of events. Results of both the main study and the subanalysis are promising. However, there are some potential shortcomings in this study, including the fact that the warfarin arm was not blinded. Results of the subgroup analysis were consistent with the findings of the overall patient cohort; however, the subgroup was too small to demonstrate a statistically significant superiority of the higher dabigatran dose over warfarin, as demonstrated in the overall RE-LY cohort. Further evaluations of the long-term safety and efficacy data from RE-LY data are needed to determine the optimal choice of the dabigatran dose for patients with prior TIA or stroke of treatment with dabigatran.

Figure 1. Stroke/SSE All Patients.

Connolly SJ et al. *N Engl J Med* 2009.
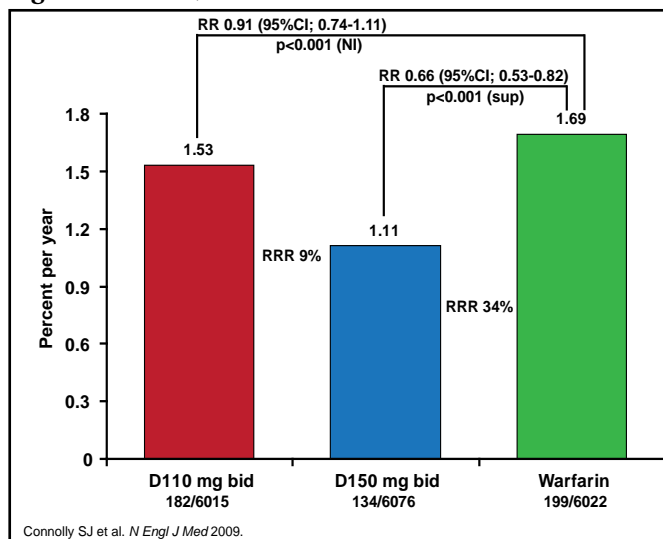
Reproduced with permission from H.C. Diener, MD.

Figure 2. Stroke/SSE Patients with Prior Stroke or TIA.

Connolly SJ et al. *N Engl J Med* 2009.
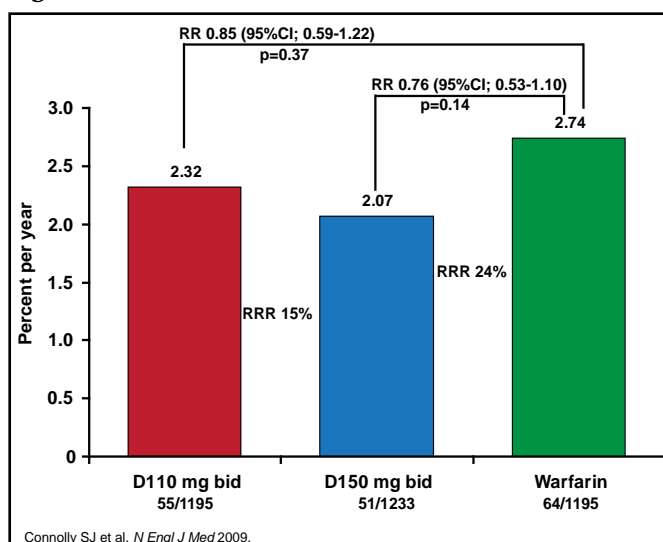
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Randomized Trial of Robot-Assisted Rehabilitation for Chronic Stroke

Robot-assisted therapy (RT) and intensive comparison treatment (ICT), structured to match that of RT with regard to number of sessions, type, and intensity of movement, were superior to customary chronic poststroke care (usual care – UC) for the treatment of chronic stroke that affected the upper extremities. Extremity function greatly affects the overall outcome of chronic stroke; therefore, improvement of extremity function is a critical aim of rehabilitation [Olsen TS et al. *Stroke* 1990]. Albert Lo, MD, PhD, Providence VA Medical Center, Providence, RI, discussed the use of novel RT as a rehabilitation strategy to improve functionality and quality of life in patients ≥6 months poststroke.

In this study by Lo and colleagues, patients with an index stroke that occurred at least 6 months prior to enrollment (mean time since stroke 4.7 years), resulting in moderate to severe upper extremity impairment as measured by Fugl-Meyer score of 7 to 38 (out of a possible 66 points), were randomized to receive RT (n=49), ICT (n=50), or UC (n=28) for 36 sessions over a 12-week period. Patients who experienced multiple strokes (33%) were also included in this study, provided the index stroke was ≥6 months prior to enrollment. There was no significant difference in baseline characteristics across the groups. RT entailed using a 4-module robotic system, which included a vertical, horizontal, hand, and wrist unit, and produced >1000 intensive movements per session. ICT was equivalent to the RT model (also producing >1000 intensive movements/session), and UC utilized conventional methods, such as a 5-foot pole with a sliding base, a hand odometer, and a horizontal "hand skate."

Evaluations were performed at Weeks 6, 12, 24, and 36. The primary endpoints were motor capacity, as assessed by Fugl-Meyer score, and safety, as determined by spasticity (using modified Ashworth) and pain (using a numerical scale) immediately following the completion of therapy at 12 weeks. Secondary endpoints were the difference in Wolf Motor Function Test and Stroke Impact Scale (composite of hand, mobility, activities of daily life tasks, and participation) over 36 weeks (including treatment and 6 months of follow-up).

There was no significant difference in Fugl-Meyer score between RT and ICT or UC at 12 weeks. However, at 36 weeks, 12 weeks posttreatment, a mean point difference of +2.88 in Fugl-Meyer score was observed in RT patients versus UC (p=0.016). Additionally, the mean change in

Wolf Motor Function for RT versus UC was statistically significant at 36 weeks (p=0.005), though no other significant changes in Wolf Motor Function were noted at either 12 or 36 weeks. RT demonstrated significant improvement in Stroke Impact Scale at 12 weeks (p=0.009) and 36 weeks (p=0.04) compared with UC. There was no difference between RT and ICT for any outcome.

There were no treatment-related serious adverse events (AEs) that were observed. However, there were some treatment-related AEs that were associated with RT (12%) and ICT (9%) that were considered transient and mild (Table 1). None of these events occurred in the UC group.

Table 1. Number of Patients Experiencing Treatment-Related AEs (Not Serious).

Treatment-Related AE	RT	ICT	UC
Pain, Stiffness, Soreness	23	7	0
Fatigue	6	0	0
Cut, Scratch, Swell, Bruise	3	5	0
Numbness	2	0	0

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Outcomes were better for RT and ICT than UC over the 36-week evaluation period despite the high severity, chronicity, and incidence of multiple strokes in this patient population. Additionally, RT and ICT curtailed the use of additional health services over time, resulting in overall costs that were similar to those that were associated with UC. This study has shown that high-intensity repetition of movement can improve quality of life and extremity functionality in individuals with stroke-related impairment, concluded Dr. Lo. RT is a safe and effective rehabilitation strategy that merits further investigation.

Improvement in In-Hospital Clinical Outcomes for Ischemic Stroke 2003-2009: Findings from Get With The Guidelines-Stroke

There are many factors that contribute to the increased length of stay and the high morbidity and mortality rates that are associated with acute ischemic stroke. Get With The Guidelines (GWTG)-Stroke, a stroke registry component of a continuous evidence-driven performance improvement program that includes a web-based patient management tool to provide clinical decision-making support, reporting,

and patient education elements, was developed to track, measure, and improve the quality of care and outcomes for patients with acute stroke or transient ischemic attack (TIA) in the United States. Recently, GWTG-Stroke data from the first one million stroke and TIA patients demonstrated that quality of care improved significantly from 2003 to 2009 [Fonarow GC et al. *Circulation Cardiovasc Qual Outcomes* 2010]. Lee H. Schwamm, MD, Massachusetts General Hospital, Boston, MA, presented a subset of these findings, including only patients with acute ischemic stroke.

A total of 1392 hospitals participated in GWTG-Stroke, with 601,599 patients admitted for ischemic stroke. Of these 1392 hospitals, 301 were considered core hospitals, defined as participating since 2004. There were 287,477 ischemic stroke patients who were admitted to core hospitals. Analysis was performed on the subset of 601,599 patients from all hospitals and on the subset of 287,477 patients who were admitted to participating core hospitals. The median age was 73 years. Fifty-two percent was female, and 73% was Caucasian. Comorbidities included atrial fibrillation (19%), coronary artery disease/prior myocardial infarction (29%), diabetes mellitus (32%), hypertension (79%), and smoking (20%). The primary outcomes were percentage of patients with lengths of stay (LOS) >4 days, which was the median LOS for the entire cohort, percentage that was discharged to the home with or without services, and percentage of in-hospital deaths.

In the large cohort that included all participating hospitals, mortality and LOS decreased significantly between 2003 and 2009 (p<0.001 for both). There was an increasing trend in the rate of patient discharge to the home (p<0.001) as well (Table 1). However, no significant difference in NIH Stroke Scale was observed over time. The subset of core hospitals demonstrated similar results with regard to mortality, LOS, and discharge home (p<0.001 for all). After adjusting for patient characteristics, such as age, gender, comorbidities, hospital arrival mode, and time of presentation (on vs off hours), and hospital characteristics, such as region, number of beds, annual stroke volume, and teaching versus nonteaching hospital, the core hospitals still demonstrated improvement with regard to mortality (p=0.006), LOS (p<0.001), and discharge home (p=0.309) over the 6-year period.

Overall, hospitals that participated in GWTG-Stroke demonstrated substantial reductions in LOS and in-hospital mortality in patients with acute ischemic stroke, even after adjusting for patient and hospital characteristics and accounting for hospitals that joined midstudy. Results from GWTG-Stroke are quite promising. However,