Stroke Unit Care Combined With Early Supported Discharge

Long-Term Follow-Up of a Randomized Controlled Trial

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Background and Purpose—Early supported discharge from a stroke unit reduces the length of hospital stay. Evidence of a benefit for the patients is still unknown. The aim of this trial was to evaluate the long-term effects of an extended stroke unit service (ESUS), characterized by early supported discharge. The short-term effects were published previously.

Methods—We performed a randomized controlled trial in which 320 acute stroke patients were allocated to either ordinary stroke unit service (OSUS) (160 patients) or stroke unit care with early supported discharge (160 patients). The ESUS consists of a mobile team that coordinates early supported discharge and further rehabilitation. Primary outcome was the proportion of patients who were independent as assessed by modified Rankin Scale (RS) (RS $\leq$2=global independence). Secondary outcomes measured at 52 weeks were performance on the Barthel Index (BI) (BI $\geq$95=independent in activities of daily living), differences in final residence, and analyses to identify patients who benefited most from an early supported discharge service. All assessments were blinded.

Results—We found that 56.3% of the patients in the ESUS versus 45.0% in the OSUS were independent (RS $\leq$2) (P=0.045). The number needed to treat to achieve 1 independent patient in ESUS versus OSUS was 9. The odds ratio for independence was 1.56 (95% CI, 1.01 to 2.44). There were no significant differences in BI score and final residence. Patients with moderate to severe stroke benefited most from the ESUS.

Conclusions—Stroke service based on treatment in a stroke unit combined with early supported discharge appears to improve the long-term clinical outcome compared with ordinary stroke unit care. Patients with moderate to severe stroke benefit most. **(*Stroke*. 2003;34:2687-2692.)**

Key Words: clinical trials ■ home care services ■ stroke management ■ outcome

It is a challenge to organize a healthcare service that can provide effective management of patients who have suffered from a stroke. Many trials have shown that care of acute stroke patients in stroke units improves outcome.[1-6] Hence, access to stroke unit care is recommended for all acute stroke patients and should be the first link in the chain of care.[7] However, the manner in which subsequent care should be organized is still an open question. A few small randomized controlled trials have emphasized early supported discharge and rehabilitation at home or in day hospitals. These trials showed no significant improvement in functional outcome.[8] A weakness of most of the trials is that optimal stroke unit care had not been provided in the acute phase. Hence, it has been difficult to draw definite conclusions about the benefit of such a service.[8] The aim of the present trial was to compare the effect of an extended stroke unit service (ESUS) with the effect of evidence-based ordinary stroke unit service (OSUS). The essential elements of ESUS were initial treatment in a stroke unit combined with early supported discharge coordinated by a mobile stroke team, cooperation with the primary healthcare system, and greater emphasis on rehabilitation at home.

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Subjects and Methods

All acute stroke patients who were admitted to our stroke unit were assessed for inclusion in the trial. Inclusion criteria were as follows: patients from the city of Trondheim, Norway, admitted to the stroke unit with signs and symptoms of an acute stroke[9]; inclusion within 72 hours of admission and <7 days after the onset of symptoms; Scandinavian Stroke Scale (SSS) score between 2 and 57 points; ability to live independently before the onset of stroke; and no participation in other trials. Informed consent was obtained. The methodology of this study has been reported previously, as well as the short-term results.[9]

Received April 14, 2003; final revision received June 8, 2003; accepted July 8, 2003.

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Stroke **is available at http://www.strokeaha.org** **DOI: 10.1161/01.STR.0000095189.21659.4F**

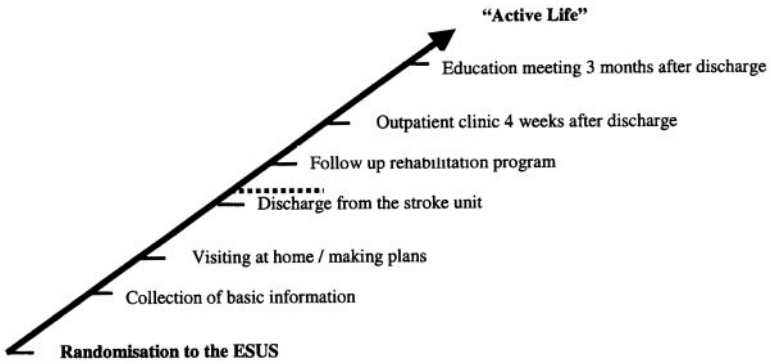

Figure 1. Extended stroke unit service.

Interventions

Patients who satisfied the criteria for inclusion were randomized to either a constructed ESUS or OSUS. Both groups received similar stroke unit care during the acute phase (eg, the first 1 to 2 weeks), with focus on early mobilization/rehabilitation combined with a standardized acute medical treatment program.[9,10] This treatment has been shown to improve outcome compared with treatment provided in general medical wards.[2,11,12] In the OSUS group, further follow-up was organized by the primary healthcare system.

Patients in the ESUS group were offered a comprehensive follow-up stroke service organized by a mobile team.[9] This hospital-based team consisted of a physiotherapist, an occupational therapist, a nurse, and the consulting service of a stroke physician.

This is a long-term follow-up of a previously published trial, and the elements of the ESUS have been described previously. The most important elements of the ESUS are shown in Figure 1 and are as follows: (1) After inclusion, a systematic assessment of the patient and the patient's needs was performed. (2) A visit at home was planned, if possible together with the patient, as soon as the patient was medically stable (often within 3 to 5 days after admission to the stroke unit). Discharge planning, including further needs for help, support, and rehabilitation, was initiated at that point and in the most comprehensive manner possible. (3) A discharge meeting with the patient, relatives, physician, and a member of the mobile team was arranged before discharge from the hospital and after ongoing assessment of rehabilitation needs. (4) Follow-up visits, if necessary, were performed in cooperation with the primary healthcare system. A large part of the rehabilitation was provided in day hospitals and outpatient clinics, and further needs of rehabilitation and secondary prevention were outlined to the primary healthcare service. (5) A visit to the outpatient clinic at the hospital was arranged 3 to 5 weeks after discharge. An evaluation of the period after discharge from the stroke unit was made. (6) An educational meeting was arranged 3 months after discharge for the patients and their relatives.

After the visit at the outpatient clinic approximately 1 month after discharge, the primary healthcare system became responsible for further follow-up. They could consult the mobile team if problems occurred.

The Regional Committee on Medical Research Ethics approved the study protocol.

Method of Randomization

After consent, randomization was restricted in permuted blocks with random number tables provided in sealed opaque envelopes.

Assessments

Baseline characteristics were recorded before inclusion. The primary outcome was a modified Rankin Scale (RS) score at 52 weeks after inclusion, with RS $\leq$2 classified as independence. Secondary outcomes at 52 weeks were performance on the Barthel Index (BI), with BI $\geq$95 characterized as independent, differences in final residence, and length of stay in an institution before discharge to final residence. A preplanned subgroup analysis of patients with a baseline score on the SSS $\leq$52 was also a secondary outcome. Finally, we performed analyses to identify patients who benefited most from an early supported discharge service.

All assessments were blinded as far as is possible in such a trial and conducted by neutral physiotherapists specially trained in use of the assessment scales.

Statistical Analyses

Age and severity of stroke measured by SSS and differences in BI and RS score at baseline were analyzed by the Mann-Whitney test. The other baseline characteristics were analyzed by the Pearson χ^2 test. In all the main analyses, the intention to treat population was used. We also used the Pearson χ^2 test to investigate the difference between the groups in place of stay (home, institution, deceased). The significance level was set at 0.05. Logistic regression was performed with the use of RS score ($\leq$2) as the dependent variable and treatment, SSS score, sex, age, and cohabiting status as independent variables. The number needed to treat (NNT) in the ESUS group versus the OSUS group to achieve 1 more independent patient was calculated for all patients, with additional stratification for severity of stroke, age, and sex. These analyses were also preplanned.

Results

A total of 468 acute stroke patients from the city of Trondheim were admitted to our stroke study during a period of 24 months from March 1995. They were all screened for inclusion in the trial. Three hundred twenty of these patients fulfilled the inclusion criteria and were included and randomly allocated to ESUS (160 patients) or OSUS (160 patients). One hundred forty-eight patients were excluded. Details of the exclusion criteria were published earlier.

There were no significant differences in baseline characteristics between the groups.[9]

Table 1 shows that 56.3% of the patients treated in the ESUS and 45.0% of the patients treated in the OSUS were independent according to the primary outcome of modified RS score (P=0.044). NNT to achieve 1 more independent patient in the ESUS group versus the OSUS group was 9 (95% CI, 4.6 to 345). Odds ratio for independence was 1.56 (95% CI, 1.01 to 2.44; P=0.045). With adjustment for independent variables (treatment, SSS score, sex, age, and cohabiting status), the effect of the ESUS was even greater (odds ratio=1.93; 95% CI, 1.12 to 3.32; P=0.018) (Table 2). No interactions between the independent variables were significant.

TABLE 1. Number and Proportion of Patients With Barthel Index ≥95 and Rankin Scale ≤2 and the Proportion of Patients at Home, in Institutions and Deceased After 52 Weeks From Onset of Stroke in the Extended Stroke Unit Service and the Ordinary Stroke Unit Service

	ESUS (n=160)		OSUS (n=160)		
	n	%	n	%	*P*
Primary outcome					
RS ≤2	90	56.3	72	45.0	0.044
Secondary outcome					
BI ≥95	84	52.5	74	46.3	0.264
At home	120	75.0	110	68.8	0.265
In institution	19	11.9	24	15.0	0.516
Dead	21	13.1	26	16.3	0.429

RS indicates Rankin Scale; BI, Barthel Index; ESUS, Extended Stroke Unit Service; OSUS, Ordinary Stroke Unit Service.

The proportion of patients with a BI score ≥95 was not significantly higher in the ESUS group (52.5% versus 46.3%; $P=0.264$). The number of patients living at home was significantly higher in the ESUS group at discharge and 6 weeks[9] but not at 52 weeks (Table 1). We performed a subgroup analysis for patients with baseline SSS score ≤52, and the results were even more favorable according to modified RS score: 47% of the patients treated in the ESUS and 28% treated in the OSUS were independent according to modified RS score ($P=0.005$). NNT to achieve 1 more independent patient in the ESUS group versus the OSUS group was 7 (95% CI, 3.6 to 27.3).

The total average length of inpatient stay was 18.6 days in the ESUS group and 31.1 days in the OSUS group ($P=0.0324$). The average stroke unit stay was similar in both groups (11 days).

Using the fitted logistic regression model, we analyzed the relation between the severity of stroke and the NNT in the ESUS group versus the OSUS group to achieve 1 more independent patient (Figure 2). The figure shows the whole group and the patients divided into 2 age groups: patients aged <75 years and patients aged ≥80 years. As shown for the whole group, a baseline SSS score between 35 and 54 corresponds to a NNT <10. For younger patients, the greatest benefit was seen for mild and moderate stroke with SSS score between 28 and 50. For older patients, the curves show the greatest benefit with SSS score >41.

Discussion

The results of this trial show for the first time that stroke patients who are offered stroke unit treatment combined with early supported discharge have a better long-term functional outcome after 1 year of follow-up than patients offered ordinary stroke unit care.

The modified RS documents significantly better functional outcome in the ESUS group ($P=0.044$). The NNT to avoid dependency or death of 1 patient was 9; in the subgroup analysis for patients with a moderate to severe stroke, NNT was approximately 7. This effect is comparable to that achieved with treatment with alteplase within 3 hours of stroke onset.[13] The early supported discharge treatment seems to be highly effective.

The present trial is a randomized controlled trial and appears to be one of the few trials in which the included patients have been an unselected hospitalized stroke population.[8] Another strength of the present trial is that all patients received optimal treatment in a stroke unit in the acute phase.[2] We have previously shown a positive effect of ESUS up to 6 months,[9] but the results now indicate that this service has important long-term effects as well. Furthermore, we have created a model to calculate the benefit of early supported discharge care for patients with different levels of stroke severity (Figure 2). In a study of this size with a limited number of patients, we should be careful to draw definite conclusions. However, the results indicate which patients benefit most and which patients might be given priority for such a service.

A limitation of this kind of trial is that we do not know exactly why the present service system works so well. The strength of the blinded evaluation procedure is also unclear, and no evaluation of the efficacy of this blinding procedure was performed. The trial lacked sufficient power to detect moderate differences in the secondary outcome BI. Alternatively, the BI may not be sensitive enough in long-term follow-up because of a "ceiling effect."

Evidence is accumulating that supports the development of services that allow stroke patients to be sent home from the

TABLE 2. Fitted Logistic Regression Model for Rankin Scale (RS≤2) at 52 Weeks

					95% CI for OR	
	Values	B	*P* Value	OR=Exp(B)	Lower	Upper
Treatment	OSUS, ESUS	0.657	0.018	1.929	1.120	3.323
SSS	As given	0.118	0.000	1.125	1.091	1.160
Sex		−0.663	0.035	0.515	0.279	0.954
Living alone	Cohabiting Living alone	−0.532	0.090	0.588	0.317	1.088
Age group	<75, 75–79, ≥80	−0.784	0.000	0.456	0.326	0.640
Constant		−3.586	0.000	0.028		

The effect of the Extended Stroke Unit Service (ESUS) versus the Ordinary Stroke Unit Service (OSUS), adjusted for SSS, sex, cohabiting status, and age group.

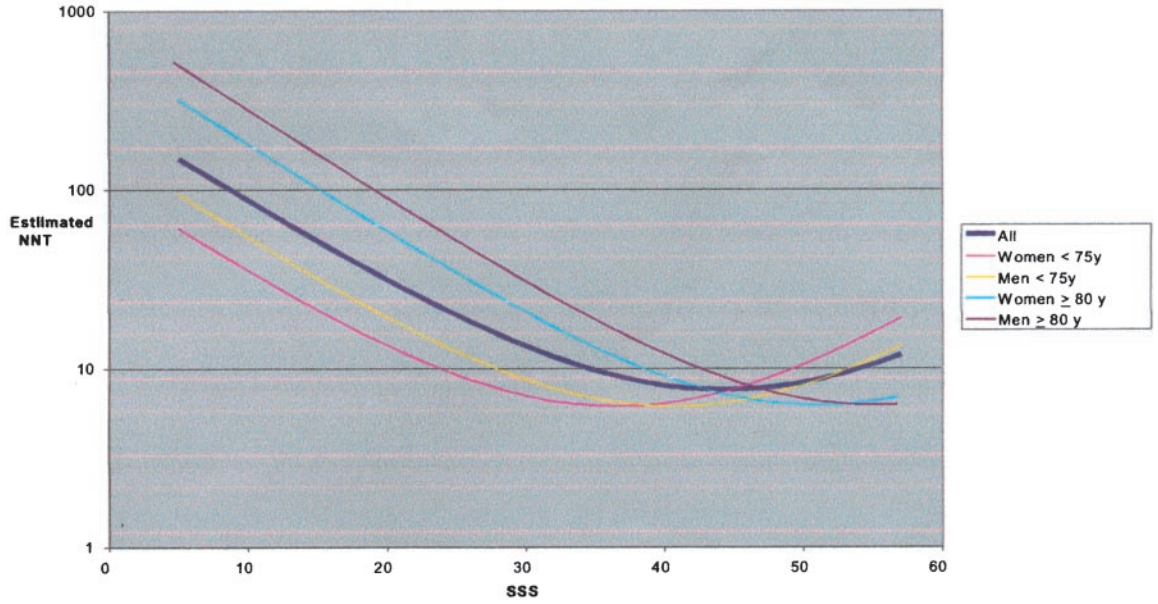

Figure 2. Relation between severity of stroke assessed by SSS and NNT in ESUS vs OSUS to achieve 1 independent patient. Curves for the effect of sex and age at different levels of severity of stroke are also shown.

hospital earlier than usual, with appropriate levels of support. A few studies have already shown that early supported discharge reduces the use of inpatient rehabilitation.[14–19] A meta-analysis of 7 published early supported discharge trials showed recently that the mean difference in inpatient rehabilitation was 13 days between early supported discharge care and traditional care (95% CI, 7 to 19).[20] This corresponds to the results of our trial. However, our trial also shows a significantly better outcome at 1 year. Characteristics of this trial compared with most of the others[8] are as follows: standard care in a stroke unit for both groups; inclusion soon after the onset of stroke; a relatively large number of participants; and an unselected patient population with greater functional impairment. These factors may explain some of the favorable results.

Our service with a mobile team coordinating the rehabilitation efforts with an emphasis on rehabilitation in familiar surroundings may allow for an "enriched environment" for the patients and their relatives. In contrast, it appears that early discharge from the hospital without enhanced stroke services may lead to an increase in morbidity.[21] Community rehabilitation may offer a significant advantage concerning the long-term consequences of stroke.[22] We also believe that continuity in the chain of care is of great importance for the efficacy of the rehabilitation process. Compared with the other studies, we likely have more links in the chain of care in our ESUS. This includes various combinations of home service and inpatient rehabilitation.

In our trial, ESUS, which combines stroke unit care with early supported discharge, shows not only a reduction in hospital stay, similar to other early supported discharge trials, but also a significant improvement of long-term functional outcome compared with OSUS. This is the first long-term follow-up of an early supported discharge service combined with stroke unit care, and other similar trials are necessary to confirm the benefits of such a service. In addition, the effect on quality of life, resource implications, and economic consequences need further research.

Acknowledgments

This study was supported by the Norwegian Department of Health and the Norwegian Foundation for Health and Rehabilitation. We thank all the staff and patients who participated in this study. We also thank Gitta Rohweder for linguistic revision.

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Editorial Comment

Early Supported Discharge: An Idea Whose Time Has Come?

In most developed countries, stroke patients follow a broadly predictable pathway of care beginning with hospital admission. In hospital they receive acute care and a variable period of rehabilitation, but rehabilitation services frequently stop or are significantly reduced after discharge home from hospital. Early supported discharge (ESD) services aim to alter this conventional pathway of care in 2 ways; first, by moving forward the time of discharge from hospital, and second, by providing a more continuous process of rehabilitation spanning both the period in hospital and the first few weeks at home.[1]

There have been several arguments made in favor of the ESD concept. First, in countries like the United Kingdom it has been argued[2] that more stroke patient care should be provided in a community setting. Second, it has been claimed that ESD services can be less costly than conventional services and allow a freeing up of hospital beds.[3] Finally, it has been suggested that ESD services can improve patient care by providing a "seamless service" that spans the period of discharge home, a time that patients and carers frequently find difficult. In contrast, critics have argued that most stroke patients are discharged as early as is reasonably possible. They also point out the potential hazard of trying to manage dependent patients at home with the risk of increasing stress on carers and causing poorer patient outcomes.[4]

Until recently, none of these assertions had been adequately tested in clinical trials. However, since 1997 several single-blind randomized controlled trials have reported, initially from the United Kingdom,[5,6] Scandinavia,[7,8] Australia,[9] and Canada.[10] These single-center trials recruited a selected group of stroke patients (15% to 50%) admitted to hospital who were randomized to receive input from an ESD service or conventional hospital care and discharge procedures. The ESD service was based on a coordinated multidisciplinary team comprising physiotherapy and occupational therapy staff with variable amounts of medical, nursing, and speech and language therapy input. These trials demonstrated that such ESD services could significantly reduce the length of hospital stay and achieve similar patient outcomes at 6 months after stroke, although the confidence intervals were wide. Economic analyses[11–13] indicate that the total costs of ESD services could be less than the notional value of hospital bed days freed by the service.

This issue of *Stroke* features a 1-year follow-up of a clinical trial of an early supported discharge service from Trondheim, Norway.[14] The trial is of high methodological quality and evaluated an ESD service within a well-established and well-proven hospital stroke unit.[15] The surprising result was that 1 year after the index stroke, patients who received the ESD service had not only spent less time in hospital but were more likely to be independent and to be living at home. In a subsequent subgroup analysis the benefits were seen most clearly among patients with intermediate stroke severity.

How could such good results have been achieved? It seems unlikely that the early pathological process of stroke and the associated impairments are influenced by this type of service. A more credible explanation is that the ESD service has improved the patient's ability to regain normal activities despite residual impairment. In particular, the patient's own home is probably the best place to relearn the skills needed to function in that environment.

The Trondheim study certainly indicates that ESD services can work well within the Norwegian context, where the ESD team was also able to access a high quality of rehabilitation services in primary care. What is less clear is whether these positive findings can apply equally to other settings in other countries. The suggestion that particular patient groups may benefit also requires further exploration. We also need to establish whether other patient and carer outcomes, such as mood, satisfaction, and subjective health status, are affected. The ESD service trialists are currently undertaking a detailed

analysis of all available trials to try and answer these questions. In the meantime, the ESD approach appears to offer a promising contribution to a comprehensive stroke service.

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