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Benefit of a Stroke Unit: A Randomized Controlled Trial

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In a randomized controlled trial we compared the clinical outcome of acute stroke patients, 110 of whom were allocated to treatment in a stroke unit and 110 to treatment in general medical wards. No significant difference existed between these groups with regard to sex, age, marital status, medical history, or functional impairment on admission. Outcome was measured at 6 and 52 weeks after the stroke by the proportion of patients at home, the proportion of patients in an institution, the mortality, and the functional state. After 6 weeks 56.4% of the patients randomized to the stroke unit and 32.7% of the patients randomized to the general medical wards were at home ($p=0.0004$), and after 52 weeks 62.7% and 44.6%, respectively, were at home ($p=0.002$). After 6 weeks 36.3% of the patients from the stroke unit and 50.0% from the general medical wards were in an institution ($p=0.02$); after 52 weeks 12.7% and 22.7%, respectively, were institutionalized ($p=0.016$). After 6 weeks mortality was 7.3% for the stroke unit group and 17.3% for the general medical wards group ($p=0.027$). After 52 weeks mortality was 24.6% for the stroke unit group and 32.7% for the general medical wards group (difference not significant). Functional state was significantly better for patients treated in the stroke unit after both 6 and 52 weeks. We conclude that care of patients with acute stroke in a stroke unit improves clinical outcome compared with treatment in general medical wards. (*Stroke* 1991;22:1026-1031)

No treatment has been conclusively shown to be effective in limiting the neuronal damage associated with stroke,¹⁻³ and the effectiveness of stroke rehabilitation is still being discussed.⁴⁻⁸ This may lead to a therapeutic nihilism, with inconsistent treatment ranging from fatalistic resignation to recovery or demise at home to intensive care in specialized units.⁹

Intensive care of stroke patients was tried in the 1970s but did not significantly reduce mortality and morbidity.¹⁰⁻¹³ In controlled trials, some investigators have shown a benefit of treatment of stroke patients in nonintensive stroke units,¹⁴⁻¹⁶ with team care and early rehabilitation as important aspects of the treatment program. However, the effect of team care on acutely hospitalized stroke patients was very limited in a study in which the care was organized very much

like care in a stroke unit.¹⁷ Thus, there is continuing uncertainty about the value of stroke units, and more randomized studies are required.^{9,18}

The primary aim of this randomized trial was to evaluate the clinical outcome of a maximum of 6 weeks' treatment in a stroke unit compared with treatment in general medical wards.

Subjects and Methods

University Hospital of Trondheim serves as the local hospital for about 200,000 inhabitants in the county of South Trøndelag, Norway. About 90% of the stroke patients in this area who need hospitalization are admitted to the Department of Medicine, and in 1985 a six-bed stroke unit was established in the Section of Cardiology.

Patients admitted to the Department of Medicine between February 11, 1986, and October 15, 1987, with acute focal neurological deficits of no apparent cause other than that of vascular origin were screened for inclusion in the study. We excluded patients whose symptoms began >1 week before arrival at the hospital; unconscious patients since previous investigators have shown that such patients receive no benefit from treatment in a stroke unit;¹⁹ patients living in nursing homes because one of our main objectives was to find the proportion of patients

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able to return to their homes after treatment in a hospital; patients from other districts as they were going to be transferred to their local hospital as soon as possible; patients with subdural hematoma, subarachnoid hemorrhage, or brain tumor since these patients were transferred to and treated in other departments in our hospital; and patients who arrived at the hospital when the stroke unit was full (six beds occupied) because randomization required two alternatives for allocating the patients.

Patients fulfilling the inclusion criteria and having none of the criteria for exclusion were then randomly assigned to treatment in the stroke unit or the general medical wards using serially numbered sealed envelopes.

During the study period, 373 patients with acute focal neurological deficits were admitted to the Department of Medicine. Sixteen of these patients were "missed" by the physicians on call; the remaining 357 patients were evaluated for inclusion. Of these, we excluded 47 because the stroke unit was full, 42 with coma, 21 who were living in nursing homes, 15 who were living in another district, and 12 whose symptoms began >1 week before arrival. The remaining 220 patients were included and randomly allocated, 110 to the stroke unit and 110 to the general medical wards. Fourteen of these patients (eight allocated to the stroke unit and six to the general medical wards) were returned to nursing homes or transferred to other hospitals or departments soon after arrival because they had come from nursing homes or other districts or had a brain tumor or subdural hematoma. Hence 206 patients (102 allocated to the stroke unit and 104 to the general medical wards) were actually treated.

For management of acute stroke in the stroke unit, we constructed a program that was standardized with regard to diagnostic evaluation, acute treatment, and rehabilitation. All patients received computed tomography (CT) within 24 hours, electrocardiogram, and routine blood tests on admission; other diagnostic procedures were performed when indicated. The acute treatment followed some of the guidelines that were recommended in 1985 when we constructed this program.²⁰⁻²⁵

During the first days in the stroke unit all patients underwent a standardized systematic observation and examination of neurological deficits, blood pressure, cardiac and pulmonary disorders, fever, glucose level, and fluid and electrolyte balance. Oxygen therapy was employed in the presence of decreased oxygen levels, but glucose infusion was avoided during the first 2 days, antiedema agents were not used, and hypertension was not treated during the acute stage except for very high blood pressure levels (>250/130 mm Hg). In patients with embolic infarction or progression of neurological deficits, the early use of anticoagulants was standard treatment in patients <75 years old. In older patients anticoagulants were used only after careful individual evaluation. We also used low doses of heparin (5,000 IU s.c.

twice a day) to prevent deep venous thrombosis in patients with extensive paresis but no sign of hemorrhage on CT scan.

The stroke unit was organized with a team approach to the patient's care. When a patient arrived, diagnostic and functional evaluation was done immediately and a treatment plan was made. The staff was well trained in the rehabilitation of stroke patients, and a systematic program for recovery of function was started soon after arrival. We believed that giving information to the patient and relatives was extremely important and designated a particular stroke nurse to manage these aspects.

The maximum period for treatment in the stroke unit was 42 days. If the patient had not returned home within 42 days, he was transferred to the general medical wards, a rehabilitation clinic, or a nursing home. There was no difference between the groups in the patients' ability to get treatment in rehabilitation clinics or nursing homes. After discharge, the family physicians were responsible for the patients' treatment; however, we recorded each patient's treatment during the period from 42 to 365 days and found no significant differences between groups.

Six wards in the Department of Medicine received stroke patients. Treatment in these wards was the common one for patients with acute stroke in Norwegian hospitals, but there was no standardized program for diagnostic evaluation and treatment. Physical therapy and occupational therapy were given when the physicians in the wards prescribed it.

All patients were evaluated clinically, and 108 patients (98%) allocated to the stroke unit and 92 (84%) allocated to the general medical wards had a CT scan. Patients with focal neurological deficits of presumed vascular origin and with duration of <24 hours were classified as having transient ischemic attacks. Cerebral hemorrhage, tumor, and subdural hematoma were diagnosed by positive findings on a CT scan. All other patients with deficits lasting >24 hours were considered to have cerebral infarction. If the onset of symptoms was sudden and a potential source of cardiogenic emboli was present, the diagnosis was embolic infarction; otherwise, the diagnosis was thrombotic infarction. Diagnoses other than stroke, tumor, and subdural hematoma were used if they definitely could explain the symptoms.

The following four aspects of clinical outcome were used as end points: 1) proportion of patients at home, 2) proportion of patients in an institution, 3) mortality, and 4) functional state assessed by the score on the Barthel Index²⁶ and by a neurological score (see below). The primary time for evaluation was after 6 weeks, which marked the end of the period for treatment in the stroke unit. The secondary time for evaluation was after 52 weeks.

In addition, we counted the total number of days each patient stayed in institutions during the first year after the stroke and calculated the average for each group. A patient not able to live at home and

needing permanent care in a nursing home was considered to stay in an institution for 365 days in our calculation.

The Barthel Index was used to assess the patient's ability to perform the activities of daily living. The other score we used was developed by the Scandinavian Stroke Study Group,²⁷ giving a prognostic score for acute evaluation and a long-term score for subsequent changes in neurological deficits and functional state over longer periods. This latter score is referred to as the neurological score in this study.

The Barthel Index was scored 24–48 hours after randomization, at days 21±2 and 42±2, at discharge, and at days 90±7 and 365±14. The prognostic score was evaluated only at day 0 (before randomization). The neurological score was evaluated at day 0 (before randomization), at days 21±2 and 42±2, at discharge, and at days 90±7 and 365±14.

The prognostic and neurological scores on admission were evaluated by the physicians on call. A specialized trained team consisting of a physician, a physical therapist, and a nurse performed all the other functional tests without any kind of blinding. To evaluate the possibility of bias in favor of the stroke unit in this open study design, all of the patients living in the city of Trondheim were also assessed by their score on the Barthel Index and by their neurological score after 1 year in a single-blind design (100 patients). This blind testing was performed by two physical therapists not working in the hospital and not knowing where the patients had been treated.

Differences between groups in the proportion of patients at home, in an institution, and deceased were compared with use of life-table methods. Kaplan-Meier survival curves were calculated, and the difference between the curves was analyzed with the log-rank test. The primary analysis was an intention-to-treat one performed for all 220 randomized patients. In addition, an on-treatment analysis was performed only for the patients actually treated in the stroke unit or the general medical wards (206 patients). The differences between groups in Barthel Index and neurological scores were analyzed by the Mann-Whitney test and only for the on-treatment analysis because we did not follow up the 14 patients who were not treated in the stroke unit or the general medical wards closely enough to evaluate their functional state. The Mann-Whitney test was also used for on-treatment analysis of the difference between groups in length of stay in institutions. Spearman's correlation coefficient was used to compare results from the open and blind testing of functional state after 1 year (Barthel Index and neurological scores). Group homogeneity was analyzed with a χ^2 test for sex, medical history, and marital status. Age and time from debut of symptoms to admission were analyzed by the Mann-Whitney test. In all analyses, a probability value of less than 0.05 was considered significant.

TABLE 1. Baseline Characteristics of Patients in Stroke Unit and General Medical Wards

Characteristic	Unit (n=110)	Wards (n=110)
Sex (% female)	49	50
Age (mean±SD yr)	72.2±8.6	73.7±8.7
Medical history (%)		
Manifest stroke	25	22
Transient ischemic attack	17	15
Hypertension	26	29
Myocardial infarction	22	18
Angina pectoris	20	20
Atrial fibrillation	19	19
Diabetes mellitus	19	16
Cancer	12	9
Side of predominant neurological deficits (%)		
Right	55	53
Left	45	47
Functional state		
Prognostic score* (mean)	14.9	15.1
Neurological score* (mean)	25.4	26.5
Barthel Index† (mean)	46.9	43.7
Time from debut of symptoms to randomization (mean±SD hr)	16.5±16.4	15.8±21.1
Marital status (%)		
Married	52	54
Widowed	31	26
Living alone (%)	29	29

*Assessed before randomization.

†Assessed 24–48 hours after randomization.

Results

Table 1 shows the basic characteristics of the two groups. No significant difference existed concerning sex, age, medical history, marital status, time from debut of symptoms to admission, and functional impairment on admission. The distribution of diagnoses was almost identical in the two groups (Table 2).

Table 3 shows the proportion of patients at home, in an institution, and deceased after 6 and 52 weeks. After 6 weeks, the intention-to-treat analysis shows significant differences between groups in the propor-

TABLE 2. Final Diagnosis for Patients in Stroke Unit and General Medical Wards

Diagnosis	Unit (n=110)	Wards (n=110)
Nonembolic infarction	56	57
Embolic infarction	33	29
Hemorrhage	14	15
Transient ischemic attack	3	4
Tumor in central nervous system	3	1
Subdural hematoma	0	2
Epileptic seizures	0	1
Septicemia	1	1

TABLE 3. Number and Proportion of Patients Allocated to Stroke Unit and General Medical Wards at Home, in Institution, and Deceased After 6 and 52 Weeks

Time	Intention-to-treat analysis					On-treatment analysis				
	Unit (n=110)		Wards (n=110)		p	Unit (n=102)		Wards (n=104)		p
	No.	%	No.	%		No.	%	No.	%	
6 weeks										
Dead	8	7.3	19	17.3	0.027	7	6.9	17	16.4	0.037
In institution	40	36.3	55	50.0	0.020	34	33.3	51	49.0	0.012
At home	62	56.4	36	32.7	0.0004	61	59.8	36	34.6	0.0003
52 weeks										
Dead	27	24.6	36	32.7	0.155	25	24.5	33	31.7	0.220
In institution	14	12.7	25	22.7	0.016	11	10.8	23	22.1	0.0076
At home	69	62.7	49	44.6	0.002	66	64.7	48	46.2	0.001

Value of *p* by log-rank test.

tion of patients at home ($p=0.0004$), in an institution ($p=0.02$), and deceased ($p=0.027$). After 52 weeks, differences in the proportion of patients at home ($p=0.002$) and in an institution ($p=0.016$) were still significant, but the difference in mortality was not ($p=0.155$). The on-treatment analysis showed similar results.

In Figure 1 the cumulative mortality curves during the first year show that the difference in mortality developed during the subacute period (5–42 days after the stroke). The cause of death during the first 42 days varied and was determined clinically because only a few patients were autopsied. Pneumonia, pulmonary embolism, and recurrent stroke seemed to be more frequent among patients allocated to the general medical wards.

The Barthel Index and neurological scores during the first year were compared for all patients who were alive after 1 year (77 patients treated in the stroke unit and 71 patients treated in the general medical wards). After 6 weeks, mean score on the Barthel Index was 79.7 in the stroke unit group and 65.8 in the general medical wards group ($p=0.0014$), and after 52 weeks it was 84.7 and 72.4, respectively ($p=0.001$) (Figure 2). The mean neurological score

was 38.7 in the stroke unit group and 34.3 in the general medical wards group after 6 weeks ($p=0.007$), and after 52 weeks the score was 40.1 and 35.8, respectively ($p=0.004$) (Figure 3). Table 4 shows a very high correlation between open and blind testing of functional state after 1 year for patients living in the city of Trondheim.

The mean time in institutions, including nursing homes, during the first year after the stroke was 75 days for the stroke unit group and 123 days for the general medical wards group ($p=0.004$ by on-treatment analysis).

Discussion

Treatment differed between the groups only during the first 6 weeks, making this the most important period regarding the immediate effects of treatment in the stroke unit. After 6 weeks a significant difference existed in all reported outcomes, and after 1 year the differences were still significant except in mortality. Since patient characteristics in the two

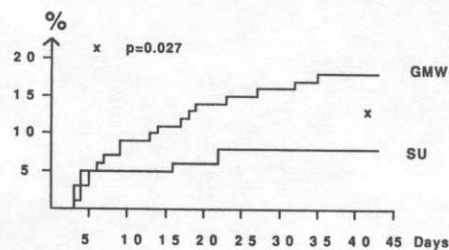


FIGURE 1. Cumulative mortality (%) from 0 to 42 days after stroke in patients treated in stroke unit (SU) and general medical wards (GMW) by intention-to-treat analysis. In SU group eight patients (7.3%) were dead after 42 days, and in GMW group 19 (17.3%) were dead.

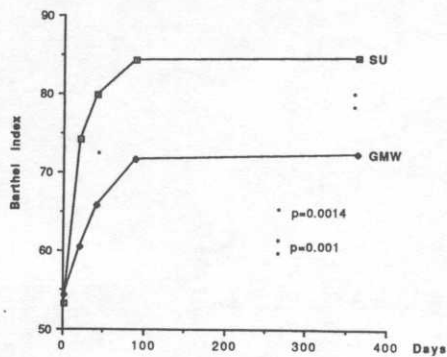


FIGURE 2. Graph of score on Barthel Index from 1 to 365 days. Mean for 77 patients in stroke unit group (SU) and 71 patients in general medical wards group (GMW) alive after 1 year.

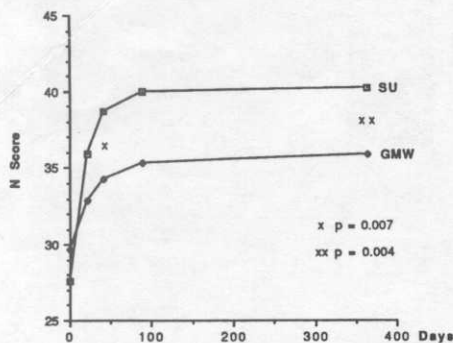


FIGURE 3. Graph of neurological (N) score from 0 to 365 days. Mean for 77 patients in stroke unit group (SU) and 71 patients in general medical wards group (GMW) alive after 1 year.

groups were comparable, there is no indication that the better outcome of the stroke unit patients was due to a preselection of milder cases to this group.

A weakness in a study of this type is the lack of blinding and the possibility of bias. It is possible to influence the proportion of patients living at home after 6 weeks in an open study like ours, but it is more difficult to influence this proportion after 1 year. Concerning the functional state, the possibility of bias is obvious, but the correlation between our open test and the single-blind test after 1 year was high and indicates that no great favoritism for the stroke unit patients had taken place.

There are differences between our study and previous studies in the selection of patients, time from onset of symptoms to start of treatment, acute medical treatment, rehabilitation program, and evaluation of outcome, making the results difficult to compare. However, the increased proportion of patients who were able to live at home, both immediately and after a follow-up period, agree with the studies from Sweden¹⁴ and England.¹⁶ The better functional outcome immediately after the end of treatment in the stroke unit is similar to that in both the Swedish study¹⁴ and a Scottish study.¹⁵ The difference in outcome in favor of the stroke unit disappeared after

a follow-up period in the Scottish study²⁸ but persisted in both the English¹⁶ and Swedish studies.¹⁴

In a study from Canada,¹⁷ the benefit of team care was very limited. These researchers had an ambulatory team of stroke specialists who consulted throughout the hospital, wherever the patient was situated, while we had a defined geographic area of the hospital with beds specially designated for acute stroke patients and a trained staff 24 hours a day. These differences may be important for the great difference in outcome in these two studies.

The most unexpected result in our study was the difference in mortality. Neither previous studies of intensive stroke care nor the Swedish study showed any reduction in mortality,^{10,11,14} and in the two British studies there was only a slight reduction.^{15,16} In our study there was no difference during the first 5 days after the stroke (Figure 1). The patients with the greatest brain damage probably could not have been saved whether treated in a stroke unit or not. The difference in mortality was present during the subacute period between days 5 and 42 and was mainly due to three clinical diagnoses (pneumonia, new strokes, and pulmonary embolism). It is possible that factors in our acute medical treatment program together with the very intensive and early mobilization may have affected this subacute mortality. In future analyses of the subgroups we will try to explore these aspects more closely.

The acute medical treatment may also have contributed to the better functional state and increased proportion of patients discharged and living at home. We believe, however, that the early and intensive rehabilitation and nursing program was the most important factor in this improved result. A team approach to nursing and rehabilitation, emphasizing patient and family participation, is generally accepted as a crucial concept in stroke unit policy.²⁹ Our stroke unit has combined these principles with a very early onset of rehabilitation, usually <24 hours after the onset of symptoms. This may have had a positive influence on the final results.

Another contribution to the difference in outcome may be the psychological effects of the stroke unit. The stroke unit can be envisaged as a therapeutic community in which the close relationship between the staff and the patients plays an important part in achieving a higher level of functional independence in the patients than occurs in general medical wards offering a more conventional institutional approach. It is difficult to evaluate the importance of these aspects.

Previous investigators have also had the problem of determining which specific aspects in the treatment package are most important.^{14,15} Any general clinical strategy to treat stroke patients will face the problem of isolating the specific components that are important to the overall results. In an integrated approach, acute treatment and early mobilization/rehabilitation are closely linked. Improved education

TABLE 4. Correlation Between Open and Blind Testing of Functional State (Barthel Index and Neurological Scores) of 100 Patients Living in City of Trondheim

Group	n	Correlation coefficient (Spearman's ρ)
Barthel Index		
Stroke unit	53	0.91
General medical wards	47	0.94
Neurological score		
Stroke unit	53	0.94
General medical wards	47	0.92

of the staff, the patients, and the family will also affect all aspects of the treatment.

Our treatment program was a systematic combination of acute medical treatment and acute rehabilitation. The rehabilitation aspects were probably more pronounced than in earlier intensive care studies,^{10,11} and the acute medical treatment was probably more systematic than in previous studies from nonintensive stroke units.¹⁴⁻¹⁶ Although many other differences exist among these studies, these differences provide the most consistent reason why our results seem to be somewhat better than those in earlier trials. We believe that our treatment program works better than either acute treatment alone or early rehabilitation alone. In our opinion, such a combination of acute medical treatment and acute rehabilitation is not possible to organize in a systematic way without a stroke unit.

In conclusion, this randomized controlled trial showed that a combination of acute medical treatment and early intensive rehabilitation in a stroke unit increases the proportion of patients able to live at home, improves functional outcome, reduces the need for institutional care, and reduces early mortality.

Our results indicate that acute care in a stroke unit like ours may be the most effective treatment we can offer stroke patients today. In addition, the reduced need for institutional care suggests that establishing stroke units is good economy, which is also important if more stroke units are to be established in the future.

We expect that further analysis of the data from our study will provide additional information about which elements in the treatment program are most important and what kind of patients will benefit most from treatment in a stroke unit.

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KEY WORDS • cerebrovascular disorders • clinical trials • stroke outcome