Effectiveness of Establishing a Dedicated Acute Stroke Unit in Routine Clinical Practice in Israel

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Abstract

Background: Clinical trials have demonstrated the superiority of managing acute stroke in a dedicated stroke unit over conventional treatment in general medical wards. Based on these findings, nationwide stroke unit care programs have been implemented in several countries.

Objective: To assess the effect of establishing a new dedicated acute stroke unit within a department of neurology on indicators of process of care and outcome of acute stroke in a routine clinical setting in Israel.

Methods: Stroke patients admitted to the Sheba Medical Center during the period March 2001 to June 2002 were included in a prospective study according to selection criteria. Data on demographics, risk factors, co-morbidities and stroke severity were collected. Indicators of process of care and outcome were assessed at hospital discharge and 30 days follow-up. Comparison between outcome variables by hospitalization ward was done using logistic regression analysis adjusting for confounders.

Results: Of 616 acute stroke patients (mean age 70 years, 61% men, 84% ischemic stroke), 353 (57%) were admitted to general wards and 263 (43%) to the stroke unit. Diagnostic procedures were performed more often and the infection rate was lower in the setting of the stroke unit. Poor outcome (modified Rankin scale ≥3 or death) was present less often in patients managed in the stroke unit both at hospital discharge (adjusted odds ratio 0.5, 95% confidence interval 0.3–0.8) and at 30 day follow-up (adjusted OR 0.6, 95%CI 0.3–0.9). A Functional Independence Measure score ≤90 or death at 30 day follow-up was less frequent among patients managed in the stroke unit than in general wards (adjusted OR 0.5, 95%CI 0.2–0.8).

Conclusions: Improved outcomes and higher adherence to guidelines were observed in patients treated in a stroke unit within a department of neurology. The results suggest that patients with acute stroke should have access to treatment in a dedicated stroke unit.

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OR = odds ratio
CI = confidence interval

Stroke is a leading cause of severe long-term disability, and death, and is associated with staggering economic costs due to healthcare expenses and lost productivity [1,2]. Multiple randomized clinical trials and a systematic review have demonstrated the utility of stroke units in reducing mortality and morbidity [3,4], with persisting benefit for years [5]. Outcomes were independent of patient's age, gender and stroke severity, but appeared to be better in stroke units based in a discrete ward. Stroke units are highly cost-effective and are considered the highest priority for providers of a stroke service [6,7]. Based on these findings, multiple authoritative recommendations were issued that stroke care should take place in a stroke unit [8–10], and several national bodies have recommended wide implementation of stroke units and comprehensive stroke systems [11–14].

Despite strong evidence of benefit, stroke unit care is not available for the vast majority of patients in Israel. A dedicated acute stroke unit was established in a large medical center in Israel. The five monitored beds unit is located within the Department of Neurology; it is run by trained neurology staff and has better availability of diagnostic tests and nursing and therapy staff. We took advantage of this opportunity to assess the effectiveness of a dedicated acute stroke unit within a department of neurology in terms of indicators of process of care and outcome in a routine clinical setting in Israel.

Patients and Methods

Design

In a prospective follow-up study, patients were allocated to either general medical wards or to the stroke unit/Department of Neurology, based on bed availability. Patients admitted either to the specialized semi-intensive stroke care beds or to general neurology beds under the supervision of the stroke unit were analyzed as one group since they shared the same personnel and diagnostic facilities and were routinely transferred between beds based on their medical condition.

Patient selection

Consecutive patients hospitalized either in general wards or in the stroke unit/Department of Neurology at the Sheba Medical Center following an acute stroke during the period March 2001 to June 2002 were included according to the following selection criteria.

- I*nclusion criteria*: Patients hospitalized during the study period with a diagnosis of stroke according to World Health Organization criteria.
- E*xclusion criteria*: Stroke occurring while in-hospital, patients living in nursing homes or with severe disability or dementia prior to the index stroke, coma on admission, severe co-morbidity such as malignancy with a life expectancy of only several months, stroke in the young (age <45 years), patients receiving interventional medications for hyperacute stroke (e.g., thrombolysis or investigational neuroprotective agents), transient ischemic attacks, subarachnoid hemorrhage, or patients admitted directly to geriatric wards.

Data collection

Data were collected during hospitalization, at discharge, and at 1 month follow-up. Study coordinators evaluated the patients screened for inclusion in this study. Patients were interviewed using data collection forms especially designed for this purpose. Face, content and consensual validity of the forms were assessed by the investigators and by two additional neurologists. In-hospital data on demographics, risk factors, co-morbidities and stroke severity were assessed. Diagnosis of stroke was based on medical records, and vascular neurologists reviewed all discharge summaries and subsequent admissions during the first month after the stroke. Patients with subsequent alternative diagnoses and those not filling WHO criteria for stroke were excluded. Management, investigations and outcome variables were assessed during hospitalization and follow-up. Several indicators of the care process were evaluated based on authoritative guidelines [9,15]. Clinical subtypes of ischemic stroke were determined using the Oxfordshire Community Stroke Project classification and ischemic stroke etiology was determined using the TOAST classification. Neurologic deficits were determined according to the U.S. National Health Institutes stroke scale score [16] at hospitalization and reevaluated at hospital discharge and follow-up. Functional outcome was assessed using the modified Rankin scale [17], the Barthel index [18] and the Functional Independence Measure [19]. The study protocol was approved by the local ethics committee.

Outcome variables

- Death: all-cause mortality assessed at hospital discharge and 30 day follow-up
- Modified Rankin Scale ≥3 or death assessed at discharge and 30 day follow-up
- Barthel Index ≤60 or death assessed at 30 day follow-up
- Functional Independence Measure ≤90 or death assessed at 30 day follow-up
- Nursing-home dwelling or death assessed at discharge and 30 day follow-up.

Statistical methods

The study sample was characterized according to the distribution of age, gender, hospitalization ward, risk factors, co-morbidities, stroke severity, and management. Differences in outcome variables between patients hospitalized in the stroke unit and general wards were assessed using two-tailed Student *t*-test and chi-square test, according to the variable's distribution. Multiple logistic regression analyses were performed for the assessment of dichotomous outcome variables. We first controlled for age

Table 1. Baseline characteristics by hospitalization ward

	Medical wards (%) (n=353)	Stroke unit (%) (n=263)	*P*
Mean age (± SD) yrs	73.3 ± 10.1	64.8 ± 10.8	<0.0001
Mean education (± SD) yrs	9.9 ± 4.3	11.0 ± 4.2	0.01
Females	154 (44.0)	83 (31.7)	0.002
Marital status (married, %)	215 (61.8)	195 (74.7)	<0.0001
Health management organization			0.4
Clalit	229 (66.4)	151 (58.8)	
Meuhedet	15 (4.4)	15 (5.8)	
Maccabi	66 (19.1)	63 (24.5)	
Leumit	33 (9.6)	26 (10.1)	
Other	2 (0.6)	2 (0.8)	
Risk factors			
Hypertension	262 (74.2)	174 (66.2)	0.03
Dyslipidemia	132 (37.4)	119 (45.3)	0.05
Diabetes	128 (36.3)	86 (32.7)	0.4
Current smoking	64 (22.2)	69 (27.4)	0.2
Angina pectoris	113 (32.1)	59 (22.4)	0.008
Prior stroke	89 (25.3)	41 (15.7)	0.004
Prior transient ischemic attack	19 (5.4)	15 (5.8)	0.9
Prior acute myocardial infarction	86 (24.4)	42 (16)	0.01
Atrial fibrillation	84 (23.8)	24 (9.1)	<0.0001
Congestive heart failure	45 (13)	7 (2.7)	<0.0001
Peripheral vascular disease	31 (8.8)	19 (7.3)	0.5
Cancer	31 (8.8)	17 (6.5)	0.3
Valvular heart disease	20 (5.7)	4 (1.5)	0.009
Family history of stroke (≤55 years old)	4 (1.9)	4 (1.7)	0.9
Stroke type and severity			0.8
Ischemic	321 (90.9)	241 (91.6)	
Hemorrhagic	32 (9.1)	22 (8.4)	
Ischemic stroke etiology (by TOAST class)			<0.0001
Cardioembolic	64 (20.9)	24 (10.4)	
Large vessel atherothrombosis	9 (2.9)	24 (10.4)	
Small vessel occlusive disease	47 (15.4)	91 (39.6)	
Other	19 (6.2)	8 (3.5)	
Undetermined	167 (54.6)	83 (36.1)	
Stroke severity by NIH stroke scale			<0.0001
Score ≤10	282 (79.9)	242 (92.0)	
Score >10	71 (20.1)	21 (8.0)	
Mean systolic blood pressure (± SD) mmHg	169.2 ± 29.5	167.1± 27.2	0.4
Mean diastolic blood pressure (± SD) mmHg	83.7 ± 16.5	81.9 ± 24.4	0.2
Mean plasma glucose (± SD) mg/dl	156.7 ± 74.1	141.9 ± 59.1	0.02
Mean total cholesterol (± SD) mg/dl	209.8 ± 56.1	206.3 ± 51.3	0.4

and gender, then for age, gender, stroke type (ischemic vs. hemorrhagic) and stroke severity (NIHSS score), and finally, co-morbidities (hypertension, diabetes mellitus, atrial fibrillation, previous stroke, previous myocardial infarction, angina pectoris, congestive heart failure, valvular heart disease) were added to the multiple logistic regression models. Odds ratio with 95% confidence interval are reported. Data analysis was conducted using the SAS 8 software [20].

Results

Study sample characteristics

During the study period 1,071 patients with a stroke or transient ischemic attacks were admitted to the general medical wards or stroke unit/Department of Neurology. Of these patients, 616 fulfilled selection criteria: 517 (84%) with ischemic stroke and 99 (16%) with intracerebral hemorrhage. They were admitted as follows: 353 (57%) to general wards and 263 (43%) to the stroke unit. Baseline characteristics of the sample, by patients' hospitalization ward, are presented in Table 1. The average age was 73.3 ± 10.1 years in the general wards and 64.8 ± 10.8 years in the stroke unit ($P < 0.0001$). Fifty-six percent of the patients in the general wards and 68% of those in the stroke unit were men ($P = 0.002$). The most common vascular risk factors were hypertension (71%), dyslipidemia (41%) and diabetes (35%). Patients admitted to the stroke unit had less heart disease, prior stroke, and less severe neurologic deficits. Clinical subtype of ischemic stroke among patients admitted to the stroke unit was more often posterior circulation (49% vs. 31%) and less often total or partial anterior circulation (19% vs. 26%) than in their counterparts admitted to general wards.

NIHSS = National Health Institutes stroke scale

Diagnostic procedures and treatment

Brain computed tomography was performed in 613 cases (99.5%), mostly in the Emergency Department. Diagnostic tests for assessing stroke etiology were performed more frequently in the stroke unit than in general wards (transthoracic echocardiography 57.0% vs. 19.6%, carotid duplex 39.5 vs. 12.8%, and transcranial Doppler 54.8 vs. 4.0%) [Figure 1A]. Based on the results of the diagnostic tests performed during hospitalization, ischemic stroke etiology could be determined in 64.1% of patients in the stroke unit, compared to 44.9% of general ward patients ($P < 0.0001$).

Use of urinary catheter and nasogastric tube was more common in general wards than in the stroke unit. Age-adjusted rates for urinary catheter use were 16.8% of patients in general wards and 9.3% of patients in the stroke unit ($P = 0.03$), and for nasogastric tube 13.8% of patients in general wards vs. 4.6% of patients in the stroke unit ($P = 0.002$). Intravenous mannitol treatment for brain edema and impending herniation was used in a higher proportion of patients in the stroke unit (age-adjusted rate 3.9%) compared to patients in general wards (age-adjusted rate 0.3%) ($P = 0.01$).

Differences in age-adjusted rates of medical treatment were observed according to hospitalization ward. Statins were more

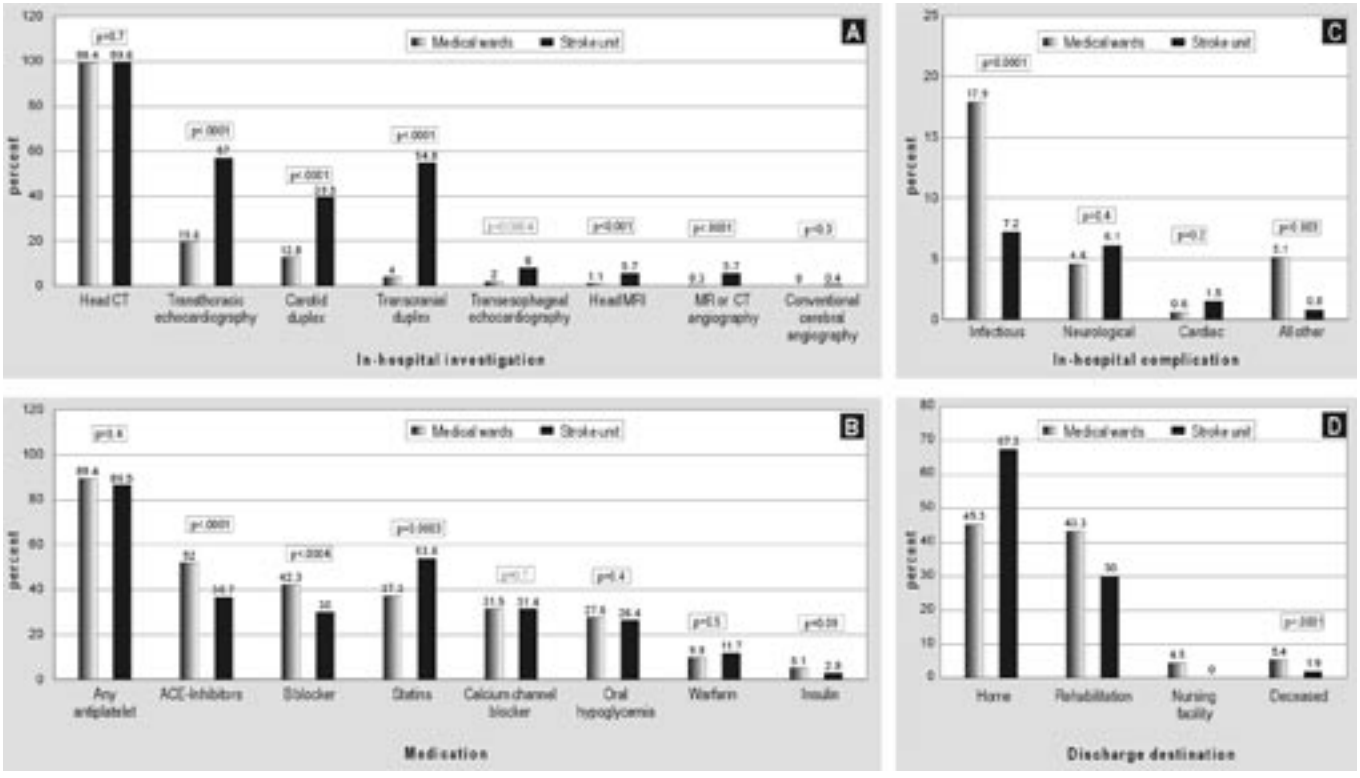

Figure 1. Distribution by hospitalization ward of: **[A]** Diagnostic tests, **[B]** Medical treatments, **[C]** Complications, and **[D]** Discharge destination.

Table 2. Indicators of process of care according to hospitalization ward

	Medical wards (%)	Stroke unit (%)	Age and gender-adjusted OR
Any vascular imaging (ultrasound, CTA and MRA) in-hospital	74 (21.0)	165 (62.7)	5.5 (3.7–8.0)
Carotid duplex in patients with ischemic stroke	44 (13.7)	103 (42.7)	3.2 (2.1–4.8)
Carotid duplex in patients with ischemic stroke excluding posterior circulation syndromes	30 (13.9)	71 (59.2)	3.3 (2.1–5.1)
Any antithrombotic (aspirin, plavix or warfarin) for ischemic stroke	315 (98.1)	237 (98.3)	1.0 (0.5–2.0)
Warfarin for atrial fibrillation excluding known dementia, malignancy, peptic ulcer or NIHSS score >20	30 (35.7)	13 (54.1)	2.3 (0.9–6.1)
Statins for ischemic stroke	126 (39.3)	136 (56.4)	1.5 (1.1–2.2)

CTA = CT-angiography, MRA = MR-angiography

frequently used in-hospital or recommended at discharge from the stroke unit (age-adjusted rate 53.8%) compared to general wards (37.3%, $P = 0.0003$). A higher rate of patients in the general wards than in the stroke unit received angiotensin-converting enzyme inhibitors (age-adjusted rate 52.0% vs. 36.7%, $P < 0.0001$) and beta-blockers (age-adjusted rate 42.3 vs. 30.0%, $P = 0.004$). Figure 1B presents the distribution of in-hospital medical treatment by hospitalization ward.

Indicators of process of care

Indicators of process of care by hospitalization ward are presented in Table 2. A vascular imaging study (ultrasound, CT-angiography or magnetic resonance angiography) was performed in-hospital among 21.0% of patients in the general wards compared to 62.7% in the stroke unit (adjusted OR 5.5, 95%CI 3.7–8.0). Among patients with ischemic stroke, carotid duplex was performed more often in the stroke unit (42.7%) than in general wards (13.7%) (age-adjusted OR 3.2, 95%CI 2.1–4.8). The difference between wards in rates of carotid duplex in patients with ischemic stroke, excluding posterior circulation syndromes, increased to 59.2% in the stroke unit and 13.9% in general wards (age-adjusted OR 3.3, 95%CI 2.1–5.1). No statistically significant differences in antithrombotic treatment for ischemic stroke were found according to hospitalization ward, but warfarin treatment for secondary prevention was more often prescribed for potential candidates with atrial fibrillation in the stroke unit.

Complications and outcomes at discharge

Infections were the most frequent complication during hospitalization and occurred less often in the stroke unit (7.2% in the stroke unit vs. 17.9% in general wards; age-adjusted OR 0.6, 95%CI 0.3–1.0). Neurologic complications were present in 6.1% of patients in the stroke unit compared to 4.6% in general wards (age-adjusted OR 1.4, 95%CI 0.7–3.1). Rates of in-hospital complications by ward are presented in Figure 1C.

Table 3. Adjusted odds ratios for poor outcome variables by hospital ward

Outcome	Medical ward (%)	Stroke unit (%)	OR (95% CI)
At hospital discharge			
Death	19 (5.4)	5 (1.9)	0.5 (0.2–1.4)*[1]
			0.6 (0.2–2.1)**
			0.6 (0.2–2.5)***
Death or modified Rankin Scale ≥3	231 (65.4)	107 (40.7)	0.5 (0.3–0.7)*
			0.5 (0.3–0.8)**
			0.5 (0.3–0.8)***
Death or discharge to a nursing home	35 (9.9)	5 (1.9)	0.3 (0.1–0.8)*
			0.3 (0.1–1.0)**
			0.4 (0.1–1.2)***
At 30 days			
Death	27 (7.7)	4 (1.5)	0.3 (0.1–0.8)*
			0.3 (0.1–1.0)**
			0.3 (0.1–1.1)***
Death or modified Rankin Scale ≥3	135 (41.3)	46 (19.6)	0.5 (0.3–0.7)*
			0.5 (0.3–0.9)**
			0.6 (0.3–0.9)***
Death or Barthel Index ≤60	76 (23.2)	24 (10.2)	0.6 (0.4–1.0)*
			0.7 (0.4–1.3)**
			0.7 (0.4–1.2)***
Death or Functional Independent Measure ≤90	95 (29.1)	25 (10.6)	0.4 (0.3–0.7)*
			0.4 (0.2–0.8)**
			0.5 (0.2–0.8)***
Death or nursing-home dwelling	38 (11.6)	6 (2.6)	0.3 (0.1–0.8)*
			0.3 (0.1–0.9)**
			0.3 (0.1–1.0)***

* Adjusted for gender and age.

** Adjusted for gender, age, stroke type (ischemic or hemorrhagic), NIH score scale.

*** Adjusted for gender, age, stroke type (ischemic or hemorrhagic), NIH score scale, hypertension, diabetes mellitus, atrial fibrillation, previous stroke, previous myocardial infarction, angina pectoris, congestive heart failure and valvular heart disease.

The mean length of hospitalization was 10.6 days in the general wards and 11.6 days in the stroke unit ($P = 0.8$). A higher proportion of patients in the stroke unit were able to return home (67.3%) compared to patients in general wards (45.3%) (adjusted OR 2.1, 95%CI 1.3–3.3). The distribution of discharge destination by hospitalization ward is shown in Figure 1D. Death during hospitalization occurred in 5.4% of patients in general wards and 1.9% in the stroke unit (adjusted OR 0.6, 95%CI 0.2–2.5). Poor outcome defined as modified Rankin Scale ≥3 or death was observed in 65.4% of patients at the general wards vs. 40.7% in the stroke unit (adjusted OR 0.5, 95%CI 0.3–0.8). Discharge to a nursing facility or death were reported for 9.9% in the general wards vs. 1.9% in the stroke unit (adjusted OR 0.4, 95%CI 0.1–1.2). Poor outcomes at discharge are shown in Table 3.

Outcomes at follow-up

Indicators of poor outcome at 1 month following the stroke were significantly less frequent in patients admitted to the stroke unit compared to the general wards [Table 3]. Death at 30 days occurred in 7.7% of general ward patients compared

to 1.5% of patients in the stroke unit (adjusted OR 0.3, 95%CI 0.1–1.1), modified Rankin Scale ≥3 or death was observed in 41.3% in the general vs. 19.6% in the stroke unit (adjusted OR 0.6, 95%CI 0.3–0.9); Barthel Index ≤60 or death was observed in 23.2% in the general wards vs. 10.2% in the stroke unit (adjusted OR 0.7, 95%CI 0.4–1.2); Functional Independent Measure score ≤90 or death was observed in 29.1% in the general wards and 10.6% in the stroke unit (adjusted OR 0.5, 95%CI 0.2–0.8); nursing facility care or death was observed in 11.6% in the general wards vs. 2.6% in the stroke unit (adjusted OR 0.3, 95%CI 0.1–1.0).

Discussion

Multiple randomized clinical trials have shown that stroke patients who receive in-patient care in an organized stroke unit are more likely to survive and be independent, and that the benefits are most apparent in units based in a discrete ward [3–10]. A meta-analysis by the Stroke Unit Trialists Collaboration showed an 18% relative reduction in mortality, a reduction in death or dependence and a reduction in death or need for institutional care when treated in a stroke unit in comparison with a medical ward. The absolute changes indicated a 3% reduction in all-cause mortality (numbers needed to treat = 33), a 3% reduction in the need for nursing-home care, and a 6% increase in the number of independent survivors (needed to treat = 16) [3,4].

All types of patients with stroke benefit from treatment in stroke units: males and females, young and elderly, and patients with mild, moderate and severe strokes. Implementation of these findings into routine clinical practice, however, represents a challenge for healthcare systems and requires surveillance of indicators of process of care and of outcome.

Our study, evaluating for the first time the effectiveness of a stroke unit within a department of neurology in a routine clinical setting in Israel, demonstrated a significant benefit of stroke care provided in a stroke unit compared to routine treatment in general medicine wards. Fewer in-hospital complications, higher adherence to guidelines and better overall outcomes were observed in patients with acute stroke treated in a dedicated short-term acute stroke unit compared to patients in general wards. Length of hospitalization was not shorter in the acute stroke unit than in general wards, as previously reported [21]. This may reflect differences, in the setting of the current study, in intensity of in-hospital investigations for stroke etiology and discharge policies between wards.

Organized stroke care in stroke units constitutes coordinated multidisciplinary care by medical, nursing and therapy staff that specializes in stroke care. Since the essence of stroke unit care lies in its comprehensive multidisciplinary approach, it is difficult to identify the specific factors responsible for the improved outcome. A stroke unit is characterized by more systematic assessments and adherence to process of care, early management policies and multidisciplinary team care [22,23]. The setting of a stroke unit facilitates monitoring of the neurologic status and physiologic parameters and providing adequate intervention accordingly. Furthermore, it allows early mobilization, and performance of diagnostic tests for early determination of underlying stroke etiology and of procedures aimed to prevent complications. Patients admitted to general wards underwent much less evaluation for ischemic stroke etiology, leading to a higher proportion of ischemic stroke of undetermined origin in general wards compared to the stroke unit (55% vs. 36% respectively).

In the current study setting we evaluated the specialized semi-intensive stroke care beds and general neurology beds as one entity since they shared the same personnel and diagnostic facilities. Further, patients were routinely transferred between the semi-intensive and general neurology beds based on their medical condition.

Management in the setting of a stroke unit resulted in a lower complication rate, allowed for a more accurate diagnosis of stroke etiology, and consequently early initiation of secondary prevention treatment tailored according to stroke etiology. The rate of performing a carotid duplex examination was substantially higher in the stroke unit setting, yet still lower than the rate of 80% observed in stroke care in Canada [15]. The rate of warfarin therapy for secondary prevention in candidates after an ischemic cerebrovascular event and atrial fibrillation was higher in patients managed in the stroke unit setting and comparable to the rate observed in stroke care in Canada [15]. Patients managed in a stroke unit achieved better outcomes at hospital discharge and 1 month later.

Acute stroke care now requires rapid assessment and triage in the acute phase to implement early reperfusion therapy. Patients receiving reperfusion therapy were excluded from the current study; however, establishing stroke units is critical for safely providing thrombolytic therapy for ischemic stroke [24], as previously shown in the setting of our stroke unit and acute stroke team [25].

Based on the randomized trials and authoritative guidelines, multiple examples of systems of care have emerged that include nationwide concepts of stroke care units. Thus, a system of acute stroke units is being set up in Austria to care for 70% of all acute strokes [11], in Germany more than 100 semi-intensive stroke units have been established within the last 10 years [12], and in Sweden about 70% of acute stroke patients had access to stroke unit care already in the year 2000 [13]. According to the paradigm shift in acute stroke care and the findings from the current study, a national program to manage stroke patients in dedicated acute stroke units in Israel is necessary. The recent approval of intravenous recombinant tissue plasminogen activator therapy for acute ischemic stroke within 3 hours of stroke treatment in Israel highlights the need for stroke units that can be available for patients afflicted with acute stroke throughout the country.

There is clear evidence from clinical trials and authoritative guidelines on the efficacy of stroke units. Therefore, despite the inherent shortcoming, the current study aimed to assess the effectiveness of a new stroke unit based on routine clinical practice rather than a randomized trial. Despite our selection

criteria – excluding patients more likely to be admitted to general wards and those more likely to be admitted to the stroke unit – age and co-morbidities were not balanced between wards. Odds ratios for poor outcomes were therefore adjusted for age, gender, stroke type and severity, and for differences in co-morbidities. Nevertheless, multiple adjustments cannot control for all possible confounders, and results should be interpreted cautiously. The findings from this study, however, are in agreement, and extend those reported from multiple randomized clinical trials demonstrating in a routine clinical practice the clinical benefits, higher adherence to clinical guidelines, and improved outcome of patients with acute stroke managed in a dedicated stroke unit. These findings support the advantages of establishing and admitting patients afflicted with acute stroke in Israel to organized stroke units.

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