Relationship Between Process and Outcome in Stroke Care

Harry McNaughton, PhD; Kathryn McPherson, PhD; William Taylor, FRACP; Mark Weatherall, FRACP

Background and Purpose—Better processes in stroke care are assumed to lead to better stroke outcomes. We sought to test whether current measures of stroke process are related to measures of stroke outcome.

Methods—This was a prospective study of consecutive patients with acute stroke admitted to each of the 3 general hospitals in 1 region who were followed up for 12 months after hospital discharge. Process was measured by use of the Royal College of Physicians Stroke Audit Package, and outcomes were measured with a range of disability, health status, handicap, and independence measures, as well as mortality.

Results—One hundred eighty-one patients were recruited. There was evidence for a relationship between some process variables and outcomes at hospital discharge, but the relationships were generally weak. None of the process variables remained in regression models of functional outcomes at 12 months. The hospital with the best process scores had the worst case mix–adjusted outcomes.

Conclusions—The link between stroke process and outcome, through the use of currently available measures of process such as the Royal College of Physicians Stroke Audit Package, is not straightforward. Ongoing work may clarify some of these issues and provide guidance to stroke clinicians on how best to improve existing services. (Stroke. 2003;34:713-717.)

Key Words: outcome ■ process assessment (health care) ■ stroke

There is clear evidence from randomized controlled trials that stroke unit care can make a substantial difference in hospital mortality. Reviews of the various stroke unit studies have focused on the idea that it is the organization of stroke services that is responsible for the difference in outcome, hence the title of the Stroke Unit Trialists’ Collaboration, Organized Inpatient Stroke Care.1 Along with a satisfactory structure (such as a stroke unit), the implication is that maintaining high-quality hospital processes should lead to the best outcomes. This combination of structure and process has been emphasized by a number of authors and panels. The Royal College of Physician Guidelines on Stroke Service Evaluation states that “assessing the quality and effectiveness of services should concentrate on recording process measures, rather than outcome, until improvements are made in methods of risk adjustment for case-mix.”2 The American Heart Association/American College of Cardiology First Scientific Forum on Assessment of Health Care Quality in Cardiovascular Disease and Stroke states that “sufficient data are not yet available to support the use of specific indicators for comparing the overall quality of stroke care between institutions.”3 However, these researchers were prepared to support “a specific set of clinical practices as an indication of quality care within institutions.” These clinical practices are items of process.

The relationship between process and outcome depends critically on how closely tied to outcomes the particular aspects of process might be. Mant and Hicks4 use the example of thrombolysis and myocardial infarction to justify the measurement of process rather than outcome. Here, the time from onset of symptoms to injection of thrombolytic agent is known to influence reperfusion of the coronary vessels, the degree of infarcted myocardium, and outcomes in terms of mortality. Hence, measurement of delays in people receiving thrombolysis might reasonably be expected to translate into measurement of worse outcomes in a sample of sufficient size. However, in stroke care (for which Mant and coworkers4 also advocate measurement of process rather than outcome), the situation is not as clear cut. Indeed, the possible items of process to be measured may not necessarily reflect what is having an impact on outcome. Currently, we remain unclear as to what it is about stroke unit care that leads to lower mortality. It may be early medical management, multidisciplinary rehabilitation teams, the enthusiasm of the nursing staff working in stroke services, early mobilization, or a number of other possible factors. Whether these items, reflected in process measures, could be used as a proxy for outcome measurement remains uncertain.

Various authors have attempted to demonstrate a connection between process and outcome in stroke,6,7 but the
relationship, particularly that between postinitial stroke incident care and longer-term outcome, is poorly understood. We report here our experience with the Royal College of Physicians Stroke Audit Package (RCPSAP) in measuring process and comparing this to case mix–adjusted outcome at hospital discharge and 12 months after hospital discharge.

Methods
Details of the stroke cohort have been presented elsewhere. In brief, 181 patients with acute stroke admitted to 1 of the 3 general hospitals in 1 region (Wellington, New Zealand) during 1997 were enrolled. None of the hospitals had a stroke unit. Case note review revealed that this was ~77% of eligible patients with stroke. The main reason for nonenrollment was failure to provide informed consent or an inability to do so because of death or early discharge. Assessments of prestroke function, stroke variables, and initial disability with the Functional Independence Measure (FIM) were made within the first week of admission. Stroke type was classified by use of the Oxfordshire Community Stroke Project classification. Patients were followed up until death or 12 months after hospital discharge in the community. Outcome measures included the modified Rankin Scale (MRS), Short Form (SF)-36, mortality, and place of residence. Discharge FIM was the last FIM assessment before discharge, which occurred a median of 3 days before discharge. Poor discharge outcome was defined as death, a move from home to residential care, or a move from rest home–level to hospital-level care.

Process was measured with the RCPSAP and 4 additional process indicators. The RCPSAP was chosen because it is a well-established quantitative measure of process with adequate interrater reliability. Its 60 items cover acute and rehabilitation aspects of care for inpatients after stroke. The RCPSAP items were scored according to the manual that comes with the audit package, which is detailed elsewhere. Case notes were reviewed by a single reviewer (H.M.) retrospectively at least 6 months after hospital discharge. A summary score for the RCPSAP (RCPSAP Sum) was derived in the following way. For each patient, each of the 60 items of the RCPSAP was scored 1 point for “yes” and no points for “no” or “no, but” values. The 60 scores were then summed; this total was divided by the number of items with a “yes” or “no” response; and this fraction was expressed as a percentage (ie, “no, but” items were excluded). This means that when sections of the process audit could not be completed for some patients (such as the rehabilitation section for patients discharged from a medical ward or who died in hospital), it was still possible to score 100% as an overall score based on the items relevant to that patient’s care. The 4 specific process indicator items were as follows: proportion of people having a swallow assessment before feeding (swallow); proportion of people having a CT head scan (CT done); proportion of people with an adequate clinical formulation (includes neurological deficits, part of the brain affected, and risk factors; clinical formulation); and proportion of people having a multidisciplinary team meeting (MDT meeting) to discuss a management plan or progress.

Statistical Analysis
Categorical variables were analyzed by use of χ² tests, and continuous variables meeting normality assumptions were analyzed by use of t tests. When normal assumptions were not met, nonparametric statistics were used. Regression equations were developed for various response variables as detailed in the Results section for each variable. Analyses were undertaken with SPSS 10.0 and SAS software.

Results
All 181 patients were followed up until hospital discharge. One hundred seventy-one (94.5%) were followed up until death or at least 1 community assessment in the 12 months after hospital discharge. Prestroke, stroke, and demographic variables are summarized in Table 1.

| Table 1. Prestroke, Stroke, and Demographic Variables |
|---------------------------------|--------------|
| **Prestroke and demographic variables** | **Age, y mean (SD)** 74.4 (12.0) |
|                                | **Prestroke FIM, median (IQR)** 124 (119, 126) |
|                                | **Female, n (%)** 96 (53) |
|                                | **Previously living at home, n (%)** 173 (95.6) |
|                                | **European ethnicity, n (%)** 148 (81.8) |

<table>
<thead>
<tr>
<th>Stroke variables</th>
<th><strong>Initial FIM, median (IQR)</strong> 62 (24.96)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of stroke</td>
<td><strong>LACI</strong> 54 (29.8)</td>
</tr>
<tr>
<td></td>
<td><strong>PACI</strong> 51 (28.2)</td>
</tr>
<tr>
<td></td>
<td><strong>TACI</strong> 33 (18.2)</td>
</tr>
<tr>
<td></td>
<td><strong>POCI</strong> 18 (9.9)</td>
</tr>
<tr>
<td></td>
<td><strong>PICH</strong> 18 (9.9)</td>
</tr>
<tr>
<td></td>
<td><strong>Unclassified</strong> 7 (3.9)</td>
</tr>
<tr>
<td></td>
<td><strong>Transferred to rehabilitation ward during inpatient stay, n (%)</strong> 90 (49.7)</td>
</tr>
<tr>
<td></td>
<td><strong>Total hospital length of stay, median (IQR)</strong> 21 (8.47)</td>
</tr>
<tr>
<td></td>
<td><strong>Hospital mortality, n (%)</strong> 35 (19)</td>
</tr>
</tbody>
</table>

FIM indicates functional independence measure; IQR, interquartile range; LAC, lacunar infarct; PACI, partial anterior circulation infarct; TACI, total anterior circulation infarct; POCI, posterior circulation infarct; and PICh, primary intracerebral hemorrhage.
TABLE 2. Final Regression Model for Discharge FIM

<table>
<thead>
<tr>
<th>Variable</th>
<th>Parameter Estimate (95% CI)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.22 (-0.47 to 0.03)</td>
<td>0.09</td>
</tr>
<tr>
<td>Initial FIM</td>
<td>0.80 (0.72 to 0.88)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Prestroke FIM</td>
<td>0.43 (0.21 to 0.64)</td>
<td>0.0001</td>
</tr>
<tr>
<td>European</td>
<td>-6.7 (-14.1 to 0.66)</td>
<td>0.07</td>
</tr>
<tr>
<td>MDT recorded</td>
<td>17.2 (11 to 23.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>RCPSAP Sum total</td>
<td>0.18 (-0.06 to 0.41)</td>
<td>0.15</td>
</tr>
</tbody>
</table>

\( R^2 = 77.5\% \)

FIM indicates functional independence measure; Discharge FIM, last FIM measure before discharge from hospital; MDT recorded, multidisciplinary team meeting recorded; and RCPSAP Sum, Royal College of Physicians Stroke Audit Package Summary score.

Comparing Results for Process and Outcome

Comparison of findings was made in 3 ways: (1) univariate analysis calculating correlations between process and outcome variables, (2) multivariate analysis of process and nonprocess variables against various outcomes, and (3) comparison of the 3 hospitals in the study in terms of process and case mix–adjusted outcome.

Univariate Analysis

There was no significant relationship between RCPSAP Sum and discharge FIM, poor discharge outcome, or the physical or mental component summary scale of the SF-36. However, there was a significant difference in RCPSAP Sum between nonsurvivors (mean, 57.1; 95% CI, 52.9 to 61.4) and survivors (mean, 64.1; 95% CI, 62.0 to 66.1) at hospital discharge \((P=0.004)\). When the MRS is expressed as a binary variable (0 to 2 versus 3 to 5), subjects with the worst functional outcome (MRS, 3 to 5) had better process scores than those with a better functional outcome (mean RCPSAP Sum, 66.5 [95% CI, 63.3 to 69.7] versus 60.9 [95% CI, 57.4 to 64.4]; \( P=0.02 \)).

Regression

The first response variable modeled was discharge FIM. The following potential explanatory variables were entered into the model: age, sex, prestroke FIM, initial poststroke FIM, European ethnicity, total anterior circulation infarct versus other types of stroke, RCPSAP Sum, clinical formulation, MDT, CT recorded, and swallow. With the use of a stepwise procedure with \( P=0.1 \) to enter and \( P=0.15 \) to leave the model, the final model presented in Table 2 is derived: older age and being European were associated with a lower FIM score at discharge. Higher initial FIM and prestroke FIM, having an MDT recorded, and higher RCPSAP Sum were associated with higher FIM at discharge. The \( R^2 \) for this model was 77.5%, and normality assumptions were met.

The first logistic regression model used the 5 process variables to predict the poor discharge outcome variable through a backward selection procedure, with \( P=0.1 \) for staying in the model. The 2 variables that remained associated with poor discharge outcome were CT not recorded (odds ratio [OR], 2.07; 95% CI, 0.93 to 4.62; \( P=0.08 \)) and swallow assessment not recorded (OR, 2.48; 95% CI, 1.10 to 5.61; \( P=0.03 \)).

The second model used the 4 case mix variables found to be significant in the regression model outlined above (age, initial FIM, prestroke FIM, and being European) to see whether, after adjustment for these variables, the 2 process measures identified above still predicted a poor discharge outcome. Again, a backward selection process was used, with \( P=0.1 \) for staying in the model. The variables remaining in the model are described in Table 3: a higher prestroke and initial FIM were associated with a lower probability of poor discharge outcome, whereas being European and having no swallowing recorded were associated with a higher probability of poor discharge outcome. The model fitting test ( Hosmer and Lemeshow test) was not significant, with a \( \chi^2 \) of 5 on 8 df \((P=0.76)\).

Response variables at 12 months after hospital discharge (MRS >2, physical component summary score of the SF-36) were also modeled in a similar fashion, and the process variables were found to have no explanatory power when combined with case mix variables.

Comparing Hospitals

One way to investigate assumptions behind the “league table” approach is to test the hypothesis that hospitals with the best process scores also have the best outcomes. The results for the process variables and selected case mix–adjusted outcomes are presented in Table 4. Case mix–adjusted outcomes were calculated from regression equations as described above with dummy variables used to separate the 3 hospitals. On ranking, hospital 1 had the poorest scores on the process variables but highest scores on outcomes, and hospital 2 had the highest mean RCPSAP Sum score but the poorest outcomes.

Discussion

The results presented here contribute to thinking and debate about how best to monitor and improve performance in hospital stroke care. We were able to establish a relationship between some process variables and outcomes, but the relationships were generally weak. On univariate analysis, RCPSAP Sum scores were significantly higher in survivors to hospital discharge. Higher RCPSAP Sum score and having an MDT meeting recorded were associated with higher discharge FIM scores in a regression model. Not having a swallow assessment recorded was associated with poor discharge outcome in a multiple logistic regression model. On the other hand, people with poorer functional outcomes at 12 months (MRS >2) had significantly higher RCPSAP Sum...
scores on univariate analysis, and none of the process variables remained in regression models of functional outcomes at 12 months. Also, the hospital with the best process scores had the worst case mix–adjusted outcomes.

This was a small, observational study, and some caution is required when the results are considered. First, the study sample did not include all patients with stroke admitted during the study period. Case note review showed that 77% of all eligible stroke subjects were enrolled. Those not enrolled were mainly patients with minimal disability who were discharged early or those with very severe strokes, some of whom died soon after admission. Nevertheless, hospital mortality, proportions of subjects with each stroke type, and initial disability were similar to comparable studies in the United Kingdom, Australia, and New Zealand, and the sample may be considered generally representative of stroke patients admitted to hospital in these countries. Second, the assessment of process was not blinded, so there was a possibility of expectation bias on the part of the single reviewer who would have had the opportunity to be aware of inpatient outcome during case note review. Third, none of the 3 hospitals in the study had a stroke unit. It could be argued that the issue of improving aspects of the process of care should apply only once a stroke unit is in place. All the hospitals in this study offered general rehabilitation wards, generally geriatric rehabilitation without a specific focus on stroke, and 50% of all patients were transferred to these wards. The Stroke Unit Trialists’ Collaboration systematic review was unable to determine an extra benefit for stroke units over generic rehabilitation wards in terms of outcome after stroke. Selection bias may be responsible for the association in our results between higher RCPSAP Sum scores and survival. Higher RCPSAP Sum scores (and having an MDT meeting) were also associated with transfer for rehabilitation. In these hospitals, patients thought likely to die are not transferred for rehabilitation. Fourth, our choice of case mix variables could be criticized because they were not externally validated. However, the final models are similar to a recently published study, we repeated the measurement of process measure. The RCPSAP is predominantly a measure of acute care. It covers issues such as whether blood pressure is recorded, whether an ECG is in the medical notes. It does not cover issues such as management of fever, elevated blood pressure, or early mobilization or what many of the (nonmedical) members of a multidisciplinary stroke team actually do. In scoring the

The Scottish Stroke Outcomes Group described variations in care fatality after stroke at 5 hospitals in Scotland. They were able to show that most of that variation was likely due to differences in case mix. However, 1 hospital in that study had significantly higher case fatality after adjustment for case mix. The authors surmise that the differences in stroke process that were recorded (in particular, no specialized and organized stroke care, many fewer CT head scans, and lowest overall process scores) may have been responsible and suggest that the quality of care at this hospital was deficient. They measured process using the RCPSAP and some other items such as whether the patient was admitted to a stroke rehabilitation unit. Their “compliance per record” factor, which varied between a median of 53 and 79 among the 5 hospitals, is very similar to our RCPSAP Sum variable, which varied between a median of 60 and 67 among our 3 hospitals. Put another way, if the worst hospital in the Scottish study is excluded, no difference in case mix–adjusted outcome is observed from the remaining 4 hospitals with large variations in process, e.g., a compliance per record factor range from 62 to 79, a 2-fold difference in admission rates to a stroke rehabilitation unit, and a 2.5-fold difference in the number of patients discharged from the care of a stroke consultant. In an unpublished study, we repeated the measurement of process and outcome in a further cohort of consecutive stroke patients, but despite a statistically significant increase in RCPSAP Sum scores to a mean 77.2, no difference in mortality or functional end points was measurable after adjustment for case mix. In the present study, the numbers of patients at each hospital were small; thus, the power to detect even sizeable differences in treatment effect would be small.

At least part of the difficulty in determining the true relationship between process and outcome may relate to the specific process measure. The RCPSAP is predominantly a measure of medical documentation, focusing heavily on acute care. It covers issues such as whether blood pressure is recorded, whether an examination for visuoperceptual deficit is documented, and whether an ECG is in the medical notes. It does not cover issues that may be directly relevant to the efficacy of inpatient stroke care such as management of fever, elevated blood pressure, or early mobilization or what many of the (nonmedical) members of a multidisciplinary stroke team actually do. In scoring the
RCPSAP, we used simple summation, rating each item as being of equal importance. A similar approach has been taken by others.6 We tested different ways of weighting individual items and groups of items of the RCPSAP but did not find any significant differences in the overall results obtained. Nevertheless, Table 4 shows that similar RCPSAP Sum scores can hide sizeable differences in individual process components between different hospitals. The Intercollegiate Stroke Audit Package20 has been developed since we undertook this study and may supplant the RCPSAP as the standard for quantitative audit of the process of stroke care. An alternative approach is that of Hoenig and colleagues,21 who have attempted to define the key characteristics of stroke rehabilitation services, aiming to relate these prospectively to differences in outcome. Holloway and colleagues22 have provided a series of performance measures in acute stroke care based on consensus of experts.

Evans and colleagues7 have presented the most compelling data to date to support the contention that better process of care is associated with better outcomes. They prospectively and comprehensively measured aspects of stroke care, including assessment and treatment in the first week, rehabilitation interventions, and secondary prevention. Many of these items are in common with those in the RCPSAP. Significant factors in multivariate analyses with good functional outcome as the end point (MRS < 4) were stroke unit management, early feeding, prevention measures for aspiration, stroke progression, chest infection, and dehydration. What constituted prevention measures was not specified. Attempts were made to reduce bias in this unblinded assessment by using 2 observers. Ultimately, however, the various prevention measures are likely to have been strongly associated with stroke unit care, which was the primary intervention. We do not know whether improving these aspects of stroke process instead of, or in addition to, providing stroke unit care improves results.

We believe that the currently available evidence does not provide an evidenced-based rationale for limiting the focus to intermediate intervention. We tested different ways of weighting individual items of equal importance. A similar approach has been taken by Hoenig and colleagues21 in trying to define the components of care at different levels of organization might also allow future research to test the relationship between different levels of organization and stroke outcomes.

In the meantime, despite the many difficulties involved, direct measurement of outcome, including mortality and functional end points, ensures measurement of the variables of interest rather than a reliance on assumptions of process measures as a proxy for outcome. Further refinement of case mix–adjustment systems is required both for interservice comparisons and for comparison of a single service at different time points if direct outcome measurement is to become the standard for quality assessment of stroke services.

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