$12,422/QALY. Sensitivity analyses showed that a 6.5% difference in case-fatality rates between low- and high-volume hospitals (base case 15%) or a risk of death during transfer of 11% (base case 3%) was required to increase the cost to $50,000/QALY, a level of borderline cost-effectiveness. Conclusions: Transfer of patients with SAH from low- to high-volume hospitals appears to be cost-effective. Regionalization remains cost-effective even with only a small difference in outcomes between low- and high-volume hospitals. However, current estimates of the impact of hospital volume on outcome are based solely on studies of administrative data and require confirmation in more detailed cohort studies.

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Development of the Stroke-Specific Quality of Life (SS-QOL) Scale: Item and Domain Reduction

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Background/Purpose: The SS-QOL is a previously validated stroke scale with 49 items in 12 patient-derived domains of health-related quality of life (HRQL). The aim of this research was to reduce the number of items and domains of the SS-QOL while retaining optimal measurement properties. Methods: 250 ischemic stroke survivors from two hospitals with no severe language or cognitive barriers completed the SS-QOL and other stroke outcome scales. Items were removed based on phrasing, ceiling/floor effects, item convergent and discriminant validity, and scale reliability. Domains were collapsed based on domain-level correlations, and items were reassigned to new domains based on item-scale correlations. The psychometric properties of the reduced SS-QOL were evaluated using exploratory and confirmatory factor analysis and by examining scaling success rates and scale reliability. Results: 14 items were eliminated: phrasing (k=2), ceiling/floor (k=2), internal consistency (k=1), and discriminant validity (k=9), resulting in 35 retained items. The 12 domains were reduced to 7 domains. Three new domains were developed: 1) Physical Function, 10 items retained from self care, mobility, work, and upper extremity domains; 2) Mood, 5 items retained from mood, personality, and family role domains; and 3) Role Function, 4 items retained from social and family role domains. Four original domains (Vision, Language, Thinking, and Energy) were retained with minor modifications. All domains were unidimensional and had correlations to other domains $<$ 0.6 except for mood and role function (0.64). Internal reliability ranged from 0.77 to 0.88, and $<$ 15% of the sample were at the ceiling or floor in all domains. Domain scores were significantly higher in those with better Rankin scores and perceived general health. Conclusions: The 35-item, 7-domain version of the SS-QOL demonstrates good reliability and validity in this sample. The underlying scale structure supports the concept of the SS-QOL as a measure tapping stroke-specific HRQL and the use of the individual scale scores. Further work testing the SS-QOL in additional clinical trials and patient populations is ongoing.

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Risk Adjustment Uncovers Greater Treatment Effect in NINDS tPA Trial

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Background: The ischemic stroke population is very heterogeneous. Even with balanced randomized trials, patient heterogeneity biases estimates of treatment effects for dichotomous endpoints toward no effect. Risk adjustment statistically addresses some of the heterogeneity and can substantially reduce bias in the estimate of treatment effect. Objective: To estimate the treatment effect of tPA in the NINDS tPA dataset with and without correction for patient variation known to be related to outcome (risk adjustment). Methods: Using a previously developed and validated clinical predictive model, we recalculated unadjusted and risk adjusted odds ratios (and 95% confidence intervals (CI)) for favorable outcome for the Barthel Index (BI) for 604 patients in the NINDS tPA stroke trial. Nine patients were excluded due to missing values. Receiver operating characteristic (ROC) curves were used to assess the ability of treatment alone and then treatment and the risk adjustment variable to discriminate favorable from unfavorable outcome. An area under the ROC curve of $>$ or $=$ 0.8 was prespecified as very good predictive capability. Results: The unadjusted odds ratio for the treatment effect on BI was 1.7; CI (1.2–2.4). The risk adjusted treatment effect was 2.0; CI (1.4–2.9). The model using treatment alone to predict outcome had an area under the ROC curve of 0.57. The model using treatment plus the single risk adjustment variable had an area under the ROC curve of 0.80. Analyses for favorable outcome as measured by the National Institutes of Health Stroke Scale (NIHSS) and the Glasgow Outcome Scale (GOS) produced similar results. Conclusions: Using an externally developed and validated predictive model, the risk adjusted estimate of the treatment effect in the NINDS tPA data set is greater than originally reported. The use of risk adjustment methodologies in design and analysis of stroke clinical trials could increase power to detect the true effect of a new therapy.

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What Is the Outcome in Patients Not Given tPA Because of a Low NIHSS Score?

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PURPOSE: To describe the impact on quality of life (QoL) and functional outcome of acute ischemic stroke (AIS) in patients excluded from recombinant tissue plasminogen activator (tPA) treatment because of a low National Institute of Health Stroke Scale (NIHSS) score. BACKGROUND: Although the NINDS tPA trial included all patients with neurological deficits on the NIHSS, experts have suggested that tPA be restricted to only those with significant deficit. Recently we have shown that subjects with mild strokes (NIHSS $<$5) often have measurable cognitive impairment and diminished QoL. This study describes the outcome of patients excluded from tPA use because of low NIHSS score. METHODS: Subjects: A stroke registry was screened to find subjects excluded from tPA use because of low NIHSS scores. Of 655 patients assessed from Sept 2001 to May 2002, 83 patients were excluded for low NIHSS score. Of 41 patients eligible for 6 month f/u 24 patients were interviewed. Procedure: Stroke fellows obtained NIHSS scores at the time of evaluation. F/u was obtained by phone interview which included the FIM, FAM, SF12, SA-SIP, and Reintegration to Normal Living (RNL) scales. The human studies committee approved this study. Analysis: Means scores were obtained on all assessments. Correlations were made between impairment and QoL measurements. RESULTS: At f/u the following mean score were reported: FAM 80.55 with maximum possible score (MPS) of 84, FIM-ADL 86.22 with MPS of 91, FIM-Cognitive 33.63 with MPS of 35, SA-SIP 8.55 with MPS of 30, RNL 47.55 with MPS of 55. Overall, the group was independent in ADL/IADL. For individual FAM items 30% reported emotional lability, 29% reported difficulty driving, 30% reported negative impact on work/volunteer activity, 28% reported decreased reading and writing ability. IADL impairments were associated with decreased life satisfaction (r=0.47), and stroke related quality of life (r=-0.70). Decreased activity was associated with cognitive impairment(r=0.41). CONCLUSIONS: Stroke patients excluded for tPA use because of mild symptoms show measurable and persistent impact of the stroke. The benefit of tPA use for this group is unclear since the NINDS trial did not assess QoL.