Minimally Invasive Surgery for Intracerebral and Intraventricular Hemorrhage

Rationale, Review of Existing Data and Emerging Technologies

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Spontaneous intracerebral hemorrhage (ICH) is the most common type of hemorrhagic stroke, ≈4 times more common than subarachnoid hemorrhage and accounting for 15% of all strokes.1 ICH is associated with higher rates of morbidity and mortality than all stroke subtypes. Overall, mortality rates for ICH are estimated to be as high as 40% to 50%, with the vast majority of survivors disabled at 6 months. When ICH is associated with intraventricular hemorrhage (IVH), outcomes are even worse, with estimated rates of mortality between 50% and 80%.1

Current standards recommend that patients with cerebellar hemorrhages measuring >3 cm with associated neurologic deterioration or significant mass effect be managed with emergency surgical decompression. Similarly, patients with supratentorial hemorrhage and impending herniation are frequently taken for surgical decompression with or without hematoma evacuation. ICH patients who do not fall into either of these 2 categories are, in the vast majority of cases, managed medically.2

With the exception of aggressive blood pressure normalization, no medical therapy has been shown to improve outcomes or reduce mortality in patients with ICH.2 In the absence of clinical evidence to guide therapy, many aspects of medical management are based on local practice patterns with significant variations between institutions.

Mechanisms of Injury in ICH

Spontaneous supratentorial ICH may be divided into 2 general categories based on anatomic location—deep (involving the deep gray matter nuclei) or lobar. Deep hemorrhages are generally caused by hypertension, whereas lobar hemorrhages are often caused by either hypertension or amyloid angiopathy.3 Either type of hemorrhage may be caused or exacerbated by an inherent or pharmacologically induced coagulopathy.1

Brain injury caused by spontaneous ICH is believed to be a biphasic process. The initial hemorrhage dissects through the brain parenchyma, creating a direct traumatic injury to the regional neurons. Although some neurons are irreversibly injured by this process, others in the region are likely compressed, displaced, and only transiently dysfunctional. In the hours after hemorrhage, if the bleeding stops, this regional compression may dissipate and varying degrees of early clinical improvement may be observed.1 Early clinical deterioration is typically related to an extension of the original hemorrhage.4 This early expansion occurs in one quarter to one third of patients.5,6

A second phase of injury manifests as perihematomal edema (both vasogenic and cytotoxic) and occurs in the days following the initial hemorrhage. This perihematomal edema is typically attributed to 2 phenomena. First, it is hypothesized that pressure on the brain adjacent to the hemorrhage limits regional perfusion, causing ischemic injury. Evidence to support this mechanism is somewhat limited. On the contrary, existing positron emission tomographic data suggest that the level of perfusion impairment in the perihematomal region may not be severe enough to generate an infarction.7 Second, preclinical data have indicated that blood degradation products are directly toxic to the brain—that is, the hemotoxicity concept. This hemotoxicity induces edema within the brain adjacent to the hematoma and may result in delayed clinical deterioration with progression of mass effect days after the original hemorrhage.8 This process has been observed as late as 3 weeks after the original hemorrhage.4 Moreover, the edema resulting from ICH has been described to persist for much longer than that associated with acute ischemic stroke, reaching maximum severity between 10 and 20 days.8,9 Thus, these 2 physiological mechanisms of secondary injury may extend the initial mechanical injury, sometimes leading to delayed clinical deterioration. This prolongs recovery and potentially reduces the capacity of the patient to achieve a functional outcome.

Conventional Surgical Evacuation of ICH

The putative benefit of surgery for these patients is based on avoiding or mitigating the secondary wave of injury after ICH. Two large surgical trials have investigated this strategy. The Surgical Trial in Intracerebral Hemorrhage (STICH I) was a multicenter, randomized, controlled trial of 1033 patients with...
favorable outcomes observed in 26% of patients undergoing surgery and 24% of those undergoing medical management. Subsequent subgroup analyses suggested that patients with superficial hemorrhages (those within 1 cm of the cortical surface) potentially benefited from surgical intervention. These outcomes were nearly identical in the surgical and medical management groups, with favorable outcomes observed in 40% of patients in both groups. The failure of conventional surgical management to improve outcomes in neurologically stable patients with spontaneous supratentorial ICH has been attributed to the fact that the surgical approach, in many patients, creates enough trauma to the surrounding brain to negate the benefit of hematoma evacuation. This leaves minimally invasive surgeries (MIS) as the most promising surgical strategy for ICH patients.

MIS Evacuation of ICH

As opposed to open surgical evacuation, no definitive trials evaluating minimally invasive approaches to ICH evacuation have been completed. However, several smaller trials have generated encouraging data. In addition, new technologies are being developed to facilitate the minimally invasive evacuation of intracranial hemorrhage.

Methods of ICH Evacuation

There are 2 general approaches to MIS ICH evacuation—primarily pharmacological catheter–based and primarily mechanical. The first typically involves the placement of a drainage catheter under image guidance, followed by the irrigation of the catheter with a lytic solution to prevent clogging and facilitate passive drainage of the hematoma. This requires the maintenance of an in situ catheter for several days with intermittent imaging to verify a stable catheter position and to monitor the progress of the drainage. Secondarily, mechanical methods for hemorrhage evacuation involve the removal of the hematoma in a single procedure. The evacuation of the hematoma is performed with either an endoscope or exoscope. In some cases, a drainage catheter is left in place after the procedure.

Data Supporting MIS for ICH

Mechanical MIS for ICH

Auer et al reported the results of an early pilot trial of 100 patients randomized between mechanical endoscopic evacuation of ICH and medical management. The surgical goal of this study was to achieve partial evacuation, with most patients achieving 50% to 70% reduction of hematoma volume after the procedure. The study demonstrated the feasibility and general safety of this approach. Lower mortality rates at 6 months were observed in the MIS group (30% with MIS versus 70% with medical management). However, functional outcomes were not observed throughout the entire cohort, in patients with smaller hemorrhages (<50 cm³), functional outcomes were improved after MIS. In addition, no analyzed subgroup in the study performed better with medical management than MIS.

A larger study evaluating a second, primarily mechanical, evacuation method of MIS for ICH was reported by Kim et al. In this trial, 387 patients with small (<30 cm³) basal ganglia or thalamic hematomas were randomized to either MIS using an Archimedes aspirator or to medical management. If a residual hematoma of >10 cm³ was observed after the evacuation, the operator could elect to place a drain and irrigate it with a lytic solution. Patients treated with MIS demonstrated better functional outcomes with lower average modified Rankin scale (mRS) scores at 180 days (1.2 after MIS versus 3.0 after medical management) and higher average Barthel scores (90.9 versus 62.4) at 180 days.

Pharmacologically Based MIS for ICH

Wang et al conducted a randomized, controlled MIS trial in 377 patients with relatively small (25–40 cm³) basal ganglia hematomas. Patients were allocated to undergo either computed tomography (CT)-guided craniopuncture with aspiration followed by 3 to 5 days of lytic infusion or medical management. The MIS resulted in a substantial reduction in dependence at 90 days, which was observed in 40.9% of patients versus 64% of those undergoing medical management (P<0.01). The procedure had no effect on mortality.

The Minimally Invasive Surgery Plus Tissue-Type Plasminogen Activator for ICH Evacuation (MISTIE II) trial was a phase II, randomized, controlled trial which included 123 patients randomized (2:1) between pharmacologically based MIS and medical management. In patients randomized to MIS, catheter irrigation with tissue-type plasminogen activator (tPA) was allowed for ≤4 days. MIS led to a significant reduction in peri-hematoma edema volume at the end of treatment. Moreover, a 14% absolute reduction in the percentage of patients with mRS score >3 was reported for those with 1-year follow-up. Patients undergoing MIS also demonstrated greater gains in mobility and activities of daily living scores on the Stroke Impact Scale, with the majority of improvement seen between 180 and 365 days. Patients undergoing MIS also had a shorter overall length of stay and reduced hospital costs. End of treatment hemorrhage volumes were shown to correlate closely with the clinical status at 180 days.

Meta-Analyses of MIS Trials

Gregson et al presented a meta-analysis of 14 ICH surgical trials including 2186 patients. This analysis included both conventional surgical trials and MIS trials. The authors concluded that there was evidence of benefit for surgery in patients randomized within 8 hours of ictus with hemorrhage volumes between 20 and 50 cm³ and in patients between 50 and 69 years of age. Interestingly, the aggregate data in each of the cohorts demonstrating benefit were heavily influenced by the aforementioned Wang et al data set, which ultimately drove the overall signal. So although most of the open surgical trials did not show a definitive benefit for intervention, the Wang...
et al MIS data set was sufficiently positive to influence the overall conclusion.

Zhou et al compiled a meta-analysis of 12 high-quality trials of MIS for ICH which enrolled 1855 patients collectively. These authors reported a highly significant reduction in the end points of both death and dependence and death alone at the end of study follow-up. They determined that ICH patients with smaller hemorrhages (25–40 cm³) and good presenting clinical status (Glasgow Coma Scale ≥9) were the most likely to benefit from MIS.

Thus, several small to moderate-sized trials of MIS have yielded encouraging results, particularly in patients with smaller hemorrhage volumes involving the basal ganglia and also those with better presenting clinical status. The influence of these data on clinical practice varies worldwide. Although MIS for ICH is a routine clinical procedure in the Far East, with over 150,000 cases being performed per year, it is much less common in North America and Europe. The current American Heart Association guidelines provide a Class IIb, Level of evidence B recommendation for the minimally invasive surgical treatment of ICH.

New MIS Technologies for ICH Evacuation

Several new minimally invasive technologies are being developed specifically for the evacuation of ICH. These technologies are designed to maximize the efficiency of hemorrhage removal through the lowest profile system possible, thus minimizing any injury to adjacent tissue. The 2 most frequently applied technologies are the NICO devices (Indianapolis, IN) and the Apollo System (Penumbra Inc, Alameda, CA).

NICO manufactures 2 devices used for ICH removal (Figure 1)—the Myriad Handpiece and the BrainPath sheath. The NICO Myriad handpiece (NICO Corporation, Indianapolis, IN) is cleared by the United States Food and Drug Administration for the morcellation and removal of tissue during pelviscopic, laparoscopic, percutaneous, and open surgical procedures whenever access to the surgical site is limited. The NICO BrainPath (NICO Corporation, Indianapolis, IN) is cleared by the United States Food and Drug Administration to provide access to and allow for visualization of the surgical field during brain and spinal surgery. It consists of a 13.5 mm access sheath, an internal obturator designed to minimize damage to the underlying white matter tracts during placement. The BrainPath is placed through a small (≈20 mm) craniotomy with a dural opening just large enough to accommodate the device. This opening may be planned with magnetic resonance tractography to facilitate the least traumatic trans-sulcal access to the lesion possible. The sheath is stereotactically placed into the distal aspect of the clot, typically along the longest axis of the hematoma. Once the sheath is in place, the obturator is removed, and the hemorrhage can be resected either with traditional surgical tools (including standard suction catheters) or with the Myriad handpiece. The Myriad handpiece has an aspiration mechanism that pulls tissue into a small side aperture where it is then morsealized by a reciprocating cutting blade. The surgeon can control the aspiration level and activate the cutter using a foot pedal. Visualization is achieved through an exoscope that is placed over the sheath in a coaxial fashion. After the procedure, a post-op CT study is done to confirm adequate evacuation of the hematoma (Figure 2).

The Apollo System (Figure 3) received Food and Drug Administration clearance for the evacuation of tissue and fluid from the ventricular system in 2014. Since approval, the system has been used clinically for the evacuation of both ventricular and cerebral hemorrhages (off-label). In March of 2016, the clearance for the Apollo System was expanded with the current labeling: device is a nonclogging aspiration–irrigation system which allows the removal of hemorrhagic products through a low-profile (2.1 or 2.6 mm diameter) wand for the controlled aspiration of soft tissue and fluid during surgery of the ventricular system or cerebrum. A vibrational element housed within the wand vibrates at high frequency to break down the hemorrhagic products inside of the wand and prevent clogging. No energy is transferred to the tissue outside of the device. The 2 wand sizes fit through the working channels of commercially available endoscopes, and the hemorrhage evacuation is performed under continuous endoscopic visualization. The entire procedure may be performed through a standard endoscopic sheath (19–20 French) that is positioned in the distal third of the hemorrhage, along its long axis, under stereotactic guidance (Figure 4). The cranial access for the case is typically a burr hole; however, a mini craniotomy can also be performed. The dural incision need only be large enough to accommodate the sheath diameter (≈7 mm). Intraoperative cross-sectional CT imaging (cone-beam CT or portable conventional CT) immediately after the evacuation is advantageous for the active monitoring of the status of the hemorrhage evacuation. Alternatively, burr hole ultrasound may be used.

Existing Data on New Technologies

No published randomized controlled trial (RCT) data are available for either of these technologies.

Przybylowski et al presented a series of 11 patients treated with the NICO BrainPath endpoint. They reported an average reduction in hemorrhage volume of 87%. Three patients...
(27%) in this series experienced postoperative complications, including one fatal rehemorrhage. Labib et al presented a retrospective series of 35 ICH patients treated with the BrainPath system from 10 centers. In 3 quarters of the patients treated, the authors reported achieving ≥90% hemorrhage evacuation by volume. Thus, both of the existing case series have shown the feasibility of the system in achieving a substantial evacuation of hemorrhagic products.

The feasibility of the Apollo System for the removal of ICH has similarly been demonstrated in initial case reports. Spiotta et al reported a retrospective analysis of 29 patients with ICH treated with the Apollo system at 4 centers. The authors reported a mean reduction in hemorrhage volume of 54%, with 2 procedural complications.

Although direct comparisons between the 2 techniques are not possible at this point, the BrainPath system in general seems to facilitate a more complete and aggressive removal of blood products and tissue, albeit through a considerably larger access port (13.5 mm versus 6.3 mm). More clinical data will be required to determine what extent of hematoma removal is required to effect a clinical improvement and whether the drawbacks of larger access are offset by the ability to achieve a more complete evacuation of blood products.

**Future Directions**

Although existing data have been encouraging, a more definitive evaluation of the existing MIS techniques is required within the context of RCTs.

MISTIE III is a 500-patient, phase III RCT comparing MIS plus tPA with medical management. The primary efficacy end point is an improvement in clinical outcome (mRS score ≤3) at 180 days. The study was initiated in December 2013 and is expected to be complete by September 2018.

The Minimally Invasive Endoscopic Surgical Treatment With Apollo Versus Medical Management for Supratentorial ICH (INVEST) trial is a phase II trial which will compare MIS with the Apollo system and medical management in 222 patients with moderate to large (30–80 cm³) spontaneous supratentorial hemorrhages. The study will initiate enrollment early in 2016. The NICO BrainPath System will also be studied in a prospective trial, which is scheduled to begin enrollment in 2016. Details of the trial design have not yet been publically disclosed.

Data from these trials will considerably advance our understanding of the role of MIS for the management of ICH in the coming years.

**Intraventricular Hemorrhage**

IVH is most frequently related to trauma or the rupture of an underlying vascular lesion (eg, an aneurysm or arteriovenous malformation). Spontaneous IVH usually results from extension of deep parenchymal, typically hypertensive, hemorrhage into the ventricular system, but sometimes may be seen as an isolated occurrence either without an identifiable cause (ie, idiopathic) or in the setting of an inherent or drug-induced coagulopathy.

As discussed earlier, when observed within the setting of a spontaneous ICH, the finding of an associated IVH substantially worsens the prognosis. The volume of IVH has been independently correlated with clinical outcome after ICH.

**Mechanisms of Injury in IVH**

The initial injury caused by IVH is caused by acute obstructive hydrocephalus, an abrupt elevation in intracranial pressure and reduced global cerebral perfusion. These issues may be addressed initially with the placement of an external ventricular drain (EVD). However, there are several mechanisms of secondary injury by which IVH may exacerbate the acute injury associated with the hemorrhage and reduce the odds of achieving a good functional outcome. First, as with ICH, massive IVH has the capacity to induce local mass effect and potentially reduce regional perfusion, creating dysfunction and ultimately ischemic injury to the brain adjacent to the ventricular system. Second, as with ICH, the hemotoxicity associated with the blood breakdown products may induce secondary brain injury in the days and weeks after IVH. Third, blood products within the ventricular system have the capacity to induce long-term impairment in the function of normal cerebrospinal fluid absorption mechanisms, resulting in chronic hydrocephalus, requiring treatment with an indwelling permanent shunt.
care already being delivered. However, the disadvantages of this method include the potential for lytic-induced expansion of the original hemorrhage, infection from repeated access of the EVD catheter, the prolonged period of time (typically 2–4 days) required for adequate clearance of blood products, and potentially the failure of the technique to achieve a substantial reduction in IVH volume in some patients. The mechanically based methods have the disadvantage of being more invasive and requiring a larger profile access than a standard EVD. Also, MIS constitutes a second surgical procedure (beyond the initial EVD placement), which would not be required for a pharmacologically based approach. On the contrary, MIS offers the potential for an immediate and substantial reduction in IVH without the requirement for lytic medications.

Data Supporting MIS for IVH

Until the recent presentation of the Clot Lysis: Evaluating Accelerated Resolution of Intraventricular Hemorrhage Phase III (CLEAR III) trial results, no large randomized, controlled trial data were available for either pharmacologically based or mechanically based treatments for IVH. Encouraging data from several smaller studies had supported some clinical application of these technologies to remove IVH and formed a foundation for the subsequent pivotal CLEAR III trial.

Pharmacologically Based IVH Treatment

Recently, the initial data regarding the safety and efficacy of intra-thecal tPA in the setting of IVH became available for the CLEAR III trial. In this pivotal trial, patients with small or no ICH (≤30 cm³) with associated IVH requiring an EVD were randomized to either placebo (normal saline) or r-tPA (1.0 mg) q8 hours (for ≤12 doses) infused through the EVD. The primary outcome measure was mRS at 180 days. The trial demonstrated that although intraventricular-tPA had no effect on clinical outcomes in the entire cohort, there was a significant (10%) reduction in mortality at 180 days. In the subset of patients with IVH volumes >20 cm³,

Figure 3. The Apollo System is composed of an aspiration–irrigation system, which can be attached via flexible tubing to the Apollo Wand. The wand (A) can be placed through the working channel of commercially available neuroendoscopes. The wand houses an internal agitator wire that vibrates at ultrasonic frequency and macerates clot material to maintain patency of the system during aspiration. The wand is attached to the freestanding aspiration–irrigation system (B). The aspiration–irrigation system (B) provides the capability for aspiration as well as continuous saline irrigation and transmits vibrational energy to the internal agitator element within the wand.

Figure 4. Adult male with a hypertensive left basal ganglia hemorrhage (A). The immediate postoperative computed tomography shows a near complete evacuation of the hemorrhagic products without a perceptible tract along the course of the access (B).
intraventricular-tPA significantly improved rates of good functional outcome (mRS score 0–3). More efficient and more complete (>80%) removal of IVH were directly correlated with patient outcomes. However, most patients (>70%) did not achieve a substantial (>80%) reduction in IVH with the CLEAR III tPA infusion technique.

This pivotal trial was predicated on encouraging results from a phase II trial which enrolled 48 IVH patients who were similarly randomized to receive either intraventricular-tPA or placebo through indwelling EVDs. In this phase II trial, tPA administration significantly increased the rate of clearance of IVH. In CLEAR IVH, the authors also reported a signal toward improved clinical outcomes at 30 days, as well as a close correlation between the rate of IVH resolution and early clinical improvement. Of note, these signals toward clinical improvement with tPA administration were observed despite a 23% rate of symptomatic bleeding events in the tPA group (versus only 5% in the control arm).

Several smaller randomized and observational studies of transcatheter-based lytic studies in IVH were evaluated in a meta-analysis performed by Gaberel et al of 316 IVH patients from 12 high-quality studies. These authors reported substantial benefit for lytics on both mortality (47.6% in the EVD-only cohort versus 22.7% with lytic therapy; odds ratio 0.32, confidence interval 0.19–0.52) and good functional outcome at ≥3 months (54% in lytic group versus 34% in the EVD-only cohort) without an associated increase in either bleeding complications or ventricular infections. An absolute reduction in the incidence of shunt-dependent hydrocephalus was observed with lytic therapy (13% versus 18.2%); however, this observation failed to meet significance.

**Mechanically Based MIS for IVH**

Several small case series and individual case reports have demonstrated the feasibility of endoscopic MIS for the treatment of IVH using both rigid and flexible endoscopy systems. However, only 2 small, prospective, RCTs evaluating endoscopic MIS are available to date.

Chen et al reported results on a population of 48 patients with thalamic hemorrhage and IVH, who were randomized 1:1 between either endoscopic-guided suction evacuation of IVH followed by EVD placement or EVD placement alone. In the endoscopic procedure, a standard suction tube was placed side-by-side with an endoscope through a rigid sheath to achieve evacuation of blood products from the ventricular system ipsilateral to the thalamic hemorrhage. These investigators reported a significant reduction in the mean length of intensive care unit stay in the MIS group (11 days versus 18 days; \( P=0.04 \)) and a marked reduction in the rates of shunt-dependent hydrocephalus in the MIS group (48% after MIS versus 98% in the EVD alone group; \( P=0.002 \)). However, mortality rates and Glasgow Outcome Scores were similar in both the cohorts.

Zhang et al randomized 44 patients (1:1) to either endoscopic IVH evacuation or EVD alone. In the endoscopic group, EVDs were placed after the procedure, and if IVH volumes remained ≥10 cm³, a urokinase solution was infused though the ventricular drain. In patients allocated to receive an EVD alone, a lytic solution was also administered through the drain. These authors observed that more patients in the neuroendoscopy group had higher rates of favorable Glasgow Outcome Scores at 2 months (\( P<0.05 \)), but they failed to observe any improvement in the overall mortality rate.

In summary, the available data supports the feasibility of mechanically based techniques to effectively remove IVH. Although they suggest the potential for improved neurological outcome in some patients, additional data are needed.

**New Technologies for IVH Evacuation**

The Apollo System, in 2014, was cleared by the US Food and Drug Administration for the controlled aspiration of soft tissue and fluid during endoscopically guided neurosurgery of the ventricular system. Its use for the treatment of IVH represents an on-label application, and it has been implemented for this purpose commercially in the United States for just over 1 year. Currently, there are no available clinical studies describing either the safety or efficacy of the system in the setting of IVH. However, conceptually, the Apollo system may provide a significant advantage over existing simple suction catheters, which are prone to clogging with tenacious blood products during these procedures. A retrospective multicenter case series describing the technical feasibility and providing a preliminary safety assessment of the Apollo System for the evacuation of IVH is anticipated.

**Future Directions**

The current American Heart Association guidelines report a Class IIb, Level of evidence B categorization for interventional approaches to IVH treatment; however, this may be revised after the publication of the CLEAR III data. The CLEAR III data demonstrate great promise for techniques which are able to achieve a reliable, safe, efficient, and substantial reduction of IVH volume to improve functional outcomes in IVH patients. The CLEAR III investigators have proposed a CLEAR IV trial, which will look at a more refined technique for intraventricular-tPA administration. The role for mechanical devices in the minimally invasive evacuation of IVH remains to be defined. Given that the CLEAR III technique was successful in removing >80% of IVH volume in only a minority of patients over 4 days of treatment, such alternate approaches certainly merit consideration. Although the potential of mechanical devices, like Apollo, to reproducibly and quickly evacuate large volume IVHs is intriguing, RCTs will be important to define their effectiveness in improving outcomes in IVH patients.

**Summary**

ICH, particularly when associated with IVH, remains a common and devastating disease, resulting in either death or permanent disability in most patients affected. To date, no neurosurgical interventions have been definitively shown to improve outcomes for ICH patients. However, encouraging data are emerging to indicate that MIS may reduce the secondary injury after both ICH and IVH and, thereby, potentially reduce both mortality and dependence. Currently, trials are underway evaluating several new minimally invasive approaches for ICH and IVH evacuation, and much more definitive evidence is expected in the near future.
Disclosures
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/content/47/5/e91.full.pdf
In the article by Fiorella et al (Fiorella D, Arthur A, Bain M, Mocco J. Minimally invasive surgery for intracerebral and intraventricular hemorrhage: rationale, review of existing data and emerging technologies. *Stroke*. 2016;47:1399–1406. DOI: 10.1161/STROKEAHA.115.011415.), which published online on April 5, 2016, and appeared in the May 2016 issue of the journal, a correction was needed.

On page 1399, in the title, “Minimally invasive surgery for intracerebral hemorrhage: rationale, review of existing data and emerging technologies,” has been changed to read “Minimally invasive surgery for intracerebral and intraventricular hemorrhage: rationale, review of existing data and emerging technologies.”

This correction has been made to the online and print version of the article, which is available at http://stroke.ahajournals.org/content/47/5/1399.