Stroke unit care revisited: who benefits the most? A cohort study of 105 043 patients in Riks-Stroke, the Swedish Stroke Register

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ABSTRACT

Background: Treatment at stroke units is superior to treatment at other types of wards. The objective of the present study is to determine the effect size of stroke unit care in subgroups of patients with stroke. This information might be useful in a formal priority setting.

Methods: All acute strokes reported to the Swedish Stroke Register from 2001 through 2005 were followed until January 2007. The subgroups were age (18–64, 65–74, 75–84, 85+ years and above), sex (male, female), stroke subtype (intracerebral haemorrhage, cerebral infarction and unspecified stroke) and level of consciousness (conscious, reduced, unconscious). Cox proportional hazards and logistic regression analyses were used to estimate the risk for death, institutional living or dependency.

Results: 105 043 patients were registered at 86 hospitals. 79 689 patients (76%) were treated in stroke units and 25 354 patients (24%) in other types of wards. Stroke unit care was associated with better long-term survival in all subgroups. The best relative effect was seen among the following subgroups: age 18–64 years (hazard ratio (HR) for death 0.53; 0.49 to 0.58), intracerebral haemorrhage (HR 0.61; 0.58 to 0.65) and unconsciousness (HR 0.70; 0.66 to 0.75). Stroke unit care was also associated with reduced risk for death or institutional living after 3 months.

Conclusions: Stroke unit care was associated with better long-term survival in all subgroups, but younger patients, patients with intracerebral haemorrhage and patients who were unconscious had the best relative effect and may be given the highest priority to this form of care.

Controlled clinical trials have shown that stroke unit care is superior to stroke care at other types of wards. A review shows that treatment in a stroke unit reduces the risk of death by almost 20%,[1] and a review of observational studies confirms this observation.[2] In guidelines, stroke unit care is recommended for patients with acute stroke in England, Sweden and other countries.[3–6] The National Sentinel Audit for Stroke of 2006, showed that stroke units have been established in 91% of English hospitals.[7] The Stroke Unit Survey in Sweden of 2005 found that 86% of Swedish hospitals have stroke units.[8]

In spite of this expansion, there is a shortage of stroke unit beds, and allocation to stroke unit care may be challenging. In England, 62% of the patients were treated in stroke units in 2006.[7] In Sweden, 52% of the hospitals reported that all or almost all patients (>90%) were admitted to their stroke unit in 2005.[8] In the other hospitals, patients were allocated to stroke units and other types of wards, depending on access to stroke unit beds.

OBJECTIVES

Knowledge about treatment effects in stroke subgroups is limited. In clinical trials, no difference has been found between men and women, patients younger or older than 75 years, and patients with severe or less severe stroke.[1] The objective of the present study is to determine the effect size of stroke unit care in subgroups of patients with stroke. This information might be useful in a formal priority setting.

METHODS

Study design

A cohort study of acute stroke care, at a non-intensive stroke unit compared with stroke care at other types of wards, was performed.

Setting

All patients reported to Riks-Stroke, the Swedish Stroke Register. In Sweden there were 9 million inhabitants and 86 hospitals treating patients with stroke during the study period. All hospitals delivered data to Riks-Stroke. The registration of data in Riks-Stroke has been described in detail in previous publications.[9 10]

The Riks-Stroke registration consists of two parts. The first is a case record form (CRF) which is completed in the acute phase by members of the hospital staff. Patients are characterised in the CRF with respect to: activities of daily living (ADL) function and living conditions before stroke, cardiovascular risk factors and their treatment, level of consciousness[11] on arrival at hospital and brain imaging. Stroke care is documented in the CRF with respect to: admission ward (first ward after leaving the emergency room) and continued care ward (second ward in the case of a change), length of stay and discharge destination. The second part of the Riks-Stroke registration is a questionnaire, which is completed by the patient or relatives after 3 months.[9 12] In the questionnaire, new data on ADL function, living conditions and general health are collected. Detailed information about the register, including an English translation of the CRF and the questionnaire, can be accessed at the Riks-Stroke website (http://www.riks-stroke.org).

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Participants and data sources

All patients who were registered in Riks-Stroke during the period 1 January 2001 through 31 December 2005 were included. The WHO definition of an acute stroke was used.[9] The following ICD 10 code diagnoses were registered by all hospitals: intracerebral haemorrhage (I 61), cerebral infarction (I 63) and unspecified stroke (I 64). The sample size of the study would ensure detailed subgroup analyses.

Cross-linking to the Swedish Hospital Discharge and Cause of Death registers was done to achieve data on previous hospitalisations and death dates respectively. This was possible by using the unique personal identification number, which all Swedish inhabitants have. Previous hospitalisations were traced back to 1 January 1987. Vital status (death date) was followed until 31 January 2007.

Variables

The impact of stroke unit care compared with care at other types of wards was studied with respect to death or institutional living (alternatively death or dependency) after 3 months and death during the whole follow-up period (mean 2.4 years). The effect of missing registrations in Riks-Stroke has been validated previously.[13] The effect of missing values within a registration has been handled by not including these registrations in the statistical models. The number of missing data is given in text and tables.

Statistical methods

SPSS version 15.01.1 was used for all analyses. Patient characteristics in the different treatment groups were compared using χ^2 test for categorical and ANOVA for continuous variables. All tests were two-tailed.

Cox proportional hazards was used to estimate the death hazard during follow-up, and logistic regression analysis to estimate the odds ratio for death or institutional living (alternatively death or dependency) after 3 months. Twelve covariates (predictor variables) were included simultaneously and adjusted for each other in the final model (table 1). There were 10 categorical predictor variables: stroke unit, sex, haemorrhagic stroke, reduced level of consciousness, ADL dependency, institutional living, previous stroke, atrial fibrillation, diabetes and treated hypertension, and two continuous: age and number of previous hospitalisations. Most of the predictor variables have been identified in previous studies.[9 10] The number of previous hospitalisations, reflecting comorbidity, was significantly associated with the outcome in simple logistic regression and therefore included in the model. Hospital size was on the other hand not significantly associated with outcome and therefore not included in the final model. The number of outcome events was high in the study cohort, ranging from 2218 to 36 064. Thus, the ratio of outcome events to the number of predictor variables was very high, ranging from 185 to 3 005.

When performing logistic regression or Cox regression, the method ENTER in SPSS was used because all predictor variables were considered equally important to the model and therefore entered at the same time. Interaction terms were considered, and the following interaction parameters were introduced in the models: age×stroke unit, sex×stroke unit, stroke subtype×stroke unit and level of consciousness×stroke unit. Interaction was tested at the $\alpha = 0.01$ level. Tests for collinearity were performed by bivariate correlation analyses. The highest correlation coefficient, 0.474, was achieved for ADL dependency and institutional living. Overall-model-fit and regression diagnostics were performed according to standard procedures. The final models were able to predict outcome by more than 80% according to the classification table of SPSS.

Finally, Kaplan–Meier curves were plotted and a logrank test performed. The latter is a test of equality of survival distributions for the different levels of stroke unit care versus care at all other wards.

Ethics approval

The present study has been approved by the Ethical Committee of Umeå University Hospital, 5 May 2006, Reg. No. 69106.

RESULTS

The total number of patients was 105 043 and the mean follow-up time 2.4 years, making a total of 254 824 patient years. A total of 79 689 patients (75.9%) were provided stroke unit care, and 25 354 (24.1%) were provided care at other types of wards. CT of the brain was performed in 97.2% of the patients. The proportion of patients who were initially treated in intensive care units was 3.7%, 3.1% among patients treated in stroke units and 5.5% among patients treated in other types of wards. The proportion of patients who were discharged for additional rehabilitation was 20.6%, 19.7% among patients treated in stroke units and 23.5% among patients treated in other types of wards. The time spent at hospital, including in-hospital rehabilitation, was 18.4 (19.1 SD) days in patients treated at stroke units and 14.7 (17.4 SD) in patients treated at other types of wards. The response rate at the 3-month follow-up was 87.1%. The number of patients with missing follow-up data, for dependency or institutional living, was 10 092 (12.7%) in stroke units and 3437 (13.6%) in other types of wards. No patient was lost to follow-up of death date.

The distribution of baseline characteristics among patients treated at stroke units and other types of wards is shown in table 1. Overall, the characteristics of stroke unit patients were more favourable. Therefore, all baseline characteristics were included in the statistical models, when hazards ratios and odds ratios were calculated (see Statistical methods).

Absolute differences

The proportion of patients who were dead or institutionalised after 3 months is shown in table 3. The largest difference in absolute terms was found among patients with haemorrhagic stroke (18.8% fewer) and among patients 64 years of age or lower (10.9% fewer).

The death rate during the whole follow-up is shown in table 2. Patients at stroke units had substantially lower death rates in all subgroups. The largest differences in absolute terms were seen among patients with haemorrhagic stroke (200 per 1000 patient-years) and unconscious patients (878 per 1000 patient-years). The Kaplan–Meier curves show that the risk reduction in these groups comes early and is durable (figs 1, 2). With regard to age, patients 85 years and older seemed to have the largest reduction in death rate, 94 per 1000 patient years compared with 54 among patients below 85 years of age. For men and women, a similar reduction was found, 71 and 74 per 1000 patient years respectively. The frequency of death or dependency after 3 months is shown in table 4. The largest absolute difference was seen among patients with haemorrhagic stroke (16.1% fewer). Bias caused by those cases who were lost to follow-up was estimated. Assuming that all patients lost to follow-up were dependent, after 3 months, this would change

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Table 1 Distribution of baseline characteristics among 79 689 patients treated at stroke units and 25 354 patients treated at other types of wards

	Stroke unit		Other types of wards		Test	Data missing
	n	%	n	%	p Value	n (%)
Male sex	40 668	51.0	12 043	47.5	<0.001	0 (0)
Haemorrhagic stroke	9265	11.6	3232	12.7	<0.001	0 (0)
Lowered level of consciousness	13 224	16.8	5881	23.7	<0.001	1324 (1.3)
Activities of daily living dependency*	9684	12.3	4020	16.5	<0.001	1810 (1.7)
Institutional living	6210	7.8	3048	12.2	<0.001	886 (0.8)
Previous stroke	16 764	21.0	5572	22.0	0.001	2304 (2.2)
Atrial fibrillation	19 889	25.0	6646	26.2	<0.001	2958 (2.8)
Diabetes	16 000	20.1	4965	19.6	0.087	1596 (1.5)
Treatment for hypertension	39 198	49.1	11 516	45.4	<0.001	2930 (2.8)
	Mean	**SD**	**Mean**	**SD**	**p Value**	**n (%)**
Age	75.1	11.2	77.0	5.2	<0.001	0 (0)
No of previous hospitalisations	4.7	5.3	5.2	5.7	<0.001	403 (0.4)

*Activities of daily living dependency, according to the definition of the present paper, was equivalent to a modified Rankin Scale score of 4–5 in a cohort of 545 patients,[21] who were investigated 3 months after hospitalisation (personal communication, Marie Eriksson, 2008).

the odds ratio (OR) for death or dependency by 0.07. Supposing that all lost patients were independent, this would change the OR for death or dependency by 0.06.

Relative differences

In the Cox and logistic regression analyses, a statistically significant interaction existed between subgroup (age, stroke subtype and level of consciousness) and stroke unit care on outcome. For that reason, statistical modelling within each subgroup was relevant to control for confounders.

The largest reduction of the death hazard, during the whole follow-up, was found among the youngest patients (HR 0.53; 0.49 to 0.58), patients with intracerebral haemorrhage (HR 0.61; 0.58 to 0.65) and unconscious patients (HR 0.70; 0.66 to 0.75) (table 5).

The most important reduction in the odds for death or institutional living, after 3 months, was seen in unconscious patients (OR 0.47; 0.39 to 0.57), patients with intracerebral haemorrhage (OR 0.56; 0.50 to 0.61) and the youngest patients (OR 0.60; 0.54 to 0.68). The odds reduction for death or dependency, after 3 months, was also large among patients with intracerebral haemorrhages and unconsciousness, while it was modest among young patients (table 5).

In our cohort, there were 17 496 patients (16.7%) below the age of 65 years, 12 497 patients (11.9%) with intracerebral haemorrhage and 5 693 patients (5.4%) who were unconscious

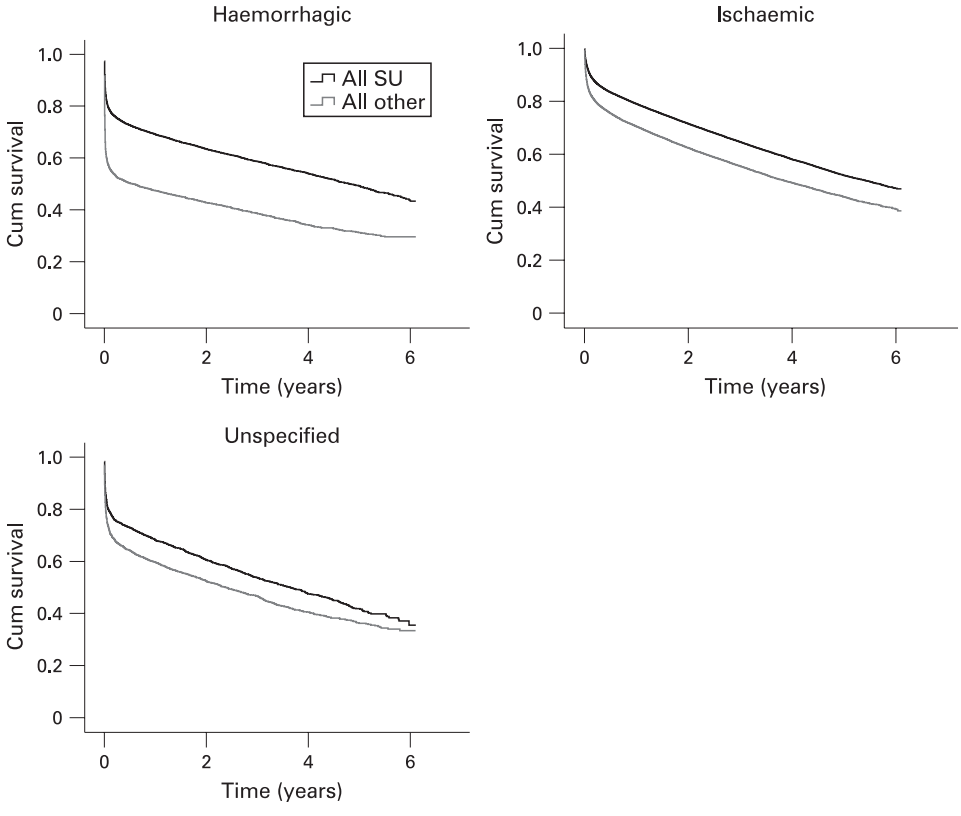

Figure 1 Kaplan–Meier curves for stroke subtypes. Patients were treated at stroke units (SU) and other types of wards.

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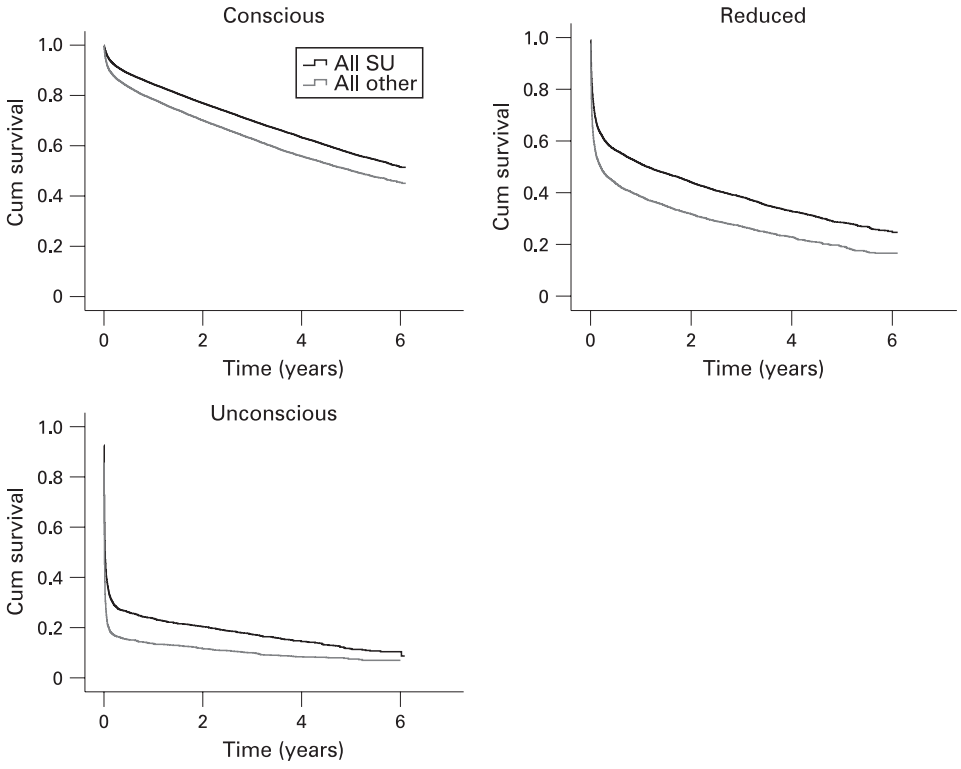

Figure 2 Kaplan–Meier curves by level of consciousness. Patients treated at stroke units (SU) and other types of wards.

on admission. Taking overlap between these indicators of marked beneficial effects of stroke unit care into account, there were 29 696 patients (28.3%) that belonged to at least one of the three high-benefit groups.

DISCUSSION

Principal findings

In this large cohort of hospitalised patients with stroke, stroke unit care had a beneficial effect in most subgroups. The largest effect size was found among patients younger than 65 years, patients with intracerebral haemorrhages and patients with lowered level of consciousness. In a formal priority setting, these subgroups could be easily identified. They constitute a reasonably small proportion, less than 30% of all patients, making their prioritisation smooth in most instances.

The relative benefits of stroke unit care were clearly higher for patients below the age of 65 than for elderly patients with stroke, in particular for survival. However, since case fatality rates are much higher among elderly patients, the picture becomes different when risk reductions are expressed in absolute rather than relative terms. The absolute risk reduction for stroke unit care versus care in other wards was actually higher among the oldest patients (94 per 1000 patient-years)

Table 2 Death during the whole follow-up period according to stroke subgroup and type of hospital ward

	Stroke units (n = 79 689)				Other wards (n = 25 354)			
Subgroup	**Total**	**Dead**	**PY**	**Deaths/ 1000 PY**	**Total**	**Dead**	**PY**	**Deaths/ 1000 PY**
Age								
18–64 years	14 068	1555	45 012	34.5	3428	797	10 158	78.5
65–74 years	18 029	4462	52 684	84.6	4962	1666	13 892	119.9
75–84 years	31 517	14 255	75 001	190.1	10 308	5596	22 844	245.0
⩾85 years	16 075	10 959	25 695	426.5	6656	4987	9573	520.9
Sex								
Male	40 668	14 804	105 036	140.9	12 043	5871	27 755	211.5
Female	39 021	16 427	93 356	176.0	13 311	7175	28 711	249.9
Stroke subtype								
Haemorrhagic	9265	4062	20 992	193.5	3232	2069	5248	394.2
Ischaemic	67 823	25 877	171 596	150.8	19 288	9390	45 855	204.8
Unspecified	2601	1292	5804	222.6	2834	1587	5364	295.7
Level of consciousness								
Conscious	65 682	21 661	178 051	121.7	18 932	7888	49 911	158.0
Reduced	9783	6277	15 964	393.2	3629	2746	4532	605.9
Unconscious	3441	2894	2603	1111.8	2252	2043	1027	1989.3

PY, person-years.

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Table 3 Death or institutional living after 3 months according to stroke subgroup and type of hospital ward

	Stroke units (n = 79 689)			Other wards (n = 25 354)		
Subgroup	Total	Dead or institutional	Percentage	Total	Dead or institutional	Percentage
Age						
18–64 years	14 068	1552	11.0	3428	751	21.9
65–74 years	18 029	3376	18.7	4962	1270	25.6
75–84 years	31 517	10 405	33.0	10 308	4030	39.1
⩾85 years	16 075	8616	53.6	6656	3923	58.9
Sex						
Male	40 668	10 418	25.6	12 043	4222	35.1
Female	39 021	13 531	34.7	13 311	5752	43.2
Stroke subtype						
Haemorrhagic	9265	3818	41.2	3232	1938	60.0
Ischaemic	67 823	19 168	28.3	19 288	6781	35.2
Unspecified	2601	963	37.0	2834	1255	44.3
Level of consciousness						
Conscious	65 682	14 542	22.1	18 932	5107	27.0
Reduced	9783	6186	63.2	3629	2535	69.9
Unconscious	3441	2869	83.4	2252	2050	91.0

than among younger patients (54 per 1000 patient-years). Taking relative as well as absolute risk reductions into account, it may seem unjustified to base priority setting for stroke unit care on age per se.

The gender perspective has been considered in previous studies. The odds ratio for death or institutional living has not been different among men and women in the controlled clinical trials,[1] and no difference was found in the Italian study.[14] Thus, data from all studies presented so far, controlled clinical trials as well as observational studies, confirm that both sexes benefit from stroke unit care.

As regards stroke subtype, no data have been presented from controlled clinical trials, probably depending on a low frequency of brain imaging in older studies.[1] In the review of observational stroke unit studies, it was not possible to analyse ischaemic and haemorrhagic stroke separately due to insufficient data.[2] In the Italian study, a significantly better effect was achieved by stroke unit care in patients with haemorrhagic stroke.[14] Thus, there is now evidence from two large observational studies, the present study and the Italian study, that patients with haemorrhagic stroke benefit more from stroke unit care than patients with ischaemic stroke.

For stroke severity, there are some important issues to consider before conclusions can be made. In the review of controlled clinical trials, strokes were divided into mild, moderate and severe, based on the Barthel ADL index or an equivalent index.[1] In that review, a positive effect of stroke unit care was achieved only among patients with severe stroke. In the review of observational studies, ''better'' and ''worse'' patients showed equally good results of stroke unit care. There is however no clear definition of these groups in the publication.[2] In the Italian study, stroke severity was characterised by the level of consciousness, and patients were dichotomised into ''conscious and unconscious.''[14] The classification was done retrospectively based on a review of patients' clinical records. No statistically significant difference was found between these two groups. In the present study, a modified version of the Scandinavian Reaction Level Scale was used. Scoring according

Table 4 Death or dependency after 3 months according to stroke subgroup and type of hospital ward

	Stroke units (n = 79 689)			Other wards (n = 25 354)		
Subgroup	Total	Dead or dependency	Percentage	Total	Dead or dependency	Percentage
Age						
18–64 years	11 819	2435	20.6	2857	896	31.4
65–74 years	15 945	5603	35.1	4326	1727	39.9
75–84 years	27 528	14 676	53.3	8919	5226	58.6
⩾85 years	13 959	10 497	75.2	5721	4613	80.6
Sex						
Male	35 406	14 542	41.1	10 412	5241	50.3
Female	33 845	18 669	55.2	11 411	7221	63.3
Stroke subtype						
Haemorrhagic	8206	4752	59.2	2871	2161	75.3
Ischaemic	58 989	27 260	46.2	16 535	8804	53.2
Unspecified	2236	1199	53.6	2417	1497	61.9
Level of consciousness						
Conscious	56 851	22 679	39.9	16 071	7285	45.3
Reduced	8552	7110	83.1	3171	2774	87.5
Unconscious	3207	2985	93.1	2167	2086	96.3

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Table 5 Outcome of stroke unit care compared with stroke care at other types of wards

	Hazard ratio for death at the end of follow-up, mean 2.4 years	OR for death or institutional living after 3 months	OR for death or dependency after 3 months
Subgroups	**HR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**
Age			
18–64 years	0.53 (0.49 to 0.58)	0.60 (0.54 to 0.68)	0.84 (0.75 to 0.93)
65–74 years	0.78 (0.73 to 0.82)	0.79 (0.73 to 0.87)	0.99 (0.91 to 1.08)
75–84 years	0.81 (0.79 to 0.84)	0.91 (0.86 to 0.96)	0.98 (0.92 to 1.03)
⩾85 years	0.86 (0.83 to 0.89)	0.90 (0.84 to 0.97)	0.83 (0.76 to 0.91)
Sex			
Male	0.79 (0.76 to 0.81)	0.82 (0.78 to 0.86)	0.91 (0.86 to 0.96)
Female	0.83 (0.81 to 0.85)	0.88 (0.83 to 0.92)	0.95 (0.90 to 1.00)
Stroke subtype			
Haemorrhagic	0.61 (0.58 to 0.65)	0.56 (0.50 to 0.61)	0.59 (0.53 to 0.67)
Ischaemic	0.87 (0.85 to 0.89)	0.92 (0.88 to 0.95)	0.98 (0.94 to 1.03)
Unspecified	0.92 (0.85 to 0.99)	0.94 (0.81 to 1.09)	0.96 (0.82 to 1.12)
Level of consciousness			
Conscious	0.88 (0.85 to 0.90)	0.91 (0.88 to 0.95)	0.97 (0.93 to 1.01)
Reduced consciousness	0.78 (0.74 to 0.82)	0.84 (0.77 to 0.92)	0.86 (0.75 to 0.98)
Unconscious	0.70 (0.66 to 0.75)	0.47 (0.39 to 0.57)	0.47 (0.36 to 0.62)

Adjusted hazard ratios (HR) and odds ratios (OR) are presented for each level within the four subgroups.

to this scale has been used in critical care in Sweden for 20 years, and the scale is well known to most Swedish physicians. The present finding of improved outcome after stroke unit care among patients with lowered level of consciousness is coherent with the findings of previous studies showing a beneficial effect in patients with severe stroke.[1 2 14]

Strengths and weaknesses of the study

The present study is large, allowing for detailed subgroup analyses with narrow confidence intervals. It is a prospective register study, including more than 80% of patients with acute stroke in Sweden.[15] Several predictor variables, known from previous analyses and the literature, could be used when adjusting for differences in case mix.[9 10 16] These include previous stroke, atrial fibrillation, ADL dependency and institutional living before stroke, all strong predictors for death. It was also possible to adjust for previous hospitalisations, reflecting comorbidity. There was no loss to follow-up with regard to long-term survival.

The observational study design bears an inherent risk of imbalance with regard to confounders between patients treated at stroke units and other types of wards. It was not possible to specifically control for lesion size, as measured by CT and neurological scales, cardiac disease and cognitive decline, all being potentially important predictors. The level of consciousness, as defined in the present paper, is a reasonable, but not perfect, measure of stroke severity. Its correlation with the NIH stroke scale is just intermediate. Lowered level of consciousness has been correlated with the NIH stroke scale in a population-based cohort.[22] The correlation coefficient was 0.373 between lowered level of consciousness, according to Riks-Stroke, and an NIH stroke scale score ⩾9 (P Appelros, personal communication, 2008). The correlation was better, 0.545, for a NIH stroke scale score ⩾21.

The level of consciousness reflects not only stroke severity, but other factors of importance for short-term survival such as raised body temperature, fluid deficit and high blood glucose. Swedish stroke units have intervention programmes for nutrition and fluid delivery, early activation of the patients and intermittent appraisal of neurological symptoms and vital parameters. The existence of these programmes provides the most plausible explanation for the remarkable effect of stroke unit care in unconscious patients and patients with haemorrhagic stroke.

The impact of registration bias has been discussed in the other publications from the register.[10 13 17] The characteristics of patients lost to follow-up have also been analysed. These patients have been more dependent and institutionalised before stroke[9] and more afflicted by haemorrhagic stroke and lowered level of consciousness during hospital stay.[13]

Strengths and weaknesses in relation to other studies

The present study is the largest within this field so far. The review of observational studies included 42 000 patients from 18 studies.[2] The present study is based on a stroke register covering all hospitals and most acute strokes in a country during a 5-year period. The data are prospectively collected on a CRF during the acute phase, and the 3-month follow-up is based on a questionnaire with a response rate of 87%. The Italian study included 11 500 of approximately 250 000 patients in seven regions during a 5-year period.[14] In that study, the data describing patient characteristics were retrospectively collected by review of patients' clinical records. The follow-up was prospectively performed, and 95% of the follow-up data were complete.

Stroke unit care reduces the risk of death after stroke by prevention and treatment of medical complications,[18] but the components which have the strongest impact on outcome have not been identified yet. Swedish stroke units are of the non-intensive type with intermittent monitoring of vital parameters but little use of bedside monitors for continuous monitoring.[8] Use of continuous monitoring is a matter of debate, and evidence for its efficiency in the major part of patients with stroke is still lacking.[1 19 20] Use of intensive care was very infrequent, 3–5%, in the present study cohort and did not have any impact on outcome.

In summary, stroke unit care was associated with a better long-term survival in all subgroups, but younger patients, patients with intracerebral haemorrhage and patients who were unconscious had the best relative effect and may be given the highest priority to this form of care.

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Competing interests: AT has received a research grant from AstraZeneca. BF and KH are employed at the Epidemiology Department, AstraZeneca R&D.

Ethics approval: Ethics approval was provided by the Ethical Committee of Umeå University Hospital.

AT initiated the study, carried out the statistical analyses and drafted the report. BF and SÅ retrieved and structured data from the databases used. KA, KHÅ, BN, BS, AT and P-OW were members of the Riks-Stroke steering committee and revised the report. KH also revised the report.

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