Diagnosing & Treating ED CNS Hemorrhage Patients

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Global Objectives

- **Improve pt outcome in CNS hemorrhage**
- **Know how to quickly evaluate stroke pts**
- **Know clinically how to use protocols**
- **Provide rationale ED use of therapies**
- **Facilitate useful disposition, documentation**
- **Improve Emergency Medicine practice**

Session Objectives

- **Present a relevant patient case**
- **Discuss key clinical questions**
- **State key learning points**
- **Review the procedure of elevated ICP Rx**
- **Treat hemorrhage in anticoagulation**
- **Evaluate the patient outcome and ED documentation**

A Clinical Case

Clinical History

A 76 year old male acutely developed aphasia and right sided weakness while eating at home. He seemed to slump over in his chair at the kitchen table, and was less responsive as he was guided to the floor by family. A call to 911 was immediately made. The paramedics reported a BP of 220/118, a glucose of 316, and a GCS of 14. The pt was aroused to verbal stimuli but seemed unable to speak clearly. The pt takes coumadin for prior AFib.

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ED Presentation

BP 224/124, P 100, RR 16, T 98.8, pulse ox 99%. The patient was slightly somnolent, but was able to slowly respond to simple commands. The patient snores a bit when not stimulated. The patient had no carotid bruits, clear lungs, and a regular cardiac rate and rhythm. The pupils were midpoint, with a neglect of the R visual field. There was facial weakness of the R mouth, R upper & lower extremities. An expressive aphasia was noted.

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Key Clinical Questions

- **What are the key diagnostic issues?**
- **How can ED patient Rx be optimized?**
- **What guidelines direct our therapy?**
- **What drugs must be available for use?**
- **How can these drugs best be used?**
- **How should this ICH Rx be documented?**

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ED ICH Patients: *Key Clinical Concepts*

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ICH Key Concepts

- **This is a high morbidity and mortality Dx**

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ICH Key Concepts

- **This is a high morbidity and mortality Dx**
- **Like ischemic stroke (core, penumbra)**

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ICH Key Concepts

- This is a high morbidity and mortality Dx
- Like ischemic stroke (core, penumbra)
- Hemorrhage volume predicts outcome

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ARTICLES

Volume of intracerebral hemorrhage. A powerful and easy-to-use predictor of 30-day mortality

JP Broderick, TG Brott, JE Duldner, T Tomsick and G Huster
Department of Neurology, University of Cincinnati Medical Center, OH 45267-0525.

BACKGROUND AND PURPOSE The aim of this study was to determine the 30- day mortality and morbidity of intracerebral hemorrhage in a large metropolitan population and to determine the most important predictors of 30-day outcome. METHODS We reviewed the medical records and computed tomographic films for all cases of spontaneous intracerebral hemorrhage in Greater Cincinnati during 1988. Independent predictors of 30-day mortality were determined using univariate and multivariate statistical analyses. RESULTS The 30-day mortality for the 188 cases of intracerebral hemorrhage was 44%, with half of deaths occurring within the first 2 days of onset. Volume of intracerebral hemorrhage was the strongest predictor of 30-day mortality for all locations of intracerebral hemorrhage. Using three categories of parenchymal hemorrhage volume (0 to 29 cm3, 30 to 60 cm3, and 61 cm3 or more), calculated by a quick and easy-to-use ellipsoid method, and two categories of the Glasgow Coma Scale (9 or more and 8 or less), 30-day mortality was predicted correctly with a sensitivity of 96% and a specificity of 98%. Patients with a parenchymal hemorrhage volume of 60 cm3 or more on their initial computed tomograms and a Glasgow Coma Scale score of 8 or less had a predicted 30-day mortality of 91%. Patients with a volume of less than 30 cm3 and a Glasgow Coma Scale score of 9 or more had a predicted 30-day mortality of 19%. Only one of the 71 patients with a volume of parenchymal hemorrhage of 30 cm3 or more could function independently at 30 days. CONCLUSIONS Volume of intracerebral hemorrhage, in combination with the initial Glasgow Coma Scale score, is a powerful and easy-to-use predictor of 30-day mortality and morbidity in patients with spontaneous intracerebral hemorrhage.

ICH Volume and Outcome

- Broderick: 1993 Stroke
- Key Concept: Hemorrhage volume and GCS predict 30 day mortality
- Data: 60 cc blood, GCS < 9, mort 91%
- Data: 30 cc blood, GCS > 8, mort 19%
- Implications: Simple ED observations allow for a reasonable outcome assessment

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ICH Key Concepts

- This is a high morbidity and mortality Dx
- Like ischemic stroke (core, penumbra)
- Hemorrhage volume predicts outcome
- Hemorrhage volume increases over time

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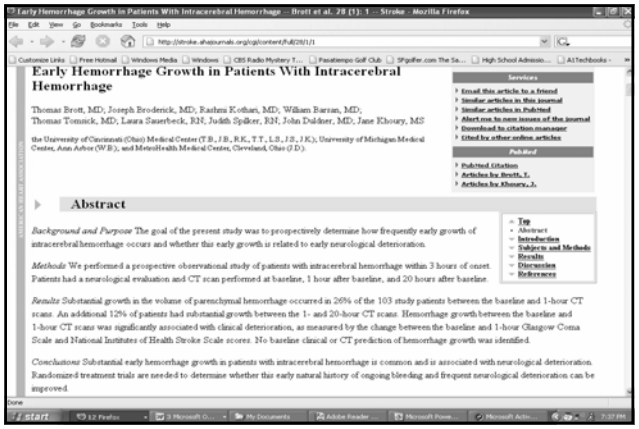

Early Hemorrhage Growth in Patients With Intracerebral Hemorrhage

Thomas Brott, MD; Joseph Broderick, MD; Rashmi Kothari, MD; William Barsan, MD; Thomas Tomsick, MD; Laura Sauerbeck, RN; Judith Spilker, RN; John Duldner, MD; Jane Khoury, MS

Abstract

Background and Purpose The goal of the present study was to prospectively determine how frequently early growth of intracerebral hemorrhage occurs and whether this early growth is related to early neurological deterioration.

Methods We performed a prospective observational study of patients with intracerebral hemorrhage within 3 hours of onset. Patients had a neurological evaluation and CT scan performed at baseline, 1 hour after baseline, and 20 hours after baseline.

Results Substantial growth in the volume of parenchymal hemorrhage occurred in 26% of the 103 study patients between the baseline and 1-hour CT scans. An additional 12% of patients had substantial growth between the 1- and 20-hour CT scans. Hemorrhage growth between the baseline and 1-hour CT scans was significantly associated with clinical deterioration, as measured by the change between the baseline and 1-hour Glasgow Coma Scale and National Institutes of Health Stroke Scale scores. No baseline clinical or CT prediction of hemorrhage growth was identified.

Conclusions Substantial early hemorrhage growth in patients with intracerebral hemorrhage is common and is associated with neurological deterioration. Randomized treatment trials are needed to determine whether this early natural history of ongoing bleeding and frequent neurological deterioration can be improved.

ICH Hemorrhage Growth

- Brott: 1997 Stroke
- Key Concept: ICH volume is dynamic, changes correlate clinically
- Data: 26% had 1/3 growth in 1 hour
- Data: 1/3 growth = drop in NIHSS, GCS
- Implications: Efforts directed at stabilizing hemorrhage volume may impact patient outcome

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ICH Key Concepts

- This is a high morbidity and mortality Dx
- Like ischemic stroke (core, penumbra)
- Hemorrhage volume predicts outcome
- Hemorrhage volume increases over time
- Guidelines exist that direct ED acute care

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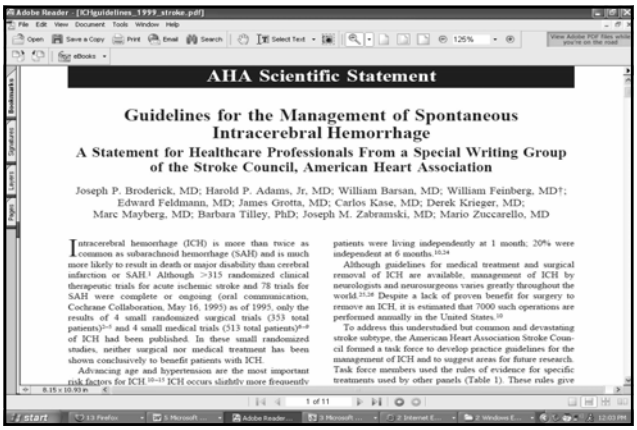
AHA Scientific Statement

Guidelines for the Management of Spontaneous Intracerebral Hemorrhage

A Statement for Healthcare Professionals From a Special Writing Group of the Stroke Council, American Heart Association

Joseph P. Broderick, MD; Harold P. Adams, Jr, MD; William Barsan, MD; William Feinberg, MD†; Edward Feldmann, MD; James Grotta, MD; Carlos Kase, MD; Derek Krieger, MD; Marc Mayberg, MD; Barbara Tilley, PhD; Joseph M. Zabramski, MD; Mario Zuccarello, MD

Intracerebral hemorrhage (ICH) is more than twice as common as subarachnoid hemorrhage (SAH) and is much more likely to result in death or major disability than cerebral infarction or SAH.1 Although >315 randomized clinical therapeutic trials for acute ischemic stroke and 78 trials for SAH were complete or ongoing (oral communication, Cochrane Collaboration, May 16, 1995) as of 1995, only the results of 4 small randomized surgical trials (353 total patients)[2–5] and 4 small medical trials (513 total patients)[6–9] of ICH had been published. In these small randomized studies, neither surgical nor medical treatment has been shown conclusively to benefit patients with ICH.

Advancing age and hypertension are the most important risk factors for ICH.[10–15] ICH occurs slightly more frequently

patients were living independently at 1 month; 20% were independent at 6 months.[10,24]

Although guidelines for medical treatment and surgical removal of ICH are available, management of ICH by neurologists and neurosurgeons varies greatly throughout the world.[25,26] Despite a lack of proven benefit for surgery to remove an ICH, it is estimated that 7000 such operations are performed annually in the United States.[10]

To address this understudied but common and devastating stroke subtype, the American Heart Association Stroke Council formed a task force to develop practice guidelines for the management of ICH and to suggest areas for future research. Task force members used the rules of evidence for specific treatments used by other panels (Table 1). These rules give

ICH Treatment Guidelines

- ASA Council: 1999 Stroke
- Key Concept: ICH guidelines exist
- Data: Detailed data on disease, epi
- Data: BP, ICP Rx recommendations
- Implications: The procedures of ICP and BP management can be uniformly applied by EM physicians

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ICH Key Concepts

- This is a high morbidity and mortality Dx
- Like ischemic stroke (core, penumbra)
- Hemorrhage volume predicts outcome
- Hemorrhage volume increases over time
- Guidelines exist that direct ED acute care
- Recent data regarding surgery important

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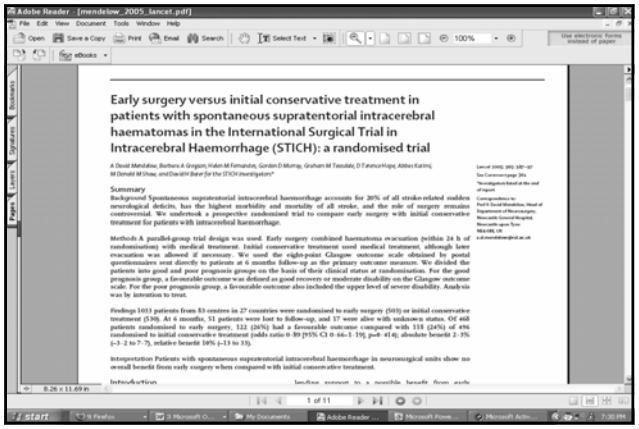
Early surgery versus initial conservative treatment in patients with spontaneous supratentorial intracerebral haematomas in the International Surgical Trial in Intracerebral Haemorrhage (STICH): a randomised trial

Summary

Background Spontaneous supratentorial intracerebral haemorrhage accounts for 20% of all stroke-related sudden neurological deficits, has the highest morbidity and mortality of all stroke, and the role of surgery remains controversial. We undertook a prospective randomised trial to compare early surgery with initial conservative treatment for patients with intracerebral haemorrhage.

Methods A parallel-group trial design was used. Early surgery combined haematoma evacuation (within 24 h of randomisation) with medical treatment. Initial conservative treatment used medical treatment, although later evacuation was allowed if necessary. We used the eight-point Glasgow outcome scale obtained by postal questionnaires sent directly to patients at 6 months follow-up as the primary outcome measure. We divided the patients into good and poor prognosis groups on the basis of their clinical status at randomisation. For the good prognosis group, a favourable outcome was defined as good recovery or moderate disability on the Glasgow outcome scale. For the poor prognosis group, a favourable outcome also included the upper level of severe disability. Analysis was by intention to treat.

Findings 1033 patients from 83 centres in 27 countries were randomised to early surgery (503) or initial conservative treatment (530). At 6 months, 51 patients were lost to follow-up, and 17 were alive with unknown status. Of 468 patients randomised to early surgery, 122 (26%) had a favourable outcome compared with 115 (24%) of 456 randomised to initial conservative treatment (odds ratio 0·89 [95% CI 0·64–1·15], p=0·41); absolute benefit 2·3% (–3·2 to 7·7), relative benefit 10% (–13 to 33).

Interpretation Patients with spontaneous supratentorial intracerebral haemorrhage in neurosurgical units show no overall benefit from early surgery when compared with initial conservative treatment.

Introduction

STITCH ICH Surgical Trial

- Mendelow: 2005 Lancet
- Key Concept: Surgery within 24 hours does not affect 6 month outcome
- Data: 25% of pts had a good outcome
- Data: Surgery did not change this rate
- Data: Surgery occurred after many hours
- Implications: Need to consider timely and selective neurosurgical intervention in order to impact outcome

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ICH Key Concepts

- Elevated ICP therapy in ED defined

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Elevated ICP Therapy: *The Procedure*

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ICP Rx: Driving Principles

- Know the clinical signs of elevated ICP
- Be able to detect elevated ICP on CT
- Consider decadron and mannitol use
- Consider prophylaxis with a phenytoin
- Be prepared to treat seizures and SE
- Know how to assess rostral-caudal deterioration (herniation)

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Elevated ICP Rx Procedure

- Evaluate globally all resuscitation needs

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Elevated ICP Rx Procedure

- Evaluate globally all resuscitation needs
- Consider decadron if brain edema noted

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Elevated ICP Rx Procedure

- Evaluate globally all resuscitation needs
- Consider decadron if brain edema noted
- Do not provide prophylactic osmotherapy

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Elevated ICP Rx Procedure

- Evaluate globally all resuscitation needs
- Consider decadron if brain edema noted
- Do not provide prophylactic osmotherapy
- Mannitol 20%, 200-400 cc (0.25-0.50 mg/kg) q 4 hr, not by continuous infusion

Edward P. Sloan, MD, MPH, FACEP

Elevated ICP Rx Procedure

- Evaluate globally all resuscitation needs
- Consider decadron if brain edema noted
- Do not provide prophylactic osmotherapy
- Mannitol 20%, 200-400 cc (0.25-0.50 mg/kg) q 4 hr, not by continuous infusion
- Lasix 10 mg IVP q 8 hr

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Elevated ICP Rx Procedure

- Evaluate globally all resuscitation needs
- Consider decadron if brain edema noted
- Do not provide prophylactic osmotherapy
- Mannitol 20%, 200-400 cc (0.25-0.50 mg/kg) q 4 hr, not by continuous infusion
- Lasix 10 mg IVP q 8 hr
- Measure serum osmols BID, $\leq$ 310 mOsm/L

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Elevated ICP Rx Procedure

- Do not use prophylactic hyperventilation

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Elevated ICP Rx Procedure

- Do not use prophylactic hyperventilation
- With clinical deterioration, achieve hypocarbia to pCO2 30-35 mm Hg

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Elevated ICP Rx Procedure

- Do not use prophylactic hyperventilation
- With clinical deterioration, achieve hypocarbia to pCO2 30-35 mm Hg
- Raise ventilatory rate with constant tidal volume (12-14 ml/kg)

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Elevated ICP Rx Procedure

- Do not use prophylactic hyperventilation
- With clinical deterioration, achieve hypocarbia to pCO2 30-35 mm Hg
- Raise ventilatory rate with constant tidal volume (12-14 ml/kg)
- Non-depolarizing paralytics, lidocaine to minimize ICP elevation bursts

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ICH Key Concepts

- Elevated ICP therapy in ED defined
- Treatment of ICH with elevated INR defined

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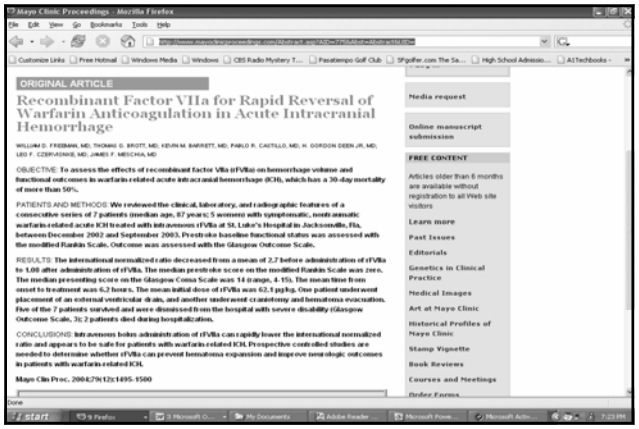
Mayo Clinic Proceedings - Mozilla Firefox

ORIGINAL ARTICLE

Recombinant Factor VIIa for Rapid Reversal of Warfarin Anticoagulation in Acute Intracranial Hemorrhage

WILLIAM D. FREEMAN, MD; THOMAS D. BROTT, MD; KEVIN M. BARRETT, MD; PABLO R. CASTILLO, MD; H. GORDON DEEN JR, MD; LEO F. CZERVIONKE, MD; JAMES F. MESCHIA, MD

OBJECTIVE: To assess the effects of recombinant factor VIIa (rFVIIa) on hemorrhage volume and functional outcomes in warfarin-related acute intracranial hemorrhage (ICH), which has a 30-day mortality of more than 50%.

PATIENTS AND METHODS: We reviewed the clinical, laboratory, and radiographic features of a consecutive series of 7 patients (median age, 87 years; 5 women) with symptomatic, nontraumatic warfarin-related acute ICH treated with intravenous rFVIIa at St. Luke's Hospital in Jacksonville, Fla, between December 2002 and September 2003. Prestroke baseline functional status was assessed with the modified Rankin Scale. Outcome was assessed with the Glasgow Outcome Scale.

RESULTS: The international normalized ratio decreased from a mean of 2.7 before administration of rFVIIa to 1.08 after administration of rFVIIa. The median prestroke score on the modified Rankin Scale was zero. The median presenting score on the Glasgow Coma Scale was 14 (range, 4-15). The mean time from onset to treatment was 6.2 hours. The mean initial dose of rFVIIa was 62.1 μg/kg. One patient underwent placement of an external ventricular drain, and another underwent craniotomy and hematoma evacuation. Five of the 7 patients survived and were dismissed from the hospital with severe disability (Glasgow Outcome Scale, 3); 2 patients died during hospitalization.

CONCLUSIONS: Intravenous bolus administration of rFVIIa can rapidly lower the international normalized ratio and appears to be safe for patients with warfarin-related ICH. Prospective controlled studies are needed to determine whether rFVIIa can prevent hematoma expansion and improve neurologic outcomes in patients with warfarin-related ICH.

Mayo Clin Proc. 2004;79(12):1495-1500

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FVIIa in Warfarin-Related ICH

- Freeman: 2004 Mayo Clin Proc
- Key Concept: Warfarin-related ICH can be treated successfully with rec FVIIa
- Data: 62 micrograms/kg Factor VIIa
- Data: INR decreased from 2.7 to 1.1
- Implications: This therapy used today as an adjunct to blood therapies in ICH patients whose bleed is INR-related

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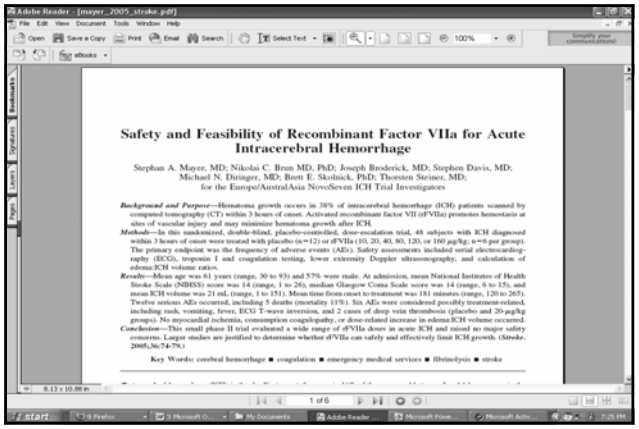
Adobe Reader - [mayer_2005_stroke.pdf]

Safety and Feasibility of Recombinant Factor VIIa for Acute Intracerebral Hemorrhage

Stephan A. Mayer, MD; Nikolai C. Brun MD, PhD; Joseph Broderick, MD; Stephen Davis, MD; Michael N. Diringer, MD; Brett E. Skolnick, PhD; Thorsten Steiner, MD; for the Europe/AustralAsia NovoSeven ICH Trial Investigators

Background and Purpose—Hematoma growth occurs in 38% of intracerebral hemorrhage (ICH) patients scanned by computed tomography (CT) within 3 hours of onset. Activated recombinant factor VII (rFVIIa) promotes hemostasis at sites of vascular injury and may minimize hematoma growth after ICH.

Methods—In this randomized, double-blind, placebo-controlled, dose-escalation trial, 48 subjects with ICH diagnosed within 3 hours of onset were treated with placebo (n=12) or rFVIIa (10, 20, 40, 80, 120, or 160 μg/kg; n=6 per group). The primary endpoint was the frequency of adverse events (AEs). Safety assessments included serial electrocardiography (ECG), troponin I and coagulation testing, lower extremity Doppler ultrasonography, and calculation of edema:ICH volume ratios.

Results—Mean age was 61 years (range, 30 to 93) and 57% were male. At admission, mean National Institutes of Health Stroke Scale (NIHSS) score was 14 (range, 1 to 26), median Glasgow Coma Scale score was 14 (range, 6 to 15), and mean ICH volume was 21 mL (range, 1 to 151). Mean time from onset to treatment was 181 minutes (range, 120 to 265). Twelve serious AEs occurred, including 5 deaths (mortality 11%). Six AEs were considered possibly treatment-related, including rash, vomiting, fever, ECG T-wave inversion, and 2 cases of deep vein thrombosis (placebo and 20-μg/kg groups). No myocardial ischemia, consumption coagulopathy, or dose-related increase in edema:ICH volume occurred.

Conclusion—This small phase II trial evaluated a wide range of rFVIIa doses in acute ICH and missed no major safety concerns. Larger studies are justified to determine whether rFVIIa can safely and effectively limit ICH growth. (*Stroke*. 2005;36:74-79.)

Key Words: cerebral hemorrhage ■ coagulation ■ emergency medical services ■ fibrinolysis ■ stroke

Rec FVIIa Safety in ICH

- Mayer: 2005 Stroke
- Key Concept: FVIIa is safe when given within 3 hours of presentation
- Data: 36 patients, 6 doses tested
- Data: No safety issues preclude phase III
- Implications: Larger study is justified, given data on hemorrhage volume growth and outcome

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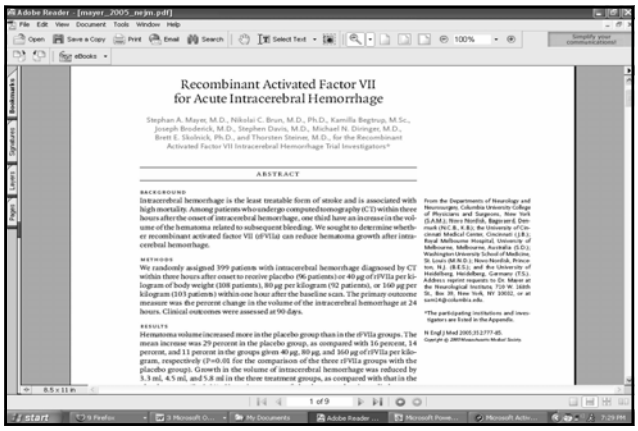

Recombinant Activated Factor VII
for Acute Intracerebral Hemorrhage

Stephan A. Mayer, M.D., Nikolai C. Brun, M.D., Ph.D., Kamilla Begtrup, M.Sc., Joseph Broderick, M.D., Stephen Davis, M.D., Michael N. Diringer, M.D., Brett E. Skolnick, Ph.D., and Thorsten Steiner, M.D., for the Recombinant Activated Factor VII Intracerebral Hemorrhage Trial Investigators*

ABSTRACT

BACKGROUND

Intracerebral hemorrhage is the least treatable form of stroke and is associated with high mortality. Among patients who undergo computed tomography (CT) within three hours after the onset of intracerebral hemorrhage, one third have an increase in the volume of the hematoma related to subsequent bleeding. We sought to determine whether recombinant activated factor VII (rFVIIa) can reduce hematoma growth after intracerebral hemorrhage.

METHODS

We randomly assigned 399 patients with intracerebral hemorrhage diagnosed by CT within three hours after onset to receive placebo (96 patients) or 40 μg of rFVIIa per kilogram of body weight (108 patients), 80 μg per kilogram (92 patients), or 160 μg per kilogram (103 patients) within one hour after the baseline scan. The primary outcome measure was the percent change in the volume of the intracerebral hemorrhage at 24 hours. Clinical outcomes were assessed at 90 days.

RESULTS

Hematoma volume increased more in the placebo group than in the rFVIIa groups. The mean increase was 29 percent in the placebo group, as compared with 16 percent, 14 percent, and 11 percent in the groups given 40 μg, 80 μg, and 160 μg of rFVIIa per kilogram, respectively ($P=0.01$ for the comparison of the three rFVIIa groups with the placebo group). Growth in the volume of intracerebral hemorrhage was reduced by 3.3 ml, 4.5 ml, and 5.8 ml in the three treatment groups, as compared with that in the

FVIIa Safety, Efficacy in ICH

- Mayer: 2005 NEJM
- Key Concept: FVIIa is safe when given within 3 hours of presentation
- Data: 399 pts, 3 doses, ICH growth, 90-day
- Data: Less ICH growth, improved outcome
- Data: Thrombo-embolic events noted
- Implications: Larger study is critical in order to establish clear benefit, safety

Elevated INR Therapy: *The Procedure*

INR Rx: Driving Principles

- Establish the extent of INR elevation and presence of bleeding (< 5, 5-9, >9)
- Administer Vitamin K IV
- Order fresh frozen plasma
- Consider Factor IX use
- Consider recombinant Factor VIIa use
- Monitor INR until < 5

Elevated INR Rx Procedure

- Vitamin K 5-10 mg IVP

Elevated INR Rx Procedure

- Vitamin K 10 mg subq or IVP
- Fresh frozen plasma (5-8 ml/kg, 1-2 units, 250-500 cc total)

Elevated INR Rx Procedure

- Vitamin K 10 mg subq or IVP
- Fresh frozen plasma (5-8 ml/kg, 1-2 units, 250-500 cc total)
- Prothrombin complex concentrate (FACTOR IX) 25-50 IU/kg

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Elevated INR Rx Procedure

- Vitamin K 10 mg subq or IVP
- Fresh frozen plasma (5-8 ml/kg)
  1-2 units, 250-500 cc total
- Prothrombin complex concentrate (FACTOR IX) 25-50 IU/kg
- Recombinent Factor VIIa (40-60 µgr/kg)
  3-4 mg total

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ED Treatment and Patient Outcome

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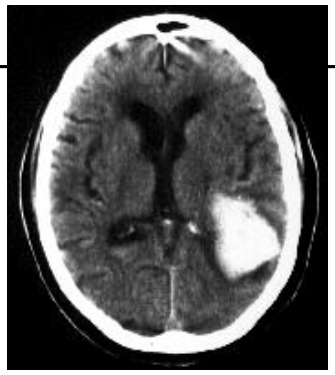

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ED Patient Management

- The patient had a basal ganglia ICH
- The BP improved with IV labetalol
- The INR was noted to be 5.6
- Vitamin K was administered
- Fresh frozen plasma was ordered
- Factor VIIa was given, 1.6 mg total
- The pt was admitted to neurosurgery, ICU

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Patient Outcome

- The hemorrhage did not extend
- INR reversal occurred
- Stable clinical status over time
- No thromboembolic events
- Discharged to rehab 10 days later

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ED ICH Patient Rx:
A Retrospective

Edward P. Sloan, MD, MPH, FACEP

ED ICH Patient Dx & Rx

- Changing ED treatment paradigm
- More use of teleradiology
- Surgical Rx variable, ED Dx critical
- Be prepared to medically manage these critically ill pts
- INR reversal may be required

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Questions??

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