Stroke Unit Treatment
10-Year Follow-Up

B. Indredavik, MD; F. Bakke, RPT; S.A. Slørdahl, MD, PhD; R. Rokseth, MD, PhD; L.L. Håheim, MSc

Background and Purpose—We have previously shown that treatment in our combined acute and rehabilitation stroke unit (SU) improves the outcome during the first 5 years after onset of stroke compared with that for stroke patients treated in general wards (GW). The aim of the present trial was to examine the effects of SU care after 10 years of follow-up.

Methods—In a randomized controlled trial, 110 patients with symptoms and signs of an acute stroke were allocated to the SU and 110 to GW. No significant differences existed in baseline characteristics between the groups. The outcome after 10 years was measured by the proportion of patients at home, the proportion of patients in an institution, the mortality, and the functional state as assessed by the Barthel Index, in which a Barthel Index score of ≥60 was classified as independent or partly independent and a score of ≥95 was classified as independent.

Results—After 10 years, 21 (19.1%) of the patients randomized to the SU and 9 (8.2%) of the patients randomized to the GW were at home ($P=0.0184$). Eighty-three (75.5%) of the patients from the SU and 96 (87.3%) of the patients from the GW were dead ($P=0.0082$), and 6 (5.4%) and 5 (4.5%), respectively, were in an institution (eg, nursing home; NS). Twenty-two (20.0%) of the SU patients and 9 (8.2%) of the GW patients had a Barthel Index score of ≥60 ($P=0.0118$), and 14 (12.7%) and 6 (5.4%), respectively, had a score of ≥95 ($P=0.0606$).

Conclusions—For the first time it has been shown that SU care improves survival and functional state and increases the proportion of patients able to live at home 10 years after their stroke. Treatment in combined acute and rehabilitation SU seems to have important long-term effects on outcome for stroke patients. (Stroke. 1999;30:1524-1527.)

Key Words: randomized controlled trials ■ stroke management ■ stroke units ■ treatment outcome

Several trials have shown that treatment of stroke patients in stroke units (SU) improves the outcome compared with treatment in general wards (GW).1–9 Meta-analysis of all available randomized controlled trials has shown that care of stroke patients in SU reduces mortality, institutionalization, and dependency. Most SU trials have followed the patients only to discharge or 6 to 12 months after onset of the stroke. We have previously presented favorable results of SU care after 5 years’ follow-up.12 The results showed that the better survival and functional outcome in the SU achieved during the first few weeks were still present after 5 years.12 A higher quality of life was also present in the SU group compared with the stroke patients treated in GW.13

The purpose of the present study was to test the hypothesis that the better outcome of the SU treatment compared with the GW was still present after 10 years’ follow-up.

Subjects and Methods
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 program. The program is standardized with regard to diagnostic evaluation, observation, acute treatment, mobilization, and rehabilitation. We have a team approach to nursing and rehabilitation that emphasizes patient and family participation. Functional training and a modified motor relearning program are the basic rehabilitation approaches. The details of the treatment program have been previously published, as have the differences between the treatment in the SU and the GW.9,14

On admission to the hospital, 110 patients with symptoms and signs of acute stroke were 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 the 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 or severity of the stroke in the 2 groups.7 The maximum period of treatment in the SU was 42 days (average 16 days). Differences in treatment and care were present only during this period of a maximum of 6 weeks. For both groups, the family physicians were responsible for further treatment and follow-up after the first 6 weeks.15

We have previously reported the results of SU care up to 5 years after the stroke.9,12,13 In the present study the patients were reassessed 10 years ±3 months after the onset of stroke, and the end...
TABLE 1. Patients in the SU Group and the GW Group at Home, in Institutions, and Dead 10 Years ± 3 Months After Stroke

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SU</th>
<th>GW</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home</td>
<td>21 (19.1)</td>
<td>9 (8.2)</td>
<td>0.0184</td>
</tr>
<tr>
<td>Institution</td>
<td>6 (5.4)</td>
<td>5 (4.5)</td>
<td>0.75</td>
</tr>
<tr>
<td>Dead</td>
<td>83 (75.5)</td>
<td>96 (87.3)</td>
<td>0.0082</td>
</tr>
</tbody>
</table>

Results

As shown in Table 1, the proportion of patients at home was higher in the SU group after 10 years: 19.1% of the patients treated in the SU were at home compared with 8.2% in the GW (P = 0.0184). Both groups had a low proportion of patients in institutions (eg, nursing homes) after 10 years, and there was no difference in institutional care between the 2 groups, with 5.4% in the SU group and 4.5% in the GW group in an institution (NS; Table 1).

A significant difference in survival was present 10 years after the onset of the stroke. The death rate was 75.5% in the SU group and 87.3% in the GW group (P = 0.0082) (Table 1 and the Figure). Hence, 9 patients are needed to prevent 1 death for a period of 10 years. The relative reduction in mortality calculated by Cox proportional hazards regression analysis was 33% (RR 0.67, 95% CI 0.50 to 0.90).

Differences between groups in the proportion of patients at home and in institutions were compared by the χ² test. Difference in survival during 10 years, presented graphically by Kaplan-Meier survival curves, was estimated with the log-rank test. The proportion of patients with BI ≥ 95 (independent or partly independent) was also analyzed by the χ² test. All the analyses were performed on an intention-to-treat basis.

TABLE 2. Differences in Mortality Between the SU Group and GW Group by Time Period

<table>
<thead>
<tr>
<th>Time Period</th>
<th>SU</th>
<th>GW</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 6 w</td>
<td>8 (7.3)</td>
<td>19 (17.3)</td>
<td>0.027</td>
</tr>
<tr>
<td>6 w to 1 y</td>
<td>19 (17.3)</td>
<td>17 (15.5)</td>
<td>NS</td>
</tr>
<tr>
<td>1 to 5 y</td>
<td>38 (34.5)</td>
<td>42 (38.2)</td>
<td>NS</td>
</tr>
<tr>
<td>5 to 10 y</td>
<td>18 (16.4)</td>
<td>18 (16.4)</td>
<td>NS</td>
</tr>
<tr>
<td>0 to 10 y</td>
<td>83 (75.5)</td>
<td>96 (87.3)</td>
<td>0.0082</td>
</tr>
</tbody>
</table>

The differences in mortality occurred during the initial treatment period of a maximum of 6 weeks (average 16 days), in which 8 (7.3%) of the patients in the SU group and 19 (17.3%) of the patients in the GW group died (P = 0.027; Table 2). The mortality rate during the period from 6 weeks to 5 years was similar in the 2 groups: 57 patients (51.8%) in the SU group and 59 patients (53.6%) in the GW group died (NS; Table 2). There was no difference in mortality rates during the period from 5 to 10 years, either: 18 patients in both groups (16.3%) died. The average mortality rate per year during the period from 1 to 5 years after stroke was 8.8% in the SU group and 9.6% in the GW group, whereas the rate from 5 to 10 years was 3.3% in both groups.

The proportion of independent patients (BI ≥ 95) after 10 years’ follow-up was 12.7% in the SU group and 5.5% in the GW group (P = 0.0606; Table 3). The proportion of patients who were independent or partly independent (BI ≥ 60) was 20.0% in the SU versus 8.2% in the GW group (Table 3; P = 0.0118). The proportion of patients at home in the 2 groups corresponded well with the proportion of patients with BI ≥ 60. In the SU group 21 (19.1%) of the patients were at home (Table 1) and 22 (20%) of the patients had a BI ≥ 60 (Table 1). In the GW group 9 (8.2%) of the patients were at home (Table 1), and the same number of patients had a BI ≥ 60 (Table 3). In the SU group 1 patient with a BI score of <60 lived at home, whereas 2 patients were institutionalized despite having a score of ≥60. In the GW group all the patients at home had a BI ≥60, and none with a BI ≥60 were in an institution. The proportion of patients at home who received some kind of help after 10 years is shown in Table 4. No significant differences were present.

TABLE 3. SU and GW Patients Independent in Activities of Daily Living (BI ≥ 95) or Independent or Partly Independent (BI ≥ 60) After 10-Year Follow-Up

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SU</th>
<th>GW</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI score ≥95</td>
<td>14 (12.7)</td>
<td>6 (5.4)</td>
<td>0.0606</td>
</tr>
<tr>
<td>BI score ≥60</td>
<td>22 (20.0)</td>
<td>9 (8.2)</td>
<td>0.0118</td>
</tr>
</tbody>
</table>

Cumulative survival during 10 years for patients from the stroke unit (SU) and the general wards (GW).
TABLE 4. Patients With Help/Support in Homes 10 Years After Onset of Stroke

<table>
<thead>
<tr>
<th>Source of Help</th>
<th>SU, n=21</th>
<th>GW, n=9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Family</td>
<td>3 (14.3)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td>Home service</td>
<td>4 (19.0)</td>
<td>4 (44.4)</td>
</tr>
<tr>
<td>Nursing at home</td>
<td>4 (19.0)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td>Some type of help</td>
<td>8 (38.1)</td>
<td>6 (66.7)</td>
</tr>
</tbody>
</table>

The number of patients receiving some type of help do not match the sum of the numbers of patients receiving help from a specific source, because some of the patients are receiving >1 source of help.

*Calculated from the number of patients at home.

**Discussion**

For the first time it has been shown that stroke patients treated in SU have a better 10-year outcome than stroke patients treated in GW. A standardized systematic treatment and rehabilitation program in SU during the acute stage of stroke seems to improve 10-year survival and functional state and increase the proportion of patients able to live at home.

The differences of treatment in this trial were limited to the first 6 weeks. We have carefully examined the information and records of treatment of every patient and found no differences in treatment, prophylaxis, or follow-up between the 2 groups in the period from 6 weeks to 10 years. Hence, if the better 10-year outcome in the SU group was a consequence of treatment, it has to be caused by the initial treatment and rehabilitation in the SU.

A completely blinded assessment is not possible in a trial like ours. The nurse who performed all the assessments was, however, not informed of where the patients had been treated. Hence, the assessments were blinded as far as possible.

The present analysis shows the same results in favor of SU treatment as the 5-year follow-up analysis. The proportion of patients at home was 1.9 times higher in the SU group after 5 years than in the GW group, and it was even higher (2.3 times) in the SU group after 10 years (SU 19.1% versus GW 8.2%; Table 1).

As noticed also in the 5-year follow up, the number of patients with help from home care was similar in the 2 groups (Table 4). We found no indication of more support from relatives or help from the healthcare system in the SU group (Table 4). The higher proportion of patients at home in the SU group was therefore probably due to a better functional outcome.

We used the BI for evaluation of activity of daily living in our SU trial. The higher proportion of patients who were independent or partly independent (BI score ≥60) after 10 years in the SU group compared with the GW group is probably the reason for the higher proportion of patients at home in the SU group (Table 1, Table 3). It seems, at least in our country, that BI ≥60 is the functional level needed for long-term ability to live at home for stroke patients.

The proportion of patients living in institutions was low after 10 years. The explanation may be that the patients who were long-term survivors were the most independent stroke patients.

In previous studies we have shown that our SU treatment reduced the initial mortality (after 6 weeks) and that this reduction was still present after 5 years. However, the mortality rate between 6 weeks and 5 years was similar between the 2 groups. The 10-year follow-up results show no difference in death rate between the 2 groups in the period from 6 weeks to 10 years, but the initial difference in mortality during the first 6 weeks was still present. It is worth noting that the mortality rate seems to decrease in both groups if we compare the death rate from 1 to 5 years with the rate from 5 to 10 years. We do not know the reason for this decline, but it is probably the healthiest stroke patients who survive for 5 years. This particular group might then have a good prognosis for a long life.

Altogether, there was a high 10-year mortality. Some of the explanations might be that the average age at inclusion was about 73 years. During the 10-year follow-up many patients reached a very old age, and this fact may explain some of the high death rates. However, the high death rates should also be a challenge for better follow-up and better secondary prophylaxis, because most of the deaths probably were caused by such vascular diseases as myocardial infarction and stroke.

The lack of difference in death rates between the SU- and GW groups in the period from 6 weeks to 10 years supports the evidence of no difference in treatment/secondary prophylaxis after the first 6 weeks between the groups.

Consequently, it is hard to find any other explanation for the better outcome in the SU group after 10 years other than that the differences were caused by the effect of the acute treatment and early rehabilitation in our SU.

The reasons that SU treatment seems to improve long-term outcome are not known. We have in a previous article identified some factors that seemed to be important for the better outcome after 6 weeks. The factors identified were mainly the same that have proved to be effective in other SU trials. The factors most frequently present in SU trials have been team care, focus on rehabilitation, and participation of patients and relatives in the treatment and rehabilitation process.

Most of the controlled SU trials have emphasized rehabilitation, but unlike most trials we have a very strong focus on the very early mobilization/rehabilitation, starting within 24 hours after admission. We have previously presented some data supporting the theory that this very early mobilization may have been important for the results in our trial. Compared with most of the other SU trials, we have also placed somewhat more emphasis on the very acute treatment. One of the most important elements in our acute treatment program has been the extensive use of intravenous saline solutions during the first 12 hours after admission. The aim of this hydration program was to avoid dehydration and low blood pressures and to stabilize blood pressure. Some results exist which indicate that low blood pressure during the acute stage of a stroke might be harmful. A systematic observation of fever and reduction of temperature >38°C was also part of the standard treatment program in our SU. These factors might also have contributed to the better outcome in the SU group.
However, we believe that the combination of strong and early rehabilitation efforts and the standardized acute medical treatment program are responsible for the somewhat better results we have achieved compared with most of the trials from other units.\textsuperscript{2, 3–6} Acute stroke patients need both acute care and acute rehabilitation. A unit dedicated to both of these elements might be more effective than units that focus only on acute treatment\textsuperscript{13} or only on rehabilitation.\textsuperscript{3–5} With only 220 patients, our trial alone cannot prove this assumption, but it gives some support to such a view. However, we need trials in which we can directly compare different SU models and treatment programs before we really know whether this combined SU model is superior to others.

In conclusion, the results of this trial show that care of patients with acute stroke in a combined acute treatment and rehabilitation SU improves 10-year survival and functional state and increases the proportion of patients able to live at home 10 years after the stroke. No other SU trial or no other treatment for stroke has shown such promising long-term results. Hence, treatment in a combined acute treatment and rehabilitation SU is a treatment modality for acute stroke that has the strongest evidence of effectiveness. The combined SU, which focuses on both acute care and acute rehabilitation, seems to be very important for a favorable short- and long-term outcome for stroke patients.

Acknowledgments

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