Stroke Unit Care Combined With Early Supported Discharge Improves 5-Year Outcome
A Randomized Controlled Trial

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Background and Purpose—Early supported discharge (ESD) seems to be a promising alternative to conventional follow-up care after acute stroke. We have previously shown that stroke unit care combined with ESD has beneficial effects on functional outcome and the use of resources for up to 1 year. The aim of this trial was to evaluate outcome after 5 years.

Methods—We performed a randomized controlled trial with 320 acute stroke patients allocated to ordinary stroke unit care (160 patients) or stroke unit care with ESD (160 patients). The ESD service consisted of a mobile team that co-coordinated hospital discharge and further rehabilitation during 1 month of follow-up in cooperation with the primary health care. Mortality, residence, and functional outcome including modified Rankin scale were registered after 5 years. All assessments were blinded.

Results—There was no difference between the groups with modified Rankin scale score ≤2 (P=0.213), but there was a trend toward greater improvement in modified Rankin scale score in the ESD group from onset of stroke (38% versus 30%; P=0.106). More patients were dead or institutionalized in the ordinary stroke unit care group (P=0.032); 158 patients were alive, 84 were in ESD, and 74 were in ordinary stroke unit care. Of the 158 patients alive, a greater proportion were living at home in ESD (86%/70%; P=0.019).

Conclusions—Stroke unit care combined with ESD seems to reduce death and institutional care and to improve patients’ chances of living at home 5 years after stroke compared to traditional stroke care. There is a trend toward improved functional outcome in the ESD group. (Stroke. 2011;42:1707-1711.)

Key Words: organized stroke care ■ outcomes ■ rehabilitation ■ stroke delivery ■ stroke recovery ■ stroke units

The organization of inpatient stroke care was, for the first time, seriously considered and addressed in the 1950s.1 It was important, despite the lack of scientific evidence. Today, we know that organizing the care of acute stroke patients is essential, and the effectiveness of stroke unit care as the first link in the chain of care is documented by scientific evidence.2 Stroke unit care is a widely accepted component of stroke care and is recommended in many official guidelines.

The optimal organization of stroke care after discharge has been undergoing discussion during the past 15 years. Randomized controlled trials of early supported discharge (ESD) and further rehabilitation at home have documented great benefits, mostly in reduced length of hospital stay (8 days).3,4 Some trials also have documented improved functional outcome, improved quality of life, and reduced costs3–8 up to 1 year after stroke. The current recommendation from the ESD trialsists group, based on a meta-analysis on 12 randomized controlled trials,3,4,5 is an ESD service consisting of a coordinating multidisciplinary team, because this is the most effective form of organization in follow-up and rehabilitation. The service is useful for most patients with mild to moderate disability, ie, for 30% to 50% of stroke patients. Our previous publications are a part of this systematic review. The long-term effects of ESD after 1 year are not well-documented in the literature. Whether ESD has a long-term effect surpassing 1 year of follow-up is a question not yet answered by the literature.

This analysis is based on methods and results from a randomized controlled trial of ESD service for patients at the Stroke Unit at St. Olavs University Hospital, Trondheim, Norway, in which we compared extended stroke unit service (ESD) with traditional treatment (ordinary stroke unit service [OSUS]) after stroke. The benefits attributed to the ESD group consisted of improved functional ability,4,8 health-related quality of life,6 resource use, and reduced costs7 during the first year after a stroke, as presented. We have also previously explored the association between stroke severity and benefit of ESD versus OSUS.8

The primary focus of this analysis was to assess and compare patients’ functional outcomes, survival, and place of residence 5 years after stroke for the patients treated in the 2 groups.
Secondarily, we also examined other measures of social function and cognition. Finally, we tried to define baseline predictors for good and bad outcomes 5 years after stroke.

**Materials and Methods**

This 5-year follow-up study was performed based on a randomized controlled trial of 320 acute stroke patients; 468 acute stroke patients admitted to the Stroke Unit at St. Olav University Hospital of Trondheim, Norway, during a 2-year period from 1995 to 1997 were assessed for inclusion in the trial and 320 fulfilled the inclusion criteria and were randomly allocated either to the extended stroke unit service (ESD) or to the OSUS. The time of follow-up was 1 year after inclusion. We recorded the baseline characteristics of age, sex, severity of stroke, medical history, and functional status before entrance into the trial.

During the acute phase in the stroke unit (eg, the first 2 weeks), both groups received identical evidence-based stroke unit care with a standardized medical treatment combined with a focus on early mobilization/rehabilitation.

The follow-up service for the ESD group was organized by a coordinating mobile team that followed-up the patient for the first month after discharge from the hospital. They established a program and support system that allowed the patient to live at home as soon as possible and to continue rehabilitation at home or in a day clinic. The mobile team consisted of a physiotherapist, an occupational therapist, a nurse, and the part-time service of a physician. One of the therapists acted as a case manager for the patient.

The follow-up for the OSUS group after discharge from the stroke unit was organized by the primary health care service with further inpatient or outpatient rehabilitation on discharge. Details regarding the study design, the method of randomization, the inclusion criteria, and the intervention have been reported previously. The Regional Committee for Medical Research approved the study protocol.

**Evaluation**

As the primary outcome, we have used the modified Rankin scale (mRS) and improvement of mRS score from stroke onset to 5 years. Because this is a long-term follow-up of a randomized trial, we also decided to have the proportion of patients deceased, at home, and in an institutions after 5 years as the primary outcome.

Secondary outcomes were the results of the following assessment scales: Frenchay Activity Index, Scandinavian Stroke scale (SSS), Mini Mental Status Examination, and Barthel Index. The Frenchay Activity Index has been developed specifically for measuring disability in stroke patients. It measures complex physical activities and social functioning with a separate score for each of the 15 items (maximum score, 60). The Mini Mental Status Examination is a simplified scored form of the cognitive status examination and includes 11 questions with a maximum total score of 30.

Finally, a subgroup analysis examining independence at 5 years (mRS score ≤2) was performed for patients with mild to moderate stroke, defined as baseline SSS score ≥30. We also tried to define baseline predictors for good and bad outcomes 5 years after stroke measured by mRS. A blinded external assessor performed these clinical evaluations during a visit of the patients at their place of residence. Informed consent was obtained before the examination. The same assessments measures were used at baseline, 6 months, 12 months, and 5 years after stroke.

**Statistics**

Pearson χ² test was used to investigate the difference between the groups regarding baseline characteristics and place of residence (death, home, or institution). The intention-to-treat population was used in the main analysis. To investigate differences between the groups in the other primary and secondary outcomes, we used the Mann–Whitney U test. Logistic regression was performed with the use of mRS score (≤2) as the dependent variable and treatment, age, sex, SSS score, and cohabiting status as predictor variables. To answer the question about whether the direct analysis of original ordered data is more efficient and more likely to yield reliable results in this kind of trials, we performed different analyses of mRS as outcome using both the entire ordinal scale and dichotomization (independent score 0–2 versus dependent or dead score 3–6). The significance level was set at 0.05. In the secondary outcomes, the on-treatment population (patients alive) was used.

**Results**

Four hundred sixty-eight patients were screened for inclusion in the trial, and 320 patients fulfilled the inclusion criteria. After 5 years, 5 patients were missing in the ESD group and 9 patients were missing in the OSUS group. Respectively, 155 and 151 patients were evaluated (Figure 1).

Table 1 shows the baseline characteristics of the 2 groups. No significant differences existed concerning age, sex, living conditions, or comorbidities. The functional status assessments within 24 hours after randomization were almost identical in the groups.

The primary outcome of independence was measured by mRS score ≤2 and showed no statistically significant difference between the groups 5 years after stroke (35% versus 29%; P=0.213; Table 2). Adjusted for potentially confounding independent variables (treatment, SSS score, sex, age, and cohabiting status), the analysis showed a strong trend toward a larger proportion of patients with mRS score ≤2 in ESD (P=0.079; Table 3). Our analyses showed no difference between outcomes using the entire ordinal scale or dichotomization. No significant interaction between the independent variables was found.

There was a strong trend toward a larger proportion of patients with improvement in mRS score from onset of stroke to 5 years after stroke in ESD (38% versus 30%; P=0.106). Additionally, a larger proportion of patients in ESD versus OSUS also showed improvement in mRS score from 1 year to 5 years (16% versus 9%; P=0.048; Table 2). There were no differences in mortality between ESD (46%) and OSUS (51%) at 5 years (P=0.364), but a significantly larger group of patients was dead or institutionalized in the OSUS group (P=0.032). The odds ratio for living at home in the ESD group (versus the OSUS group) was 1.699 (95% CI, 1.08–2.68; P=0.022). One hundred fifty-eight patients (84 ESD/74 OSUS) were alive after 5 years; of those, a larger proportion of patients was living at home versus at an institution in ESD (86%) versus OSUS (70%; P=0.019; Figure 2).

The secondary outcomes SSS, Barthel Index, Frenchay Activity Index, and Mini Mental Status Examination showed no differences between the groups at 5 years (Table 4). The subgroup analysis for patients with mild to moderate stroke (SSS score ≥30) showed no significant differences between the groups in mRS after 5 years, but a trend toward more independent patients (mRS score ≤2) in the ESD group (37% versus 29%; P=0.126).

A subgroup analysis of the ESD group with regard to predictors for good outcome (mRS score ≤2) versus bad outcome (mRS score >2) after 5 years yielded lower age at stroke onset (median age, 69.0 years for good outcome/76.6 years for bad outcome), a lower mRS score (mean score, 2.8 for good outcome/3.5 for bad outcome), and cohabitation (living alone 26.4% for good outcome/48.5% for bad outcome) at baseline.
Discussion

We have previously shown that extended stroke unit service combined with ESD reduces length of institutional stay, improves clinical outcome, and reduces costs up to 1 year after stroke compared to traditional stroke care.5–8 This is in accordance with other trials.3 In this 5-year follow-up, we show that ESD can reduce death and institutional care and can improve patients’ chances of living at home up to 5 years after a stroke compared to traditional follow-up care. There is a strong statistical trend toward improved functional outcome assessed by mRS in the ESD group, as was shown at the 1-year follow-up. After 4 years, the difference between the groups in the proportion of patients living at home up to 5 years after a stroke compared to traditional follow-up care. The early supported discharge regime also seems to be effective in the long-term. The findings with increased improvement in the mRS score from 1 to 5 years in the ESD group are interesting, because no formal interventions were performed in this period. It is possible that the initial intervention during ESD leads to a process that caused the patients and their immediate networks to better-manage life after stroke. Our result is based on a long-term follow-up of a randomized trial with a relatively short term of intervention. A weakness of the trial is that we do not know what services the patients received from the health care service in the period between 1 year and 5 years after their stroke. This time period carries within it the possibility of confounding factors for the results of the trial. However, we have no evidence that specific interventions, such as therapy-based rehabilitation services at 1 year after a stroke, influence outcome.18 It also might have been interesting to know the hospital readmission rate during this time, because few stroke patients seem to survive 5 years without readmissions.19 Unfortunately, we do not have these data available.

To our knowledge, just 1 other trial20 has published data from a 5-year follow-up of a randomized trial on ESD, in which the initial treatment for all patients was stroke unit care. It found beneficial effects on measures of extended activities of daily living for patients with mild and moderate stroke.
Table 1. Baseline Characteristics of the Patients Allocated to the Extended Stroke Unit Service and to Ordinary Stroke Unit Service

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ESD (n=160)</th>
<th>OSUS (n=160)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean/median)</td>
<td>74.0/74.5</td>
<td>73.8/74.0</td>
</tr>
<tr>
<td>Male (%)</td>
<td>54</td>
<td>44</td>
</tr>
<tr>
<td>Living alone (%)</td>
<td>41</td>
<td>43</td>
</tr>
<tr>
<td>TIA (%)</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>Stroke (%)</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>33</td>
<td>35</td>
</tr>
<tr>
<td>Myocardial infarction (%)</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>Atrial fibrillation (%)</td>
<td>17</td>
<td>15</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>15</td>
<td>12</td>
</tr>
</tbody>
</table>

The strengths of our trial are the randomized controlled design from the beginning and the enrollment of an unselected hospitalized stroke population. All included patients received the best available care in the acute phase (stroke unit treatment).2 Our stroke unit has previously shown beneficial results not only in the short-term but also in the long-term,21 which makes the additional long-term effects of the ESD even more impressive.

Table 2. Number and Proportion at Home, in an Institution, and Deceased After 5 Years and Number, Proportion of Patients With Modified Rankin Scale Score ≤2, and Patients With Improvement in Modified Rankin Scale Score From Onset of Stroke Up to 5 Years and From 1 Year to 5 Years in the Extended Stroke Unit Service Versus the Ordinary Stroke Unit Service

<table>
<thead>
<tr>
<th></th>
<th>ESD (n=160)</th>
<th>OSUS (n=160)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dead</td>
<td>71</td>
<td>77</td>
</tr>
<tr>
<td>At home</td>
<td>72</td>
<td>52</td>
</tr>
<tr>
<td>In institution</td>
<td>12</td>
<td>22</td>
</tr>
<tr>
<td>mRS ≤2</td>
<td>54</td>
<td>43</td>
</tr>
<tr>
<td>Improvement in mRS*</td>
<td>58</td>
<td>45</td>
</tr>
<tr>
<td>Improvement in mRS*</td>
<td>24</td>
<td>13</td>
</tr>
</tbody>
</table>

One of the questions this kind of trial raises is which components of the present service cause it to be so successful. We know that well-coordinated multidisciplinary teams with weekly meetings are the most effective,9 but measuring the specific parts of the service is difficult.

Trials have documented reduction in short-term and long-term mortality22-24 for stroke patients treated in stroke units. This finding of increased survival brings forth the need for effective care of stroke patients after discharge. ESD seems to be the most useful component of an integrated stroke service for a large proportion of stroke patients up to 1 year after stroke, and 2 randomized trials have now shown benefits up to 5 years after stroke.20 There is definitely a need for more research to confirm the long-term benefits.

It is a challenge to integrate ESD in clinical practice, because the service depends on available resources in the community and some difficult financial barriers have to be overcome. A few trials25-27 have documented that ESD is a cost-effective alterna-

Table 3. Binary Logistic Regression Model for Modified Rankin Scale Score ≤2 at 5 Years and Effect of the Extended Stroke Unit Service Versus the Ordinary Stroke Unit Service Adjusted for Severity of Stroke, Sex, Cohabiting Status, and Age

<table>
<thead>
<tr>
<th></th>
<th>Values</th>
<th>B</th>
<th>P</th>
<th>OR=Exp(B)</th>
<th>95% CI for OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>OSUS</td>
<td>ESD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSS</td>
<td>As given</td>
<td>0.095</td>
<td>0.000</td>
<td>0.909</td>
<td>0.879 0.941</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td>1.109</td>
<td>0.001</td>
<td>3.032</td>
<td>1.547 5.943</td>
</tr>
<tr>
<td>Living alone</td>
<td>Cohabiting</td>
<td>0.846</td>
<td>0.014</td>
<td>2.330</td>
<td>1.188 4.571</td>
</tr>
<tr>
<td>Living alone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>0.132</td>
<td>0.000</td>
<td>1.141</td>
<td>1.093 1.192</td>
</tr>
<tr>
<td>Constant</td>
<td></td>
<td>-6.156</td>
<td>0.001</td>
<td>0.002</td>
<td></td>
</tr>
</tbody>
</table>

Values B: 95% CI for OR

Figure 2. Subgroup analysis for patients alive after 5 years.

Place of residence 5 years after stroke in extended stroke unit service (early supported discharge [ESD]) vs the ordinary stroke unit service (OSUS). Pl of residence 5 years after stroke for patients alive in the extended stroke unit service (early supported discharge) vs the ordinary stroke unit service (OSUS).
Follow-Up of Early Supported Discharge

Table 4. Secondary Outcomes of Scandinavian Stroke Scale, Frenchay Activity Index, and Mini Mental Status Examination and Dichotomized Scandinavian Stroke Scale and Barthel Index Assessed by 5 Years in the Extended Stroke Unit Service and the Ordinary Stroke Unit Service

<table>
<thead>
<tr>
<th></th>
<th>ESD (n=84)</th>
<th>OSUS (n=74)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSS Mean</td>
<td>51.9 (10.7)</td>
<td>51.4 (8.7)</td>
<td>0.346</td>
</tr>
<tr>
<td>Median</td>
<td>57.0 (50)</td>
<td>55.0 (32)</td>
<td></td>
</tr>
<tr>
<td>FAI Mean</td>
<td>33.5 (11.3)</td>
<td>31.3 (12.2)</td>
<td>0.256</td>
</tr>
<tr>
<td>Median</td>
<td>33.0 (38)</td>
<td>32.0 (39)</td>
<td></td>
</tr>
<tr>
<td>MMSE Mean</td>
<td>25.9 (4.8)</td>
<td>25.0 (5.9)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>27.5 (25)</td>
<td>27.0 (24)</td>
<td></td>
</tr>
<tr>
<td>SSS ≥52, n (%)</td>
<td>62 (73.8)</td>
<td>50 (67.6)</td>
<td>0.389</td>
</tr>
<tr>
<td>BI ≥95, n (%)</td>
<td>48 (57.1)</td>
<td>38 (51.4)</td>
<td>0.285</td>
</tr>
</tbody>
</table>

B1 indicates Barthel Index; ESD, early supported discharge; FAI, Frenchay Activity Index; MMSE, Mini Mental Status Examination; OSUS, ordinary stroke unit service; SD, standard deviation; SSS, Scandinavian Stroke scale.

...tive to usual care, and a systematic review concludes with “moderate evidence” that ESD provides care at lower total costs than usual care. There are several methodological challenges in this area. Because long-term follow-up studies of randomized trials have weaknesses, these results should be treated with caution. Further trials in different cultural settings are necessary to confirm the results.

We have previously defined the balance of cost and benefit of ESD up to 1 year after stroke. However, more research on the economic consequences of ESD is also required.

In this trial, we have been able to show that our extended stroke unit service combined with ESD increases the patients’ chances of living at home with improved function up to 5 years after a stroke compared to traditional follow-up after stroke. Together with the other evidence of stroke unit care, ESD seems today to be the best-documented and most effective alternative for follow-up after stroke.

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Disclosures
None.

References
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