Home Hospitalization Service for Acute Uncomplicated First Ischemic Stroke in Elderly Patients: A Randomized Trial

Nicoletta Aimonino Ricauda, MD, Mario Bo, MD, Mario Molaschi, MD, Massimiliano Massaia, MD, Dominga Salerno, MD, Dario Amati, MD, Vittoria Tibaldi, MD, and Fabrizio Fabris, MD

OBJECTIVES: To evaluate whether home treatment of elderly patients with acute uncomplicated first ischemic stroke is associated with different mortality rates and clinical outcomes from those of patients treated on a general medical ward (GMW).

DESIGN: Randomized, controlled, single-blind trial.

SETTING: S. Giovanni Battista Hospital of Turin.

PARTICIPANTS: One hundred twenty elderly patients admitted to the emergency department of the hospital with first acute ischemic stroke were randomized to home treatment from a geriatric home hospitalization service (GHHS) or to GMW treatment.

MEASUREMENT: Main outcome was cumulative survival at 6 months in the two groups. Residual functional impairment, neurological deficit, depression, morbidity, and admission to rehabilitation and long-term care facilities were considered as secondary outcomes in survivors.

RESULTS: One hundred twenty patients (mean age 82; 54 men and 66 women) were enrolled (60 in each study arm). The cumulative proportion of cases surviving at 6 months was 0.65 in the GHHS group and 0.60 in GMW group (log-rank test $P = .53$). Functional and neurological parameters were significantly improved in both GHHS and GMW patients, without significant differences between the two groups. Depression score was significantly better in home-treated patients ($P < .001$), who were more likely to remain at home at 6 months than hospital-treated patients and had a lower rate of select medical complications.

CONCLUSION: Home-treated elderly patients with ischemic stroke have better depressive scores and lower rates of admission to nursing homes. These results should prompt further studies to evaluate home hospitalization for elderly stroke patients. J Am Geriatr Soc 52:278–283, 2004.

Key words: elderly; stroke; home
The primary outcome of this study was to evaluate whether home-treated patients have different mortality rates from those of patients admitted to and treated on a general medical ward (GMW). The secondary outcome was the evaluation of residual functional impairment, neurological deficit, depression, morbidity, and admission to long-term facilities in the two groups of patients.

METHODS
This randomized study was planned in 1996 by the GHHS of the geriatric section of San Giovanni Battista Hospital, in collaboration with the emergency department (ED) of the hospital. Ethics approval for the study was obtained from the hospital ethical committee.

In San Giovanni Battista Hospital of Turin, a university teaching and tertiary-care hospital, the GHHS has been operating since October 1985. The service is under the medical responsibility of the GHHS team, which includes geriatricians, nurses, dietitians, physiotherapists, speech therapists, occupational therapists, psychologists, and social workers and is specifically dedicated to the home management of stroke. It is able to perform, at the patient’s home, diagnostic, therapeutic, and rehabilitative interventions that are usually performed in the hospital. The main characteristics of the service include referral by general practitioners or physicians of hospital units, 24-hour-a-day care, rapid access to equipment needed for home nursing, multidisciplinary care, and admission if required in the hospital catchment area. Availability of a carer (family member or other caregiver) is necessary for participation in the program.

The sample studied (120 patients) was obtained from a larger group of 455 patients, aged 70 and older, who were consecutively admitted to the ED of the hospital with a diagnosis of acute ischemic stroke.

This study is considered a randomized, single-blind study because the patients were aware of the treatment assignment. Physicians and nurses evaluating patients on admission and at the end of follow up were blinded to the patient’s allocation. Baseline evaluation was performed within the ED before randomization. Interviewers who were blinded to the group allocation and medical history of the patients evaluated survivors at the end of follow-up at their site of residence at that time (home, nursing home, or hospital).

The sample size estimation was performed according to the one-sample binomial test. No data were available on mortality rates of stroke patients treated by home hospitalization service. Therefore, for estimating the sample size, the 6-month and 1-year cumulative survival rates in patients treated on general medical wards were estimated. On this basis, 120 patients need to be included in the study to have an 80% chance (1 - \( \beta \)) setting at 0.80) of detecting no significant difference in mortality between the two groups using a two-sided test with \( \alpha = 0.05 \).

The random assignment was referred to as block randomization; a block size of 2n patients is determined in advance, where for every 2n patients entering the study, n patients are randomly assigned to Treatment A (GHHS), and the remaining n patients are assigned to Treatment B (GMW). Intention-to-treat analysis was used.

In the ED, all patients underwent baseline standard clinical evaluation, including physical, functional, and neurological assessment; blood tests (blood cell count and routine biochemical tests); 12-lead electrocardiography; chest radiography; and brain computed tomography (CT) scan. Further investigations (including duplex scanning of epiaortic arteries and echocardiography) were performed selectively when required, according to the clinical judgment of the ED physician. The ED neurologist validated the diagnosis of ischemic stroke based on clinical history, neurological examination, and cerebral CT scan. Clinical subtypes of acute ischemic stroke were classified according to the Oxfordshire Community Stroke Project as lacunar syndromes, posterior circulation syndromes, total anterior circulation syndromes, and partial anterior circulation syndromes. Uncomplicated ischemic stroke was defined based on a Canadian Neurological Scale mental status of greater than 0.5 and absence of symptoms or signs of cardiovascular and respiratory instability. Only patients who were admitted to the ED within 24 hours of the onset of symptoms and who had been evaluated for at least 24 hours since the onset of symptoms were considered eligible to be included in the study. Subjects living outside the hospital catchment area were not included in the study. Additional exclusion criteria were history of dementia before the acute stroke, history or evidence of prior stroke, and absence of family and social support. Patients fulfilling inclusion criteria were informed about the nature of the study and asked to give their informed consent. Extensive information was also provided to patients’ relatives to obtain their collaboration. Patients fulfilling the inclusion criteria and having none of the criteria for exclusion were then randomly assigned to treatment in GHHS or GMW according to the procedure previously described.

Overall, 455 patients aged 70 and older were consecutively admitted to the ED from January 1997 to February 1998 with a diagnosis of acute ischemic stroke (Figure 1). Two hundred ninety-nine were excluded (127 because they were not resident in the hospital catchment area, 69 because they had history of dementia or of previous stroke, 39 because familial or social supports were not available, and 64 because they had central nervous system mental status less than 0.5 or symptoms or signs of cardiorespiratory instability), and 36 patients did not give informed consent to participate in the study.

Sixty of the 120 patients eligible for the study were randomly assigned to home treatment by GHHS, and 60 were referred for treatment in a hospital GMW. Patients assigned to home management were immediately transferred home after the preliminary evaluation in the ED.

Historical variables were collected before randomization, including history of hypertension, diabetes mellitus, myocardial infarction, atrial fibrillation, and chronic obstructive pulmonary disease. The medical history was gathered from the patient and from the clinical documentation exhibited at the moment of admission. Data collected from surrogates were used in those patients who were unable to be interviewed. For each patient, hematocrit, blood glucose, serum creatinine concentration, and systolic and diastolic blood pressures on admission were recorded. Main outcome was cumulative survival at 6 months in the two groups. Secondary outcomes in survivors at 6 months were...
residual functional impairment, neurological deficit, depressive symptoms, morbidity during hospitalization (including GHHS and GMW), and admission to rehabilitation and long-term facilities. Two geriatricians and two nurses specifically trained in the evaluation of stroke patients with the use of specific scales used standardized validated scales to evaluate these variables on admission and at 6 months. Disability and functional impairment were evaluated at baseline and at 6 months using the activities of daily living scale (number of functions lost, range 0–6)\(^{19,20}\) and the seven-item Functional Impairment Measure (level of independence, range 18–126).\(^{19,20}\) Mental status and severity of stroke-related neurological deficit was evaluated at baseline and after 6 months using the Canadian Neurological Scale (range 0–10)\(^{18,19,21}\) and the modified National Institutes of Health Stroke Scale (range 0–36).\(^{19,20,22}\) Depression was evaluated at baseline and at 6 months using the Geriatric Depression Scale (range 0–30).\(^{23}\) Physicians evaluated neurological deficit, and specifically trained nurses evaluated functional impairment and depressive symptoms. Interobserver and intraobserver variability in data collection were evaluated on 40 patients before the beginning of the study; interindividual and intraindividual reproducibility were 90% and 94%, respectively. Six-month follow-up evaluation was performed on survivors by visiting them wherever they were residing at that moment (home, nursing home, or hospital). As at baseline, information collected from proxy was used only for patients who could not be interviewed.

Morbidity during at-home or inpatient care (including urinary tract infection and catheterization, pneumonia and respiratory infections, pressure sores) was evaluated through chart review at the time of discharge from GHHS or GMW.\(^{21}\)

In-hospital and at-home medical treatments were performed following the American Heart Association Guidelines.\(^{24}\) The home rehabilitation program emphasized a task- and context-oriented approach, which recommends that the patient perform guided, supervised, and self-directed activities in a functional and familiar context. The choice of activities was based, whenever possible, on patients’ personal interests; the caregiver was encouraged to be an active participant in the rehabilitation process, and individual counseling was offered to caregivers if needed. The standard daily intervention consisted of one visit by a physician, a nurse, and a physical therapist. The inpatient control group received routine hospital rehabilitation service. The hospital rehabilitation service provided physical therapists to patients assigned to both groups of the trial. The amount of time spent in supervised rehabilitation was the same in both groups of patients. For patients treated at home, one physician and one nurse of the GHHS staff were available 24 hours a day.

Differences in length of stay between groups were evaluated using Student t test. Statistical significance for intergroup differences at baseline was assessed using the chi-square test and the Mann-Whitney test. Statistical significance for intergroup differences at 6 months was evaluated using the Mann-Whitney test. Kaplan-Meyer analysis was used to evaluate cumulative proportion survival during the 6-month period of observation. The log-rank test and the Gehan Wilcoxon test were used to compare survival in the two groups. All reported P-values are two-sided with \(\alpha = 0.05\).

RESULTS

The total sample included 54 men and 66 women; median age was 82 (interquartile range = 76–88). The main baseline clinical characteristics of the sample are reported in Table 1; no significant differences at baseline were found between the two groups of patients.

Patients managed at home by the GHHS had a significantly longer mean length of treatment (± standard deviation) than patients admitted to GMW (38.1 ± 28.6 vs 22.2 ± 11.5 days, \(t = 3.995, P < 0.001\)).

During the period of observation (6 months), there were 45 deaths (24 patients admitted to GMW and 21 patients allocated to GHHS). During the period of treatment (GHHS vs GMW), 16 GMW patients and 13 GHHS patients died (cumulative mortality 23.3% and 21.7%, respectively, \(P = .89\)). The cumulative proportion of cases surviving up to the 6-month interval was 0.65 in the GHHS group and 0.60 in the GMW group (log-rank test \(P = .53\); Gehan Wilcoxon test \(P = .49\)). No crossover between groups was observed.

Functional impairment measures (activities of daily living scale, Functional Impairment Measure), neurological deficit scores (Canadian Neurological Scale, National Institutes of Health Stroke Scale), and depression scores in patients surviving at 6 months are reported in Table 2; there were no significant differences between patients treated at home and patients admitted to the hospital with the exception of depression scores, which were significantly better in home-treated patients than in hospital-treated patients.
Respiratory infections occurred in 20 patients (30.3%) admitted to the GMW and in 16 (26.7%) treated by the GHHS; urinary tract infections were observed in 23.3% of GMW patients and 20% of GHHS patients. Altogether, the rate of select medical complications did not differ between the two groups of patients.

On discharge, 43 GHHS patients (98%) remained at home, and one was institutionalized. Only 21 GMW patients (46%) returned home after discharge; 23 (50%) were transferred to rehabilitative facilities, and two (4%) were institutionalized (chi-square = 30.867, P < .001). At 6 months, 16 GMW patients and three GHHS patients had been admitted to long-term nursing facilities (chi-square = 13.368, P = .0003).

**DISCUSSION**

The results of the present study indicate that home treatment of elderly patients with first acute uncomplicated ischemic stroke is at least as effective as traditional hospital treatment. No significant differences were observed in mortality rates or residual neurological deficits and functional impairment.

### Table 1. Baseline Demographic, Historical, and Clinical Variables in Patients Admitted to Geriatric Home Hospitalization Service (GHHS) and to General Medical Ward (GMW)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total sample (N = 120)</th>
<th>GHHS (n = 60)</th>
<th>GMW (n = 60)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>54</td>
<td>24</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>66</td>
<td>37</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td><strong>Age, median (IQR)</strong></td>
<td>82 (76–88)</td>
<td>83 (78–89)</td>
<td>80 (74–87)</td>
<td>.09*</td>
</tr>
<tr>
<td><strong>Activities of daily living score, median (IQR) (range 0–6)</strong></td>
<td>6 (4–6)</td>
<td>5 (4–6)</td>
<td>6 (4–6)</td>
<td>.59*</td>
</tr>
<tr>
<td><strong>Functional Impairment Measure, median (IQR) (range 18–126)</strong></td>
<td>43 (24–64)</td>
<td>41.5 (24.5–69.5)</td>
<td>43.5 (23.5–61.5)</td>
<td>.78*</td>
</tr>
<tr>
<td><strong>Canadian Neurological Scale score, median (IQR) (range 0–10)</strong></td>
<td>6 (4–7)</td>
<td>6 (4–8)</td>
<td>5 (4–7)</td>
<td>.75*</td>
</tr>
<tr>
<td><strong>National Institutes Health Stroke Scale score, median (IQR) (range 0–36)</strong></td>
<td>24 (22–27)</td>
<td>24 (22–26.5)</td>
<td>24 (22–26.5)</td>
<td>.88*</td>
</tr>
<tr>
<td><strong>Geriatric Depression Scale score, median (IQR) (range 0–30)</strong></td>
<td>16 (10–20)</td>
<td>17.5 (10–21)</td>
<td>15 (7–20)</td>
<td>.31*</td>
</tr>
<tr>
<td><strong>Creatinine, mg/dL, median (IQR)</strong></td>
<td>1.1 (0.9–1.5)</td>
<td>1.1 (0.9–1.4)</td>
<td>1.2 (0.9–1.5)</td>
<td>.62*</td>
</tr>
<tr>
<td><strong>Hematocrit, %, median (IQR)</strong></td>
<td>39.7 (37.4–41.6)</td>
<td>39.6 (36.9–41.4)</td>
<td>39.9 (38.3–41.5)</td>
<td>.36*</td>
</tr>
<tr>
<td><strong>Systolic blood pressure, mmHg, median (IQR)</strong></td>
<td>140 (130–160)</td>
<td>140 (130–160)</td>
<td>145 (130–160)</td>
<td>.82*</td>
</tr>
<tr>
<td><strong>Diastolic blood pressure, mmHg, median (IQR)</strong></td>
<td>80 (80–90)</td>
<td>80 (80–90)</td>
<td>80 (70–90)</td>
<td>.89*</td>
</tr>
<tr>
<td><strong>Clinical characteristics, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>83 (69.2)</td>
<td>40 (66.8)</td>
<td>43 (71.7)</td>
<td>.69†</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>27 (22.5)</td>
<td>11 (18.3)</td>
<td>16 (26.7)</td>
<td>.38†</td>
</tr>
<tr>
<td>Previous acute myocardial infarction</td>
<td>38 (31.7)</td>
<td>23 (38.3)</td>
<td>15 (25.0)</td>
<td>.17†</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>35 (29.2)</td>
<td>18 (30.0)</td>
<td>17 (28.3)</td>
<td>.99†</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>18 (15.0)</td>
<td>8 (13.3)</td>
<td>10 (16.7)</td>
<td>.79†</td>
</tr>
<tr>
<td>Current smoking</td>
<td>12 (10.0)</td>
<td>5 (8.3)</td>
<td>7 (11.7)</td>
<td>.76†</td>
</tr>
<tr>
<td>Stroke subtype, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.99†</td>
</tr>
<tr>
<td>Lacunar syndrome</td>
<td>49 (40.8)</td>
<td>26 (43.3)</td>
<td>23 (38.8)</td>
<td></td>
</tr>
<tr>
<td>Partial anterior circulation syndrome</td>
<td>55 (45.8)</td>
<td>26 (43.4)</td>
<td>29 (48.4)</td>
<td></td>
</tr>
<tr>
<td>Total anterior circulation syndrome</td>
<td>5 (4.2)</td>
<td>2 (3.7)</td>
<td>3 (5.0)</td>
<td></td>
</tr>
<tr>
<td>Posterior circulation syndrome</td>
<td>11 (9.2)</td>
<td>6 (10.0)</td>
<td>5 (8.3)</td>
<td></td>
</tr>
</tbody>
</table>

Calculated using * Mann-Whitney U test; † Chi-square test; IQR = interquartile range.

### Table 2. Six-Month Clinical Variables in Patients Admitted to Geriatric Home Hospitalization Service (GHHS) and to General Medical Ward (GMW)

<table>
<thead>
<tr>
<th>Variable</th>
<th>GHHS (n = 39)</th>
<th>GMW (n = 36)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activities of daily living scale score (range 0–6)</strong></td>
<td>4 (2–5)</td>
<td>4 (2–6)</td>
<td>.57*</td>
</tr>
<tr>
<td><strong>Functional Impairment Measure score (range 28–126)</strong></td>
<td>106.0 (67.5–121.5)</td>
<td>96.5 (56.5–116.5)</td>
<td>.26*</td>
</tr>
<tr>
<td><strong>Canadian Neurological Scale score (range 0–10)</strong></td>
<td>10.0 (8.5–10.0)</td>
<td>9.5 (7.0–10.0)</td>
<td>.39*</td>
</tr>
<tr>
<td><strong>National Institutes of Health Stroke Scale score (range 0–36)</strong></td>
<td>8 (4–26)</td>
<td>8 (6–24)</td>
<td>.37*</td>
</tr>
<tr>
<td><strong>Geriatric Depression Scale score (range 0–30)</strong></td>
<td>10 (5–15)</td>
<td>17 (13–20)</td>
<td>&lt;.001*</td>
</tr>
</tbody>
</table>

* Calculated using Mann-Whitney U test.
tional impairment. Despite the longer length of treatment, home-treated patients had less need of further rehabilitation after discharge and a lower rate of admission to long-term facilities. These findings appear to be of crucial relevance for planning healthcare strategies in elderly patients with stroke. Moreover, home-treated patients had fewer depressive symptoms than patients treated in the GMW. Finally a marginally, although not significantly, lower rate of select medical complications was observed in the home-treated group.

Although previous studies reported several advantages in early discharge from hospital for patients with stroke,25–27 the current study is probably the first to show that patients with first acute ischemic stroke treated at home by GHHS have outcomes similar to those of hospital-treated patients in terms of survival and recovery from neurological and functional impairment. Moreover, home-treated patients had significantly fewer depressive symptoms and markedly reduced rates of institutionalization at the end of the study. Home management of elderly patients with stroke may exert positive effects in educating the patient and the family on the nature and the course of the disease, emphasizing patient and family participation in nursing and rehabilitation activities and putting the patient in touch with the social services. Altogether, these aspects are likely to account for the benefit on depressive symptoms.

Although the present study was not designed to evaluate the economic effect of this intervention, a preliminary evaluation showed that each patient-day of at-home care cost about one-third of the cost of a traditional hospital setting, suggesting that this intervention may be cost-effective.

In spite of the positive results of this study, several points should be carefully evaluated before suggesting that home-management is an attractive alternative to traditional hospital treatment for elderly patients with ischemic stroke. The main conceptual issue of this study is that it compares home-management with GMW care, not stroke-unit treatment. Several reports in recent years have demonstrated that the treatment of stroke patients in stroke units can reduce mortality, length of stay in hospital, and discharge rate to nursing homes,28,29 but in Italy, as in many other countries, stroke units are not yet widely operative in the national healthcare system, and most patients with stroke, especially the oldest ones, are admitted to and treated on GMW. These patients represent a heavy burden for hospital medical wards, as shown by the long length of stay observed in the present study (about 3 weeks), which is mainly accounted for by difficulties in providing admission to rehabilitation facilities. There is strong evidence that several acute and chronic diseases can be effectively managed at home and that the benefit of home treatment is particularly evident for the oldest old patients.30,31 Therefore, it seems acceptable to compare the home-care intervention with usual care (GMW) rather than with ideal care (stroke unit). Another relevant ethical and clinical concern is treatment at home of the acute phase of stroke. In recent years, after this study was planned and had commenced, hospital-based acute care of patients with stroke has been emphasized. Nevertheless, the marked improvement in outcome shown in studies based on stroke-unit interventions is attributable more to a team approach to nursing and rehabilitation and to patient and family participation than to acute monitoring.29 This is what the GHHS performed at the older patients’ homes, because several therapies (physical, occupational, speech, nutritional, and respiratory), previously available only in an ambulatory or institutional setting, have now become widely available in a home setting. Stroke is one of the conditions suitable for hospital-at-home, although in most circumstances, home care is used to facilitate the early discharge of patients rather than to prevent admission to an acute hospital.

The high rate of transfer to rehabilitation units of patients admitted to GMW treatment might appear to defeat the purpose of the present study, but an evaluation of outcomes at the time of discharge from the two services could not be performed because of the differences in the two strategies. Hospital care for stroke patients usually includes treatment of the acute phase of the disease and the early steps of a rehabilitation program, which is often followed by a further period of care in rehabilitative facilities. In contrast, the GHHS intervention includes acute and rehabilitative care for the stroke patients.

Finally, it must be noted that this study included only uncomplicated patients not requiring hospital-based instrumental invasive approach. Although none of the GHHS-treated patients required admission to the hospital during the study, safe home-management of stroke patients requires the continuous availability of a nearby hospital medical ward. The necessity of including only patients easily accessible in their homes by the GHHS determined the exclusion of a high proportion of residents outside the catchment area of the hospital.

Home treatment of elderly patients with first uncomplicated ischemic stroke is at least as effective as traditional hospital treatment. Despite the longer length of therapy at home, these patients have fewer depressive symptoms and lower rates of admission to long-term facilities. Future studies are needed to evaluate the cost-effectiveness of this intervention compared with traditional hospital care. These findings suggest that home management of elderly patients with uncomplicated acute ischemic stroke may be an attractive alternative to traditional hospital treatment.

ACKNOWLEDGMENTS

In memory of Professor Fabrizio Fabris, who died suddenly on August 21, 2003.

REFERENCES