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Does implementation of a standardized pathway of stroke care affect functional outcome after stroke?

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Abstract

Background: A stroke care pathway (SCP) was introduced in Norway in 2018. The goal of the pathway was to avoid delay in treatment and diagnostics of acute stroke and to secure treatment according to national guidelines. In this study, we aimed to evaluate how the implementation of the SCP affects outcome after stroke.

Methods: We performed a register-based study using data from the Norwegian Stroke Register that covers 87% of acute stroke patients in Norway. Patients included 1 year before and 1 year after the introduction of the care pathway were compared (2017 vs 2019). Change in functional outcome, the proportion of independent patients 90 days post-stroke, discharge destination, proportions admitted to stroke units and 90 days mortality were compared. Functional outcome was measured using modified Rankin Scale (mRS) and functional independence was defined as mRS 0–2.

Results: In total, 11,009 patients with 90 days follow-up data were analyzed. Comparing the cohorts from 2017 and 2019, there was no change in demographics or stroke characteristics. No statistically significant differences in mRS, admission to thrombolysis time, or 90 days mortality were found. However, the proportion of patients discharged directly home and treated in a stroke unit increased from 2017 to 2019.

Conclusion: The implementation of a standardized pathway of stroke care in Norway did not lead to improvement in functional outcome or a reduction in 90 days mortality. However, the proportion of patients discharged directly home increased, and more patients were treated in stroke units in 2019 compared with 2017.

Keywords

Stroke, care pathway, function post-stroke, acute stroke treatment, treatment delay, time-use

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Introduction

Clinical care pathways have been introduced in different healthcare settings for many years to organize and standardize care processes. They are primarily implemented to improve the quality and efficiency of evidence-based treatment and to improve patient safety and satisfaction. Their effect is hard to evaluate due to widely different settings, clinical heterogeneity, and the use of different outcome measures.[1–4]

The use of clinical care pathways in stroke treatment was initiated in the 1990s. More efficient and improved quality of stroke care and reduced variations in stroke treatment are listed as reasons for their implementation. Previous

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Table 1. Characteristics of included patients.

	2017 N = 5388	2019 N = 5621	Total N = 11,009	p value
Ischemic stroke, n (%)	4786 (89.8)	5093 (91.0)	9879 (90.4)	0.026[b]
Intracerebral hemorrhage, n (%)	544 (10.2)	501 (9.0)	1045 (9.6)	
Demographics				
Age, *mean* (*SD*), years	72.5 (12.7)	72.5 (12.6)	72.5 (12.6)	0.94[a]
Female sex, n (%)	2320 (43.1)	2424 (43.1)	4744 (43.1)	0.95[b]
Living at home pre-stroke, n (%)	5110 (94.8)	5374 (95.6)	10,484 (95.2)	0.32[b]
Risk factors				
Previous stroke, n (%)	1139 (21.3)	1176 (21.0)	2315 (21.1)	0.74[b]
Previous transient ischemic attack, n (%)	556 (10.6)	545 (9.8)	1101 (10.2)	0.21[b]
Previous diabetes, n (%)	979 (18.3)	1062 (18.9)	2041 (18.6)	0.38[b]
Previous hypertension-treated, n (%)	3042 (56.8)	3241 (58.0)	6283 (57.4)	0.21[b]
Previous heart infarction, n (%)	708 (13.3)	697 (12.5)	1405 (12.9)	0.23[b]
Previous atrial fibrillation, n (%)	1201 (22.5)	1237 (22.1)	2438 (22.3)	0.62[b]

SD: standard deviation.
Data are number (%) unless otherwise indicated. N = actual number excluding missing data.
[a]*t* test.
[b]Chi-square test.

studies, including a Cochrane review from 2005 and a cluster randomized controlled trial study from Italy, show that the evidence of their effect on patient outcome is highly inconclusive.[3,5,6]

In 2017, the Norwegian health authorities decided to establish a national standardized pathway of stroke care based on national guidelines for stroke treatment and diagnostics.[7,8] The aim of the stroke care pathway (SCP) was to ensure that patients with acute stroke would receive well organized and predictable care without non-medical delay in assessment, diagnostics, or treatment. In addition, the SCP intended to reduce variations in stroke care throughout the country. Previous reports from the Norwegian Stroke Register (NSR) and studies from other countries show differences in care based on geography, urban-rural localization, and demographics. The SCP was implemented in 2018.[9–11]

In the present study, we evaluate the period from suspicion of acute stroke to the patient is ready to be discharged from hospital. The pathway is organized in phases, and each phase has a recommended target time. The goal is to ensure compliance with the target times and to avoid delay in treatment of acute stroke. The SCP is centered on procedures with significant effect on stroke outcome such as reperfusion therapy and treatment in a stroke unit. As reperfusion therapy is highly time dependent and surgery of symptomatic carotid stenosis is recommended as early as possible and preferably within 2 weeks target times regarding these treatments are highlighted (see supplementary Table 1).[12–14]

The aim of our study was to evaluate if the introduction of this SCP had an impact on functional outcomes and 90 days mortality after stroke. In addition, we aimed at comparing the proportion of patients admitted to a dedicated stroke unit and proportions discharged directly home in 2019 versus 2017.

Our primary hypothesis was that patients admitted to hospital with the diagnosis of acute stroke the year after the introduction of the pathway (2019) would have significantly better function compared with those admitted the year prior to the introduction (2017).

Methods

Study design

Data were obtained from the NSR. This register was approved as a national compulsory register in 2012.[9] All 50 Norwegian acute care hospitals are obliged to report medical data on all patients admitted to hospital with acute stroke. A study conducted in 2015 showed that this register "is adequately complete and correct to serve as valuable source of data for epidemiological, clinical and healthcare studies."[15] In 2017–2019, the coverage of the register was 87% of hospital admitted cases.[10,16,17]

Population

The study included patients ⩾18 years registered in the NSR with acute stroke in 2017 and 2019. The whole population was included in the assessment of mortality, those with a valid follow-up assessment 90 days post-stroke were included in the study comparing functional outcome.

In the relevant years, the total population of Norway was stable at 5.3 million people and about 11,000 patients were affected by acute stroke each year.[10,18]

Setting

In Norway the treatment and diagnostics of stroke is provided by the public hospitals. According to the Norwegian guidelines, all patients with the diagnosis of acute stroke should be treated in a dedicated stroke unit with focus on early diagnostics, medical management, reperfusion therapy, and early rehabilitation.[19]

Data collection

The data comprises date and time for the following: symptom onset, hospitalization, thrombolysis, and discharge from hospital. Further sociodemographic data, stroke risk factors, stroke severity at admission measured by the National Institutes of Health Stroke Scale (NIHSS), functional status before and 90 days post-stroke measured by modified Rankin Scale (mRS) and discharge destination were registered.

In the NSR, evaluation of the mRS before the stroke was based on information from the patient, their next of kin, and the patients' medical record. mRS 90 days post-stroke was mainly assessed by health personnel trained in the use of mRS.

Primary and secondary outcomes

Primary outcome was change in functional outcome measured by change in mRS pre-stroke to 90 days post-stroke from 2017 to 2019.

The mRS is the most used outcome measure in stroke trials. The scale describes six degrees of disability after stroke, from 0 to 5 where 0 corresponds to no symptoms and 5 corresponds to severe disability. A score of 6 denotes death. Functional outcome at 90 days post-stroke is shown to be a good predictor of long-time survival.[19]

Secondary outcomes were the proportion of patients discharged directly home from the stroke unit, mortality at 90 days post-stroke, and the proportion of patients admitted to and treated in a stroke unit in 2017 compared with 2019.

Statistics

The comparison of proportion of independent patients (mRS < 2) in 2017 and 2019 was defined as primary analysis. Among the 8785 patients registered in NSR during 2017, 5388 (61.3%) patients had completed the mRS questionnaire at 90 days and were included in the study. It was assumed that about the same number of patients would complete the mRS questionnaire in 2019. Considering the worst-case scenario with 50% independent patients in 2017 resulting in largest standard error and thus widest confidence interval (CI), with around 6000 patients at two time points, one can expect 95% CI of (3.2%, 6.8%) for a difference in proportion of 5%. The 99% CI would be (2.7%, 7.3%).

Patient characteristics and outcome variables were described as numbers and frequencies for categorical variables and means and standard deviations (*SD*s) for continuous variables. By using the independent samples *t* test or the chi-square test, those participating and those not participating in a 90 days follow-up for both periods were compared.

Cluster effect at hospital-, health region-, and region-level was assessed by intra-class correlation coefficient (ICC). The ICC was 3.9% on the regional level, which indicates no significant differences between the regions.

Logistic regression model was estimated to assess the difference between 2017 and 2019 in change from pre-stroke to 90 days follow-up in primary outcome. The model included dummy for period (pre-stroke vs 90 days), dummy for time period (2017 vs 2019), and interaction between these two. Post hoc analyses were performed to derive odds for difference in change. No random effects were included as cluster effect was negligible. The results with p values below 0.05 were considered statistically significant.

Statistical analyses were conducted using Stata v16 and SPSS Version 27 (IBM SPSS, Chicago, IL, USA).

Ethics

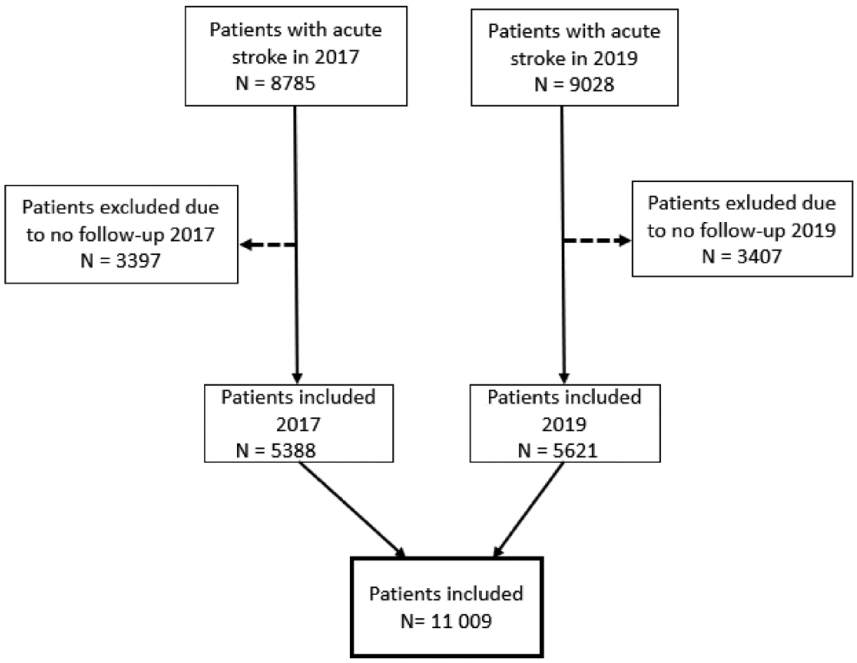
The Regional Committee for Medical Research Ethics South-East (REK 2018/498) approved the study. In accordance with the approval from the Regional Committee for Medical Research Ethics and the Norwegian law on medical research, the project did not require a written patient consent.

Results

Altogether 17,813 patients were registered in NSR with acute stroke in 2017 and 2019. The whole population was included in the assessment of mortality. Overall, 11,009 patients attended a 90 days follow-up assessment and were included in the study comparing functional outcome: 5388 in 2017 and 5621 in 2019, see Figure 1.

Prior to the main analysis, patient characteristics of the cohorts with and without a follow-up in 2017 and 2019 were compared. The no follow-up cohorts were significantly older, had poorer functioning, and were institutionalized to a higher extent than the groups with a 90 days follow-up.

Figure 1. Flow chart showing inclusion/exclusion of patients.



When comparing the two cohorts with no follow-up (2017 vs 2019), the only significant difference we found was that more patients without follow-up were treated in a stroke unit in 2019 ($p=0.004$; see Supplementary Tables 2 and 3).

Patient characteristics of the included patients are shown in Table 1. No significant differences regarding age, sex, or stroke risk factors were found between the 2017 and 2019 cohorts. However, NIHSS at arrival was significantly lower in 2019 compared with 2017 (4.2 vs 4.6, $p<0.01$).

Descriptive statistics comparing time-use, treatment, and severity of stroke are shown in Table 2. There is a significant increase in time from symptom onset to admission in 2019 compared with 2017 ($p<0.001$). Time from hospital admission to thrombolysis is equal. Length of stay is significantly shorter in 2019 compared with 2017 ($p<0.001$).

A nominal regression model comparing change in mRS from pre-stroke to 90 days post-stroke in 2017 with change in mRS in 2019 and adjusting for gender, age, and NIHSS at admission found no significant differences in change in mRS between the 2 years (odds ratio (OR) = 1.06, 95% CI = (0.86, 1.30)), see Table 3.

Descriptive statistics of the proportion of independent patients before and after 90 days shows no significant change comparing the two cohorts.

In a sub analysis comparing the change of mRS only in patients with moderate to severe stroke (NIHSS > 5), no significant change in mRS was found.

Mortality status at 90 days was assessed using the whole cohort. In all, 1407 (16%) of 8785 patients had died within 90 days in 2017, and 1380 (15.3%) of 9028 in 2019, which is a nonsignificant reduction in 90-day mortality between 2017 and 2019.

A significantly higher number of patients were discharged directly home from the stroke unit in 2019 compared with 2017 (59.2% vs 57.0%, $p=0.021$), and the number of patients treated in a stroke unit significantly increased from 2017 to 2019 (95.4% vs 97.1%, $p<0.001$).

More patients were discharged directly home in 2019, and there was a significant reduction in length of stay from 2017 to 2019 (5.61 days in 2019 compared with 6.24 days in 2017, $p<0.001$). No significant difference in functional outcome between the health regions was found.

Discussion

In contrast to our hypothesis, this study showed no significant improvement in functional outcome after the introduction of an SCP. However, significantly more patients were discharged directly home from hospital, and more patients with stroke were treated in a dedicated stroke unit after the implementation.

Previous studies evaluating the effect of SCPs on patients' functional outcome are inconclusive.[20–23] The SCP in the present study focuses on reducing delay in the treatment of acute stroke. It is well established that the effect of revascularization treatment is highly time dependent and

Table 2. Time-use, treatment, stroke severity, and function stratified by implementation of the standardized care pathway.

	2017 N = 5388	2019 N = 5621	Total N = 11,009	p value
Time and treatment				
Onset to admission, N = 8495, *median, h:min*	3:37	4:25	4:00	<0.001[a]
0–3 h, n (%)	1814 (46.1)	1911 (41.9)	3725 (43.8)	
3–4.5 h, n (%)	312 (7.9)	395(8.7)	707 (8.3)	<0.001[b]
>4.5 h, n (%)	1805 (46.0)	2258 (49.5)	4068 (47.8)	
Thrombolysis, n (%)	1061 (19.7)	1108 (19.7)	2169 (19.7)	0.97[b]
Onset to thrombolysis, *mean (SD), h:min*	1:47 (1:48)	2:04 (2:25)	1:55 (2:08)	0.003[a]
0–3 h, n (%)	850 (80.1)	833 (75.2)	1683 (77.6)	0.002[b]
3–4.5 h, n(%)	182 (17.2)	216 (19.5)	398 (18.3)	
>4.5 h	29 (2.7)	59 (5.3)	88 (4.1)	
Admission to thrombolysis, *mean (SD), h:min*	00:39 (2–355)	00:39 (4–597)	00:39	0.85[b]
Thrombectomy, n (%)	168 (3.1)	195 (3.5)	363 (3.3)	0.31[b]
Admitted to a stroke unit, n (%)	5141 (95.4)	5453 (97.1)	10,594 (96.4)	<0.001[b]
Severity of stroke				
NIHSS at arrival, N = 9106, *mean (SD)*	4.6 (5.3)	4.2 (4.9)	4.4 (5.1)	<0.001[a]
mRS pre-stroke, N = 10,027				
mRS 0–2	4444 (90.7)	4667 (91.0)	9111 (90.9)	0.56[b]
mRS 3–5	456 (9.3)	460 (9.0)	916 (9.1)	
mRS 3 months, N = 11,007				
mRS 0–2	3959 (73.5)	4115 (73.2)	8074 (73.4)	0.77[b]
mRS 3–5	1429 (26.5)	1504 (26.8)	2933 (26.6)	
Discharged home, N = 10,519, n (%)	2944 (57.0)	3168 (59.2)	6112 (58.1)	0.021[b]
Mortality				
3 months mortality, N = 17,813	1408 (16.0)	1380 (15.3)	2788 (15.6)	0.173[b]

SD: Standard deviation; NIHSS: National Institutes of Health Stroke Scale; mRS: modified Rankin Scale.
Time to treatment and function of the 11,009 patients with acute stroke in 2017 and 2019.
Data are number (%) unless otherwise indicated. N = included patients.
[a]*t* test.
[b]Chi-square test.

that early treatment in stroke units is beneficial to all patients with stroke.[12,24–26] Decreasing the time-use is therefore one of the most important factors to ensure optimal acute stroke treatment. Yet, in our study, we found that prehospital delay increased after implementation of the SCP. This may have negatively affected the primary outcome of the study. A stroke information campaign taking place in Norway from 2016 to 2017 could explain some of the increased delay. During the campaign, patients admitted to hospital within 4 h increased. However, earlier studies have shown that the effect of such campaigns decline post-intervention which could partly explain the increased delay in 2019.[27,28]

This SCP did not significantly affect the proportion of independent patients and various explanations can be suggested regarding these results. First, the incidence and mortality as well as the severity of stroke have decreased in the Western world in the last decades.[29,30] In our study, NIHSS

Table 3. Nominal regression model (mRS = 0–2 to ref.), adjusted for age, gender, and NIHSS at admission.

	2017		2019		
	Pre	3 months	Pre	3 months	2019 vs 2017
mRS = 3–5	OR (95% CI)		OR (95% CI)		OR (95% CI)
3 months vs pre OR (95% CI)	4.41 (3.79, 5.14)		4.67 (3.38, 6.46)		1.06 (0.86, 1.30)
p value					0.597

NIHSS: National Institutes of Health Stroke Scale; OR: odds ratio; CI: confidence interval.

at admission decreased significantly from 2017 to 2019, which is in line with this tendency. Furthermore, the basic structures of the stroke service in Norway highlighting treatment in a stroke unit and adherence to guidelines were already established prior to the introduction of this pathway.[7] In addition, the annual report from NSR starting from 2012 puts on display how patients with acute stroke are managed in the different hospitals by publishing statistics that are publicly available.[10] This might have drawn attention of the media, health authorities, and hospitals to the differences in stroke treatment within the country causing an increased motivation to improve treatment, prior to the introduction of the SCP. When comparing to other Nordic countries, statistics show that Norwegian stroke patients more often receive thrombolysis and more often are treated in a stroke unit.[31,32] However, many stroke units around the world do not operate to this high level of stroke care, and the value of implementing an SCP may be greater in a poorer performing health service.

Second, we believe that the results of the present study might reflect that the majority (>80%) of the cohort consisted of "mild strokes" defined as NIHSS 0–5. These patients have only minor sequela that will not cause deterioration to such a degree that it affects their functional independence. Yet, a sub analysis of the patients with NIHSS > 5 at admission did not reveal any difference between the two cohorts.

Length of stay was shorter and more patients were discharged directly home in 2019, 1 year after implementation of the SCP. This might in part be caused by better and faster treatment and early admittance to stroke units. However, other explanations like patients admitted with less severe stroke and increased access to resources in the primary health care services cannot be ruled out.

Treatment in stroke units is one of the most important factors influencing the outcome of patients with stroke.[17] In our study, significantly more patients were treated in a stroke unit in 2019 versus 2017. However, this did not transfer into an effect on functional outcome. One possible explanation might be a ceiling effect of mRS as three of four patients reached an mRS of 0–2. Another explanation could be that patients received outpatient rehabilitation up to the 90 days follow-up.

No significant difference between the health regions was revealed regarding change in mRS. However, this does not preclude the possibility that inter-regional variations do exist.

Findings from previous studies state that care pathways for stroke can be useful especially in the hyperacute phase of stroke care.[1,6] In addition, a pathway could ensure that important parameters are monitored and appropriate investigations and treatments such as endarterectomy are performed in the right patients at the right time.

Strengths and limitations

The large sample size and the high coverage rate of the NSR (87%) are strengths of the present study. Even though our sample was significantly younger compared with the general stroke population in Norway according to the NSR report (72.5 vs 76.0 years of age), it was comparable with respect to stroke severity and comorbidities.[10]

According to our inclusion criteria, only those completing the 90 days follow-up assessment were included, which might have introduced a selection bias. However, the comparison of those participating and those not participating in the 90 days follow-up for both periods showed no major differences regarding background variables. We cannot rule out that the results could have been different if patients with severe strokes were included in the study.

Using a register includes a risk of inaccurate registration and missing data. Also, it is difficult to eliminate biases due to other factors than the pathway, which may affect the results. Future research should investigate to which extent the goals of the pathway were achieved and whether good adherence to the target times is associated with outcome. It is well known that it takes time to change clinical practice. This study was conducted 1 year after the pathway was introduced, which might be too early to identify the effect of the pathway.

Using mRS as outcome variable can be discussed. There is limited information regarding sensitivity of the mRS to changes in disability levels after a stroke. With only six levels of measurements of disability, the scale might be less sensitive to functional change than more specific stroke scales.[33]

Conclusion

This study showed that introducing a standardized pathway of stroke care did not significantly affect functional outcome or mortality. Secondary results showed that patients were more often discharged directly home from the stroke unit and more patients were treated in stroke units after the implementation. An additional evaluation on its effect may be relevant when the pathway is fully effectuated.

Declaration of conflicting interests

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Supplemental material

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