Open, Randomized Pilot Study After First Stroke
A 3.5-Year Follow-Up

Lennart Welin, MD, PhD; Kerstin Bjälkefur, RN, MPH; Ingrid Roland, RN

Background and Purpose—Although care in stroke units has improved outcome in stroke patients, it is less clear whether specialized outpatient care after stroke can further improve the prognosis. We therefore conducted a pilot study comparing specialized long-term care with usual care after a first stroke.

Methods—During a 2-year period, 549 patients were discharged alive from our stroke unit. Eighty-one patients were randomized to follow-up care at the stroke outpatient clinic (intervention group), and 82 patients were randomized to follow-up care with their general practitioner (control group).

Results—No differences in baseline variables were noted between the 2 groups. At the 12-month visit, there were no significant differences between the groups with respect to handicap, depression, and perceived health. During 3.5 years of follow-up, no differences in mortality, stroke recurrence rate, and unplanned hospitalizations were observed between the groups.

Conclusions—In this small pilot study, specialized follow-up service for stroke patients was not superior to “usual care.” (Stroke. 2010;41:00-00.)

Key Words: stroke ■ follow-up ■ randomized study

Management of stroke patients in specialized stroke units has significantly improved their prognosis when compared with management in ordinary medical units. However, whether specialized outpatient care after stroke can further improve the prognosis is less well studied.

Long-term specialist nurse care has been provided to patients with a range of conditions, although there is limited evidence of the effectiveness of such care. A nurse-led intervention for patients with chronic heart failure led to improved outcomes, but a randomized, controlled trial of specialist nurse service for stroke patients failed to detect differences in perceived health or social activity between intervention and control groups.

The resources at our small countryside hospital are limited. In 2002, we planned to establish a specialized outpatient clinic for stroke patients. We realized that we should first assess whether such an outpatient clinic could better improve outcome, quality of life, and handicap compared with “usual care.” We therefore performed a randomized, follow-up study of patients after first stroke. The patients were followed up either at the hospital by a stroke nurse and stroke physician or by their general practitioner.

Subjects and Methods

Study Design and Inclusion and Exclusion Criteria
This was a prospective, open, randomized, controlled pilot trial conducted in a Swedish countryside hospital with an acute stroke unit. Patients willing to participate signed an informed consent form and then drew a sealed envelope containing information about whether they would be randomized to the special outpatient clinic or to their general practitioner. This was done on the day before or the day of discharge.

Inclusion Criteria
Inclusion criteria were first stroke (ischemic or hemorrhagic), <85 years of age, and living at home before stroke onset.

Exclusion Criteria
Exclusion criteria were previous stroke, severe dementia, severe stroke (a score of 5 on the Rankin scale), other severe cardiovascular diseases, or other severe diseases with expected survival of <1 year. Patients with alcohol and drug abuse were also excluded. The study was approved by the regional ethics committee at the University of Gothenburg.

Intervention
Patients randomized to follow-up care at the specialized outpatient clinic (intervention group, I group) were seen by 1 of 2 stroke nurses at 1.5, 6, and 12 months after discharge to assess their handicap, as measured by the modified Rankin scale, the Barthel Activities of Daily Living index, and the Scandinavian Stroke Scale. Depression was measured with the Montgomery-Åsberg depression rating scale. Perceived health was measured on a 5-point scale from 1 (excellent) to 5 (poor). The stroke nurse measured blood pressure, offered health advice and information, and if needed, referred the patients to a physiotherapist or occupational therapist. The stroke nurse also registered drugs used by the patients. A stroke physician saw the patients at 3 and 9 months, mainly to assess drug therapy, detect other medical problems, and if required, arrange referrals to other specialists or therapists.
Table 1. Baseline Characteristics During the Hospital Stay and at Hospital Discharge

<table>
<thead>
<tr>
<th></th>
<th>I Group, n=81</th>
<th>C Group, n=82</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>71.2 (9.9)</td>
<td>69.6 (11.7)</td>
<td>0.23</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>33 (41)</td>
<td>30 (37)</td>
<td>0.59</td>
</tr>
<tr>
<td>Previous myocardial infarction, n (%)</td>
<td>7 (9)</td>
<td>8 (10)</td>
<td>0.81</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>53 (65)</td>
<td>51 (62)</td>
<td>0.67</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>18 (22)</td>
<td>13 (16)</td>
<td>0.30</td>
</tr>
<tr>
<td>Atrial fibrillation, n (%)</td>
<td>13 (16)</td>
<td>16 (22)</td>
<td>0.30</td>
</tr>
<tr>
<td>Smokers, n (%)</td>
<td>14 (17)</td>
<td>13 (16)</td>
<td>0.81</td>
</tr>
<tr>
<td>Intracerebral hemorrhage, n (%)</td>
<td>7 (9)</td>
<td>13 (16)</td>
<td>0.16</td>
</tr>
<tr>
<td>Maximal p-glucose, mean (SD), mmol/L</td>
<td>7.9 (3.8)</td>
<td>7.3 (3.3)</td>
<td>0.36</td>
</tr>
<tr>
<td>Maximal body temperature, mean (SD), °C</td>
<td>37.5 (0.6)</td>
<td>37.6 (0.6)</td>
<td>0.26</td>
</tr>
<tr>
<td>Modified Rankin scale 0–2 (at discharge), n (%)</td>
<td>49 (60)</td>
<td>59 (72)</td>
<td>0.30</td>
</tr>
<tr>
<td>Barthel Activities of Daily Living index 85–100 (at discharge), n (%)</td>
<td>60 (74)</td>
<td>56 (68)</td>
<td>0.90</td>
</tr>
<tr>
<td>Scandinavian Stroke Scale 55–58 (at discharge), n (%)</td>
<td>28 (35)</td>
<td>42 (51)</td>
<td>0.09</td>
</tr>
<tr>
<td>Discharge to home, n (%)</td>
<td>64 (79)</td>
<td>60 (73)</td>
<td>0.38</td>
</tr>
<tr>
<td>Rehabilitation after discharge, n (%)</td>
<td>51 (63)</td>
<td>43 (52)</td>
<td>0.17</td>
</tr>
<tr>
<td>Antihypertensive drugs, n (%)</td>
<td>63 (78)</td>
<td>66 (80)</td>
<td>0.67</td>
</tr>
<tr>
<td>Warfarin, n (%)</td>
<td>14 (17)</td>
<td>14 (17)</td>
<td>0.97</td>
</tr>
<tr>
<td>Acetylsalicylic acid, n (%)</td>
<td>61 (75)</td>
<td>55 (67)</td>
<td>0.25</td>
</tr>
<tr>
<td>Dipyridamole, n (%)</td>
<td>27 (33)</td>
<td>16 (20)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

p-glucose indicates plasma-glucose.
Hypertension, diabetes, and atrial fibrillation groups include patients whose condition was known before admission or was detected during the hospital stay.

Patients recruited during the first year were offered a 4-year visit, whereas those recruited during the second year were offered a 3-year visit. Furthermore, the stroke nurse met the patients who were randomized to follow-up care with their general practitioner (control group, C group) at the 12-month visit and after 3 or 4 years. The general practitioners were informed by a discharge summary and an accompanying letter about the randomized study. The quality of follow-up stroke care by general practitioners varies in Sweden from no follow-up at all to regular visits every third or fourth month.

End Points
The primary end point was total mortality. The secondary end point was recurrent stroke. Tertiary end points were unplanned hospitalizations, handicap as measured by different scales,5–7 and depression.8 Drug use, blood pressure, perceived health, and the occurrence of postapoplectic epilepsy were registered.

Statistical Methods
The SPSS program was used for descriptive statistics. x² tests were calculated for categorical variables and t tests for continuous variables in the I group and C group comparisons.

Results
During the 2-year recruitment period (March 1, 2003 to February 28, 2005), 549 patients were discharged alive from our stroke unit (the Figure). After exclusion for various reasons (the Figure), 198 patients remained eligible for the study, of whom 35 refused to participate, 81 were randomized to follow-up care at the stroke outpatient unit, and 82 were randomized to follow-up care with their general practitioner.

At discharge (Table 1), there were no statistically significant differences between the I and C groups. Patients in both groups who returned for follow-up (Table 2) had improved further since discharge, as measured by the modified Rankin scale, the Barthel Activities of Daily Living index, and the Scandinavian Stroke Scale, but there were no differences between the groups. After 3.5 years of follow-up, mortality was 6% in the I group and 11% in the C group, a nonsignificant difference (Table 2). A nonsignificant difference for recurrent strokes was also found (19% in the I group and 15% in the C group). Postapoplectic epilepsy was equally common in both groups. The number of unplanned readmissions was slightly less in the C group.

No comparisons between the I and C groups were done for the visits at 3 and 4 years because a large number of the patients did not attend these visits (the Figure). Those who were still alive at these follow-up dates, however, were evaluated for mortality, recurrent stroke, postapoplectic epilepsy, and unplanned readmissions.

Discussion
This poststroke follow-up pilot study found no differences between patients referred to their general practitioners and patients cared for by a specialized stroke team in a hospital outpatient clinic. One possible explanation for the lack of differences is that the study lacked power to detect a difference, if it exists. Another explanation is that the medical care provided by the primary care physicians was comparable to that provided by the nurses and physician at the hospital’s specialized outpatient clinic. When the patients in both groups were discharged from the hospital, they were all given standard secondary prevention drugs, and for those who needed it, were offered continuous physiotherapy or occupational therapy in well-developed units in the communities adjoining our hospital. These interventions were initiated...
during the hospital stay and at discharge and not left to the discretion of the primary care physicians.

We are unaware of any study with an intervention design like that in our study. Randomized, follow-up studies have typically focused on a range of different outcomes. For instance, a Danish study found that in comparison with standard care, home visits by a physician or a physiotherapist’s instructions at home could partly prevent readmission. Early supported discharge services for selected stroke patients can reduce dependency and death. In our study, there were no differences between the groups regarding readmission. As in our study, a Danish study found no differences in functional outcome after stroke. In a New Zealand study, visits at home by a physiotherapist or occupational therapist were no better than outpatient or day-hospital therapy. Furthermore, a Dutch outreach nursing support program for discharged stroke patients was not effective in improving quality of life or handicap.

In summary, our study showed that follow-up of selected stroke patients in a specialized outpatient clinic was no better than follow-up with a general practitioner, at least not in our region.

Sources of Funding

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Disclosures

None.

References


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