vertebral duplex and/or transcrania doppler)			
Cerebral catheter angiography			
Echocardiogram			

*The numbers refer to the total personnel operating in the unit. If there are part-time staff the number may be lower than 1. For example, a physiotherapist who works half-time in the SU will be entered as 0.50.

**"Protocol" is used to mean a written management plan of care agreed on by all involved

Appendix 2 PROSIT Study Group

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