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Articles

Stroke Unit Treatment

Long-term Effects

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Abstract

Top
Abstract
Introduction
Subjects and Methods
Results
Discussion
References

Background and Purpose We have previously shown that treatment in our combined acute and rehabilitation Stroke Unit improves outcome during the first year after onset of stroke compared with stroke patients treated in general wards. The aim of the present trial was to examine the long-term effects of the stroke unit care.

Methods In a randomized controlled trial, 110 patients with symptoms and signs of an acute stroke were allocated to the Stroke Unit and 110 to general wards. No significant differences existed in baseline characteristics between the two groups. The outcome after 5 years was measured by the proportion of patients at home, the proportion of patients in an institution, the mortality, and the functional state assessed by Barthel Index.

Results After 5 years, 38 (34.5%) of the patients randomized to the Stroke Unit and 20 (18.2%) of the patients randomized to the general wards were at home (*P*=.006). Sixty-five (59.1%) of the patients from the Stroke Unit and 78 (70.9%) of the patients from the general wards were dead (*P*=.041), while 7 (6.4%) and 12 (10.9%), respectively, were in an institution (eg, nursing home) (*P*=NS). Functional state was significantly better for patients treated in the Stroke Unit.

Conclusions For the first time it is shown that stroke unit care improves long-term survival and functional state and increases the proportion of patients able to live at home 5 years after the stroke. Combined acute and rehabilitation stroke units appear to be an effective way of organizing treatment for acute stroke patients.

Key Words: clinical trials • stroke management • stroke outcome • stroke unit

Introduction

Top
Abstract
Introduction
Subjects and Methods
Results
Discussion
References

Several trials have shown better outcome for stroke patients treated in stroke units (SU) compared with stroke patients treated in general wards (GW).[1 2 3 4 5 6 7 8 9] Meta-analysis of all available randomized controlled trials has shown that care of stroke patients in SU reduces mortality, institutionalization, and dependency.[10 11] On the basis of these results, SU care has been strongly recommended.[12] However, all trials of SU care thus far have followed the patients only to discharge or 6 to 12 months after the onset of the stroke. It is not known whether the effects of SU care persist after more than 1 year of follow-up.

The purpose of the present study was to test the hypothesis that treatment of patients with acute stroke in an SU improves the long-term clinical outcome (5 years) compared with patients treated in GW.

Subjects and Methods

Top
Abstract
Introduction
Subjects and Methods
Results
Discussion
References

The SU, located in the Department of Medicine, in our hospital is a combined acute and rehabilitation SU. For management of acute stroke in our SU we have constructed an acute treatment package for stroke. The treatment program is standardized with regard to diagnostic evaluation, observation, acute treatment, mobilization, and rehabilitation. We have a team approach to nursing and rehabilitation, emphasizing patient and family participation. Functional training and a modified motor relearning program are the basic rehabilitation approaches.

One hundred ten patients with symptoms and signs of acute stroke were on admission randomly allocated to treatment in the SU and 110 to treatment in GW. Patients in deep coma on admission and patients living in nursing homes before onset of the stroke were excluded before randomization. Otherwise the patients represented an unselected hospitalized stroke population. Details regarding the method of randomization, inclusion criteria, and the study design have previously been described.[9] There were no differences in baseline characteristics, and the distribution of stroke diagnosis was similar in the two groups (Table 1).[9] Before randomization, all the patients were assessed by the prognostic score of the SSS and the original long-term items of the SSS, with 48 points as the maximum score.[13] As shown in Table 1, there were no differences in the severity of the strokes in the two groups. The patients in the GW received acute medical care, physiotherapy, and occupational therapy, but not within the framework of a team approach. Details of the treatment were published earlier.[9] The maximum period of treatment in the SU was 42 days (average, 16 days). It was only during this period of a maximum of 6 weeks that differences in treatment and care were present. For both groups, the family physicians were responsible for further treatment and follow-up after the first 6 weeks. None of the patients had been followed up by the physicians or other members of the team in the SU. All the patients with a recurrent stroke after 6 weeks or complications after 6 weeks were treated in the GW if they needed hospitalization, so that no differences in treatment should occur.

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Table 1. Baseline Characteristics of Patients in the Stroke Unit and General Wards

We have previously reported the results up to 1 year after stroke and shown a positive effect of our treatment program in the SU during the first year after stroke.[9] In the present study the patients were reassessed 5 years ±3 months after the onset of stroke, and the end points were as follows: proportion of patients at home, proportion of patients in institutions, mortality, and functional state assessed by BI.[14] All patients who died before 5 years and 3 months after the onset of stroke were included in the mortality figures, while the functional state (BI) was analyzed only for the patients who were alive at this time. Patients with a BI ≥95 were classified as independent, and patients with a BI ≥60 were classified as independent or partly independent. A specially trained nurse who did not know where the patients had been treated performed all the assessments of the functional state (blind testing). None of the patients were lost from follow-up.

The causes of deaths were determined from all available clinical evidence rather than just the death certificate, which may be inaccurate.[15 16] All available information from hospital records, family physicians, and autopsy records were reviewed. Eight-five percent of the deaths occurred in the hospital, and information on the terminal illness was therefore quite good. However, autopsy was performed

in very few cases, and therefore the cause of death was mainly based on clinical evidence. The classification of death was categorized into five different groups in accordance with a common classification system for long-term survival analysis after stroke.[17] The deaths were categorized as follows: (1) Initial mortality included deaths during the initial treatment period of 6 weeks. (2) Complications of the stroke after 6 weeks included deaths in which the stroke-related impairments were thought to be in some way responsible, and there was no other likely cause of death. The main cause in this group was bronchopneumonia due to immobilization or aspiration. (3) Recurrent stroke included deaths that were directly due to the brain lesion or complication of immobility following a recurrent stroke. If deaths from stroke-related impairment occurred after a recurrent stroke, they were viewed as being due to the recurrent stroke rather than the first stroke. (4)Vascular deaths (except stroke) were those due to definite or probable cardiac causes, ruptured aortic aneurysm, or peripheral vascular disease. Sudden deaths were regarded as cardiovascular unless alternative explanations were found from clinical evidences or autopsy. (5) Nonvascular deaths were deaths unrelated to any stroke or stroke disability and without any evidences of vascular death.

Initial death was further categorized as follows: deaths caused by the direct effect of the initial stroke (eg, brain edema and herniation), complications related to the initial stroke (complications due to immobilization such as bronchopneumonia and pulmonary embolism), vascular death (mainly myocardial infarction), and nonvascular death (mainly cancer).

Differences between groups in the proportion of patients at home and in institutions were compared by the χ^2 test. Difference in survival during 5 years, as presented graphically by Kaplan-Meier survival curves, was estimated with the log rank test. The difference in BI was analyzed by the Mann-Whitney test. The proportion of patients with BI ≥95(independent) or BI ≥60 (independent or partly independent) was analyzed by the χ^2 test. Differences between the groups in causes of deaths were also compared by the χ^2 test. Group homogeneity was analyzed with the χ^2 test for sex, medical history, marital status, and diagnosis and with the Mann-Whitney test for age and severity of the stroke assessed by SSS. All the analyses were intention-to-treat analyses.

Results

- Top
- Abstract
- Introduction
- Subjects and Methods
- Results
- Discussion
- References

As shown in Table 2, the proportion of patients at home was higher in the SU group after 5 years: 34.5% of the patients treated in the SU were at home compared with 18.2% in the GW (*P*=.006). A significant difference in survival was also present 5 years after the onset of the stroke. The death rate was 59.1% in the SU and 70.9% in the GW after 5 years (*P*=.041) (Table 2, Fig 1). The relative reduction in mortality calculated by the Cox proportional hazards regression analysis was 29% (relative risk, 0.71; 95% confidence interval, 0.51 to 0.99). There was a nonsignificant reduction in institutional care: 6.4% in the SU group and 10.9% in the GW group were in an institution (eg, nursing home) after 5 years (*P*=.230) (Table 2).

View this table:
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Table 2. Number and Proportion of Patients Allocated to Treatment in the Stroke Unit and General Wards at Home, in Institutions, and Deceased After 5 years

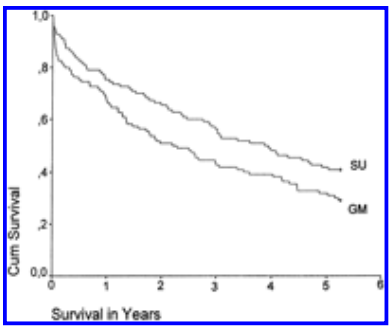

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Figure 1. Cumulative (cum) survival during 5 years of patients from the SU and GW.

The differences in mortality occurred during the initial treatment period of a maximum of 6 weeks (average, 16 days), when 8 (7.3%) of the patients in the SU group and 19 (17.3%) of the patients in the GW group died (*P*=.027) (Figs 1 and 2). The mortality during the period from 6 weeks to 5 years was similar in the two groups; in this period 57 patients (51.8%) in the SU group and 59 patients (53.6%) in the GW group died (*P*=NS) (Figs 1 and 2).

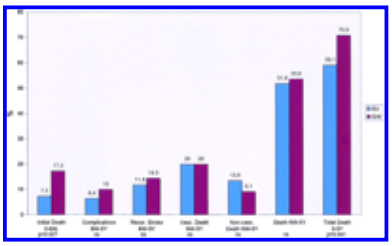

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Figure 2. Causes of deaths during 5 years in patients from the SU and GW. There was a significant difference between the two groups in initial death in the period from 0 to 6 weeks (*P*=.027) and total death in the period from 0 to 5 years (*P*=.041) but no significant differences in death rates or causes of deaths in the period from 6 weeks to 5 years. Recur. indicates recurrent; Vasc., vascular; and Non-vasc., nonvascular.

The causes of deaths during the first 6 weeks are shown in Table 3. The significant difference in initial mortality was mainly a result of a reduction in deaths caused by complications to the initial stroke, together with a small reduction in deaths caused by the direct effect of the initial stroke and recurrent stroke in the SU group compared with the GW group (Table 3).

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Table 3. Causes of Initial Death[1] in the Stroke Unit and General Wards

In the period between 6 weeks and 5 years, not only the death rates but also the causes of deaths were similar in the two groups (Fig 2). Vascular death was in this period the most frequent cause of death in both groups, followed by recurrent stroke or complications of recurrent stroke, nonvascular death, and complications of the initial stroke. Myocardial infarction was the most common cause of vascular death, while cancer was the most common cause of nonvascular death. Bronchopneumonia was the most frequent fatal complication after a stroke.

For patients who survived the first 6 weeks, 38.6% of subsequent deaths in the SU group and 37.3% in the GW group were due to vascular causes, whereas 22.8% and 27.1%, respectively, were due to a recurrent stroke or complications after a recurrent stroke. Altogether in the period from 6 weeks to 5 years, 61.4% of the deaths in the SU group and 64.4% of the deaths in the GW group were due to new events of cardiovascular or cerebrovascular diseases.

The functional level assessed by BI was higher in the SU (*P*=.042) (Fig 3), and the proportion of independent patients (BI ≥95) was also higher (*P*=.004) (Table 4). The proportions of independent or partly independent patients with BI ≥60 were 34.5% in the SU group and 18.2% in the GW group (*P*=.006). As shown in Table 4, the proportion of patients at home in the two groups corresponded well with the proportion of patients with BI ≥60. In the SU group two patients lived at home with a BI <60, while two patients were in an institution despite a BI ≥60. In the GW group all the patients at home had a BI ≥60, and none with a BI ≥60 was in an institution. The proportion of patients at home who received some kind of help after 5 years is shown in Table 5. No significant differences were present.

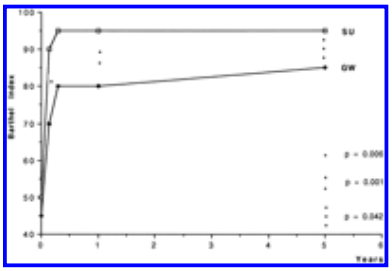

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Figure 3. BI median values during 5 years for patients treated in the SU and GW.

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Table 4. Barthel Index and Patients at Home 5 Years After Onset of Stroke

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[in this window]
[in a new window]

Table 5. Number and Proportion of Patients With Help/Support in Their Home 5 Years After Onset of Stroke

Discussion

- Top
- Abstract
- Introduction
- Subjects and Methods
- Results
- Discussion
- References

For the first time it is shown that stroke patients treated in an SU have a better long-term (5 years) outcome than stroke patients treated in GW. A standardized systematic treatment and rehabilitation program in an SU during the acute stage of stroke seems to improve long-term survival and functional state and to increase the proportion of patients able to live at home.

It is important to stress that (1) this was a controlled randomized trial in which the baseline characteristics in the treatment group and the control group were comparable; (2) intention-to-treat analyses were performed; and (3) the assessments of outcome in this long-term follow-up trial were blinded as far as possible because the person who assessed all the patients did not know where the patients had been treated (blind assessor). With this design and these methods, we strongly believe that no great bias in favor of the SU patients was present and that the better results in the SU group probably were due to real differences in outcome in the two groups.

It is also important to note that the differences in treatment in this trial were limited to the first 6 weeks. We have carefully examined the information and records of the treatment of every patient. In the period from 6 weeks to 5 years, we have not found any significant differences in treatment, prophylaxis, or follow-up between the two groups. If the better outcome in the SU group was a consequence of treatment, it must have been caused by the initial treatment and rehabilitation in the SU.

The proportion of patients able to live at home depends on several factors. The patients' functional state, support from relatives, and help from the primary healthcare system are some of the most important factors affecting the possibility of living at home. The number of patients with help from home care was similar in the two groups. We found no indications of more support from relatives or help from the healthcare system in the SU group (Table 5). The higher proportion of patients at home in the SU group was therefore probably due to a better functional outcome.

We used BI for evaluation of activity of daily living, and the better functional outcome achieved during the treatment period in the SU

still seemed to be present after 5 years (Fig 3). Most of the SU trials have shown a better functional outcome for patients treated in SU compared with patients treated in GW at discharge or at the follow-up 6 to 12 months after the stroke.[1] [2] [3] [4] [5] [6] [7] [9] [11] As time passes some of the trials have shown a declining difference in functional outcome between patients treated in SU and GW.[7] [18] The effectiveness of SU treatment is strongly supported by the fact that the functional level is higher for patients in the SU group after this long-term follow-up, and in our opinion this is the most important result in our trial. This better functional level in SU patients was present despite the increased survival in this group. At every assessment (except baseline) the functional level in the SU group was significantly higher in patients alive compared with the GW group (Fig 3). If the SU treatment had increased survival but the survivors had eventually become more dependent, the clinical benefit of the treatment could really be discussed.

We found that 23.6% of the patients in the SU group compared with 9.1% in the GW group were independent when we defined independence as BI ≥95. This indicates that the SU treatment strongly influenced the possibility of being independent 5 years after the stroke.

We also divided the BI at the point of 60, which is a common cutpoint in stroke trials. As shown in Table 4, there was a very close correlation between a BI score ≥60 and the ability of the patient to stay at home. It seems, at least in our community, that a patient needs a BI score ≥60 if he or she is going to live permanently at home. The higher proportion of patients in the SU group with BI score ≥60 probably explains why more patients live at home in the SU group than in the GW group.

The proportion of patients living in institutions was low after 5 years. One explanation may be that the patients with severe stroke and with a need to permanently stay in an institution had died before the 5-year follow-up and that the long-term survivors were the most independent stroke patients. Although not significant, there was a trend toward lower need for institutional care in the SU group.

In a previous report we showed that our SU treatment reduced the initial mortality during the first 6 weeks.[9] As shown in Table 3, the reduction in initial mortality was achieved by a reduction in deaths caused by the direct effect of the initial stroke, complications of the initial stroke, and recurrent stroke. One of the aims of our treatment program in the SU was to reduce the risk of such events, and the results indicate that the treatment program is working. In the period from 6 weeks to 5 years, the death rates were similar in the two groups (Fig 1). Therefore, the difference in mortality found after 5 years was probably due to the difference in the initial mortality.

The 5-year mortality was somewhat higher than in some of the community-based studies in which they followed first-ever stroke patients.[17] [19] [20] [21] In studies in which patients with first-ever stroke as well as recurrent strokes were included, mortality rates similar to those in our control group were found.[22] [23] [24]

However, the high death rates should be an invitation to discover ways to provide better long-term secondary prophylaxis. Vascular death (except stroke) was the main cause of death in both groups, and the combination of all vascular causes (cardiovascular and cerebrovascular) accounts for almost two of three deaths in the period from 6 weeks to 5 years. Therefore, the primary aim of secondary prophylaxis after stroke should be to reduce the risk of vascular events.

Long-term complications after initial stroke were a substantial cause of death during the 5-year follow-up period, and more knowledge about the prevention of long- term complications after stroke also seems appropriate. Most of the patients who died from complications several months or even years after the stroke were severely disabled. Emphasizing quality of life might be more important than secondary prophylaxis for these patients.

However, this trial did not focus on secondary prophylaxis. The lack of difference in both death rates and causes of death between the SU group and the GW group in the period from 6 weeks and 5 years supports the evidence of no difference between the groups in treatment/secondary prophylaxis after 6 weeks.

It is therefore difficult to find an explanation for the better outcome in the SU group after 5 years other than the fact that the differences were caused by the effect of the acute treatment and early rehabilitation in our SU.

The reasons why SU treatment works are still being discussed. Our SU has the same basic characteristics as others, with a team approach to nursing and rehabilitation and an emphasis on patient and family participation.[11]

Most of the controlled SU trials have not described the acute treatment very well, whereas the rehabilitation approach has been strongly emphasized.[10] [11] There is therefore strong evidence for rehabilitation as one of the most important aspects of SU care. In fact, a positive effect of SU without a rehabilitation approach (eg, intensive care units) has not been proven.[11] [12] [25] [26] [27] [28] [29] In our SU we do not have intensive care facilities, but we have combined the rehabilitation aspects with systematic observation of each patient and a standardized

acute medical treatment program.[9] We believe that this combination is responsible for the somewhat better result we have achieved compared with most of the trials from other units.[9] [10] [11] We need trials in which we directly compare different SU models and treatment programs before we know whether this combined SU model is superior to other models.

However, from the results of this trial we may conclude that care of patients with acute stroke in a combined acute treatment and rehabilitation SU improves long-term (5-year) survival and functional state and increases the proportion of patients able to live at home 5 years after the stroke. Combined acute treatment and rehabilitation SU appear to be an effective way to organize treatment for acute stroke patients.

Selected Abbreviations and Acronyms

BI = Barthel Index
GW = general wards
SSS = Scandinavian Stroke Scale
SU = stroke unit

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References

Top
Abstract
Introduction
Subjects and Methods
Results
Discussion
References

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Home page

Stroke HOME

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[Abstract] [Full Text] [PDF]

Home page

Stroke HOME

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[Abstract] [Full Text] [PDF]

Home page

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Brain, December 1, 2002; 125(12): 2731 - 2742.
[Abstract] [Full Text] [PDF]

Home page

Stroke HOME

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[Full Text] [PDF]

Home page

Stroke HOME

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[Abstract] [Full Text] [PDF]

Home page

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[Full Text]

Home page

The NEW ENGLAND JOURNAL of MEDICINE HOME

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Home page

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S.
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[Full Text] [PDF]

Home page

Stroke HOME

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[Abstract] [Full Text] [PDF]

Home page

Stroke HOME

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Stroke, May 1, 1999; 30(5): 917 - 923.
[Abstract] [Full Text] [PDF]

Home page

Stroke HOME

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Treatment and Rehabilitation on a Stroke Unit Improves 5-Year Survival : A Community-Based Study
Stroke, May 1, 1999; 30(5): 930 - 933.
[Abstract] [Full Text] [PDF]

Home page

Stroke HOME

S. D. Newell Jr, J. Englert, A. Box-Taylor, K. M. Davis, and K. E. Koch
Clinical Efficiency Tools Improve Stroke Management in a Rural Southern Health System
Stroke, June 1, 1998; 29(6): 1092 - 1098.
[Abstract] [Full Text] [PDF]

Home page

Stroke HOME

B. Indredavik, F. Bakke, S. A. Slordahl, R. Rokseth, and L. L. Haheim
Stroke Unit Treatment Improves Long-term Quality of Life : A Randomized Controlled Trial
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