Time Spent at Home Poststroke

"Home-Time" a Meaningful and Robust Outcome Measure for Stroke Trials

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Background and Purpose—Stroke outcome assessment requires some measure of functional recovery. Several instruments are in common use but all have recognized limitations. We examined duration of stay in the patient's own home over the first 90 days since stroke—"home-time"—as an alternative outcome likely to show graded response with improved reliability.

Methods—We examined prospectively collected data from the GAIN International trial using analysis of variance with Bonferroni contrasts of adjacent modified Rankin scale score categories.

Results—We had full outcome data from 1717 of 1788 patients. Increasing home-time was associated with improved modified Rankin scale scores ($P<0.0001$). The relationship held across all modified Rankin scale grades except 4 to 5.

Conclusions—Home-time offers a robust, useful, and easily validated outcome measure for stroke, particularly across better recovery levels. **(*Stroke*. 2008;39:231-233.)**

Key Words: cerebrovascular accident ■ health economics ■ modified Rankin scale score ■ outcome assessment ■ stroke treatment

Accurate assessment of poststroke recovery is essential for clinical and trial work. Several tools exist to quantify functional outcome. Instruments in common use include the modified Rankin scale (mRS), National Institutes of Health Stroke Scale (NIHSS), and the Barthel Index (BI).[1] Each of these scales exhibits features that limit their use in clinical practice. In brief, mRS suffers considerable interobserver variability,[1] BI differentiates disability at extremes of outcomes poorly,[2] and validity of NIHSS as a measure of functional recovery is questioned.[3] Efforts to correct these limitations have been only partially successful. For example, using standardized questioning[4] reduces but does not abolish variability of mRS and does so at the expense of increased complexity and time.

The ideal outcome measure would be simple to understand and apply with acceptable validity, variability, and responsiveness. To date, no stroke outcome measure adequately meets these criteria. Creation of a novel instrument is unlikely to achieve immediate widespread acceptance. An alternative is to derive surrogate outcome measures from routinely collected patient data. For example, duration of inpatient stay lends itself to health economic analysis because inpatient days account for much of the expenditure associated with stroke.[5] Inpatient stay is less valid as a measure of functional outcome because early mortality and transfer to a long-term care setting after severe stroke are each associated with shorter stay.

We hypothesized that duration living independently in the community could serve as an appropriate outcome measure less likely to be confounded by survival issues. To explore this, we measured duration of stay in the patient's own home poststroke—"home-time"—from a comprehensive, prospectively gathered stroke outcomes database.

Materials

We extracted and analyzed data from the multicenter, randomized, controlled trial of the candidate neuroprotectant gavestinel—GAIN International.[6]

Resource use data were collected at 90 (±7) days. Data were available for mRS, NIHSS, BI, and duration of hospitalization or nonhospital placement. Data on placement were from interviews with the patients or proxies. From the nonhospital placement subset, we extracted data on length of time spent in own home or relative's home—"home-time." Resource use was censored at 90 days. Where final follow-up occurred early, last known placement was extrapolated to 90 days. Patients with unknown dates of placement were excluded from the analysis.

For this preliminary analysis, we used one-way analysis of variance to assess home-time trends for mRS, NIHSS, and BI comparing adjacent categories by Bonferroni testing. We used analysis of variance for subanalysis of home-time by country. Analyses were performed using StatsDirect statistical software version 2.4.5 (StatsDirect Ltd, Cheshire, UK).

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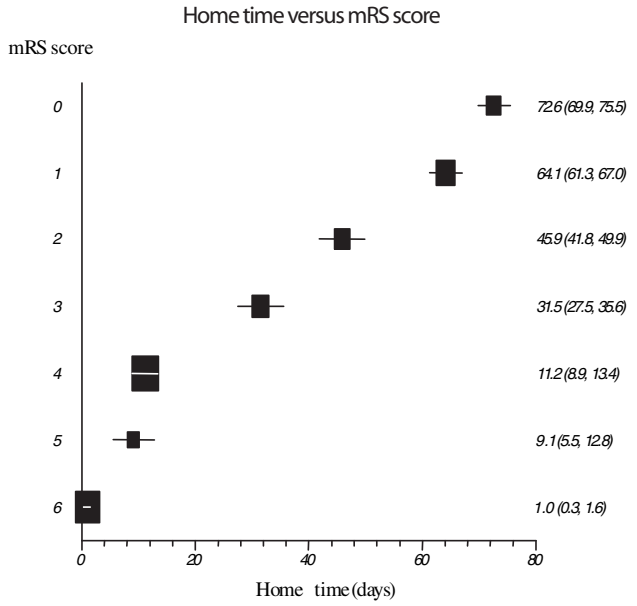

Figure. Forest plot of mean 90-day home-time ±95 CIs versus mRS. N=1717 (of which mRS 0=197; mRS 1=268; mRS 2=205; mRS 3=214; mRS 4=366; mRS 5=143; mRS 6 (death)=324. $P<0.0001$ comparing adjacent categories except mRS 4 to 5 ($P=0.37$) and mRS 5 to 6 ($P=0.0003$).

Results

Full outcome data were available for 1717 of 1788 intent to treat patients. Data were incomplete for 15 patients and 56 withdrew from the study before 90 days. Mean age was 69.7 (±12.2) years, 737 (42.9%) were female, 321 (18.7%) had intracranial hemorrhages, and mean NIHSS score was 13.1 (±6.2).

Mean time in the hospital was 28 days and mean home-time was 31 days. Home-time was significantly associated with changes across mRS ($P<0.0001$), NIHSS ($P<0.0001$), and BI ($P<0.0001$). On analysis of between-category differences, home-time was significantly associated with change across all mRS categories except mRS 4 to 5 (Figure).

Analysis of NIHSS and home-time revealed a significant association with NIHSS categories 0 to 1 ($P<0.0001$), 1 to 2 ($P<0.0017$), 2 to 3 ($P<0.0013$), and 4 to 5 ($P<0.0001$).

Home-time was significantly associated with change across BI categories 100 to 95 ($P<0.0001$) and 95 to 90 ($P<0.0001$). Change across all other categories of NIHSS and BI were nonsignificant.

There were significant differences in home-time between the countries studied ($P<0.0001$). Within all countries, the relationship between home-time and mRS held.

Discussion

We have shown that home-time has a significant association with poststroke disability as measured by mRS, particularly across better recovery levels. Although intuitive, this relationship has not been demonstrated previously. mRS is the preferred outcome measure in acute stroke trials[7] and, as such, our findings provide strong evidence of the validity of home-time as a potential outcome measure.

Home-time has potential advantages over mRS in application and interpretation. Interobserver variability limits use of mRS.[1] An objective measure such as home-time should give near-perfect reliability and would not require formal training. The continuous nature of home-time lends itself to more powerful statistical techniques than traditional dichotomized or ordinal outcome measures.[8] Home-time is generalizable and could be applied to any potentially disabling condition.

A further strength of home-time is its immediacy. Discussion of possible treatment benefit is essential for informed consent. The abstract outcome measures used in trials make this already challenging task more difficult. Home-time offers an outcome measure that should be easily understood by the lay public and other medical professionals.

Association of home-time with NIHSS and BI was less convincing. We do not interpret this as a failing of home-time; rather, home-time accentuates the limitations of NIHSS and BI. "Floor and ceiling" effects of the BI are well recognized.[2] NIHSS measures physical impairment, not taking into account the ability to compensate for functional deficit; thus, it is likely to be responsive to change at extremes of outcome only. Home-time change across grades was significant only at the lower end of these scales.

Patients in the GAIN study were broadly representative of a clinical trial population. However, all patients in GAIN were independent at baseline. Home-time may be less valid as an outcome measure if applied to a more disabled population such as seen in routine clinical practice; however, for trials, premorbid residence at home could be an objective entry criterion.

Rehabilitation is often necessary poststroke, reducing short-term home-time to achieve longer-term improved outcomes. As such, a 90-day cutoff is most appropriate for home-time analysis. It is unlikely that meaningful inpatient rehabilitation will continue past 90 days. Ninety-day outcome assessment has become standard in clinical trials and so ascertainment of home-time would not necessitate changes to study protocols.

We do not claim home-time to be the perfect measure of outcome; it is prone to many of the same limitations as other accepted outcome scales. By measuring home-time at specific cutoffs, data may be biased by "early" and "late" responders, ie, those patients whose recovery time from disabling stroke is substantially longer or shorter than average. Although important at the individual patient level, such influences are less important in the context of large multicenter trials and it is in this area that we propose the use of the home-time instrument.

We assume that increasing home-time is a positive outcome because return home is desired by patients and will reduce total costs. Home-time makes no measure of level of care required to facilitate discharge; a large package of care may allow return home but at substantial economic expense. Potential for provision of care by state or family will vary between centers in an international trial. Subanalysis confirms the expected differences in home-time among countries. Although a potential limitation, the influence of country and culture is not unique to home-time; significant differences across countries are also seen for mRS, NIHSS, and BI in the

GAIN data set.[6] The persistence of differences in home-time between mRS categories, even in those countries with high or low average home-times, offers some reassurance of its validity as an outcome measure. Other factors external to the patient such as marital status, dependents, and healthcare insurance may influence home-time, but such data are not routinely collected and so appropriate analysis could not be performed.

Despite its plausibility, we recognize that the potential use of home-time needs to be confirmed. We have derived home-time retrospectively from previous trial data and thus can make no assessment of its use in real-time clinical practice. However, GAIN was a typical, multicenter, intention-to-treat trial and, as such, we assume that our findings would hold for future trials. Rather than replace established instruments, home-time could complement other trial end points. Integration with other scales could generate a powerful global outcome statistic.[9] It would be of interest to examine home-time in existing trial data sets of thrombolysis or hemostasis.

In summary, home-time assessment offers robust, objective, easily communicated information on stroke outcomes. We encourage trialists to measure home-time and consider its inclusion as a clinical end point.

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Disclosures

K.R.L. was international principal investigator for the GAIN International trial. He has published data in support of mRS as the optimal end point for acute stroke trials. He has received fees, expenses, and institutional grants relating to these and other trials from GlaxoSmithKline, AstraZeneca, and several other pharmaceutical companies that have been or are developing treatments for stroke. K.R.L., M.W., J.D., and T.J.Q. have applied for academic grant support to continue work on developing stroke outcome assessments using mRS.

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