

Endoscopy

Image-guided endoscopic evacuation of spontaneous intracerebral hemorrhage[☆]

Chad M. Miller, MD^{a,*}, Paul Vespa, MD^a, Jeffrey L. Saver, MD^b, Chelsea S. Kidwell, MD^{c,d}, Stanley T. Carmichael, MD, PhD^b, Jeffry Alger, PhD^b, John Frazee, MD^a, Sid Starkman, MD^{b,e}, David Liebeskind, MD^b, Valeriy Nenov, PhD^a, Robert Elashoff, PhD^f, Neil Martin, MD^a

^a*Division of Neurosurgery, David Geffen School of Medicine, University of California, Los Angeles 90095, USA*

^b*Department of Neurology, David Geffen School of Medicine, University of California, Los Angeles 90095, USA*

^c*Department of Neurology, Georgetown University, Washington DC 20057, USA*

^d*Washington Hospital Center, Washington DC 20010, USA*

^e*Departments of Emergency Medicine and* ^f*Biomathematics, David Geffen School of Medicine, University of California, Los Angeles, USA*

Received 12 September 2007; accepted 17 December 2007

Abstract

Background: Spontaneous ICH is a devastating disease with high morbidity and mortality. Intracerebral hemorrhage lacks an effective medical or surgical treatment despite the acknowledged pathophysiologic benefits of achieved hemostasis and clot removal. Image-guided stereotactic endoscopic hematoma evacuation is a promising minimally invasive approach designed to limit operative injury and maximize hematoma removal.

Methods: A single-center randomized controlled trial was designed to assess the safety and efficacy of stereotactic hematoma evacuation compared to best medical management. Patients were randomized within 24 hours of hemorrhage in a 3:2 fashion to best medical management plus endoscopic hematoma evacuation or best medical management alone. Data were collected to assess efficacy and safety of hematoma evacuation and to identify procedural components requiring technical improvement.

Results: Ten patients have been enrolled and randomized to treatment. Six patients underwent endoscopic evacuation with a hematoma volume reduction of $80\% \pm 13\%$ at 24 hours post procedure. The medical arm demonstrated a hematoma enlargement of $78\% \pm 142\%$ during this same period. Rehemorrhage rates and deterioration rates were similar in the 2 groups. Mortality was 20% in the endoscopic group and 50% in the medical treatment cohort. The endoscopic technique was shown to be effective in identification and evacuation of hematomas, whereas reduction in the number of endoscopic passes and maintenance of hemostasis require further study.

Conclusion: Image-guided stereotactic endoscopic hematoma removal is a promising minimally invasive technique that is effective in immediate hematoma evacuation. This technique deserves further investigation to determine its role in ICH management.

© 2008 Elsevier Inc. All rights reserved.

Keywords:

Intracerebral hemorrhage; Endoscopy; minimally invasive surgery; Hemorrhagic stroke

Abbreviations: BI, Barthel Index; CT, Computed tomography; DDAVP, 1-deamino-8-D-arginine vasopressin; GCS, Glasgow Coma Scale; ICH, Intracerebral hemorrhage; ICU, intensive care unit; ISTICH, International Surgical Trial in Intracerebral Haemorrhage; IVH, Intraventricular hemorrhage; MR, magnetic resonance; mRS, Modified Rankin Score; N/A, not applicable; NIHSS, National Institute of Health Stroke Scale.

[☆] This work was supported by a grant from the Division of Extramural Research of the National Institutes of Health: P50-NS044378 (Alger, Vespa, Martin, Kidwell).

* Corresponding author. David Geffen School of Medicine, UCLA Medical Center, Los Angeles, CA 90095, USA. Tel.: +1 310 206 6969; fax: +1 310 794 2147.

E-mail address: chadmiller@mednet.ucla.edu (C.M. Miller).

1. Introduction

Spontaneous ICH is a devastating disease with historically poor outcomes. Medical management of these patients results in unacceptable morbidity and mortality. Only 48% to 65% of ICH victims are alive at 1-month follow-up, and only 10% of these patients are living independently [4–6,9]. The natural course of acute ICH is not static [10]. After initial irreversible tissue injury is suffered near the hemorrhage nidus, a progressive cascade of elevated local pressures, edema, and excitotoxicity causes additional secondary injury to surrounding brain [12,16,17]. Much of this secondary process is thought to be attributable to the mass effect of the new hemorrhage, as well as the toxicity associated with hematoma decomposition and release of inflammatory and free radical mediators.

As a result, there has been great interest in the potential benefits of acute hematoma evacuation. In the United States, more than 7000 patients with ICH undergo evacuation procedures each year [8]. This enthusiasm has been tempered by the lack of supportive clinical data. The efficacy of surgical evacuation was most recently studied in the iSTICH [11]. This large multicenter, international randomized trial evaluated the efficacy of early (<24 hours after randomization) surgical therapy vs best medical management in the treatment of spontaneous ICHs. Although this study has received criticism for the subjectivity of its inclusion criteria, frequency of treatment group crossover, and diversity of surgical approaches, it remains the most powerful study of hematoma evacuation to date. This trial corroborated the results of prior smaller studies that failed to show a survival or morbidity benefit of conventional surgery.

The surprising failure of conventional hematoma evacuation may be attributable to the type of surgical approach. Although standard open craniotomy is routinely effective in complete hematoma evacuation and maintenance of hemostasis, the approach commonly causes damage to uninjured brain overlying the hematoma. Minimally invasive surgical strategies have been devised to minimize this risk. The safety of image-guided and frameless stereotactic procedures has been reported in numerous small trials [7,15]. These approaches commonly necessitate use of thrombolytic therapy and require increased evacuation times. Furthermore, these methods are limited in their ability to achieve hemostasis and completely evacuate the hematoma.

Despite the success of early studies, endoscopic assisted evacuation of ICH has received little attention as a minimally invasive technique. The endoscopic approach has been shown to be effective in achieving immediate and complete hematoma evacuation [2,14]. This technique also has the benefit of improved visualization and hemostasis with electric cautery [13]. Auer et al [1] have published the most promising surgical data related to ICH evacuation. They have reported a significant survival benefit of endoscopic evacuation over medical therapy with hematomas greater than 50 mL. Although there was no improve-

ment in mortality with smaller lesions, patients undergoing endoscopic evacuation were more likely to have a favorable functional recovery at 6 months.

The lack of an effective surgical treatment for ICH, despite the persistence of a sound pathophysiologic argument for hematoma evacuation, has led us to initiate a single-center, randomized, controlled trial of acute endoscopic assisted hematoma evacuation. This phase 2 study, comparing image-guided endoscopic evacuation vs aggressive medical management, was designed to assess the feasibility and potential benefit of this minimally invasive technique. The percent volume of evacuated hematoma at 24 hours was set as the primary efficacy outcome measure. The rate of rehemorrhage, deterioration of the GCS by 2 points during the ICU stay, and fall in the NIHSS by 4 points at 30 days was used to determine the safety of endoscopic evacuation. This manuscript will report the current safety and efficacy data of this ongoing trial and investigate the technical challenges associated with this minimally invasive approach.

2. Methods

The University of California Institutional Review Board approved this study. Subjects were considered for enrollment if they presented to University of California, Los Angeles Medical Center within 24 hours of onset of symptoms for acute ICH. Patients were eligible for the study if they were 18 years or older, had an ICH volume above 15 mL, and had significant neurological symptoms resulting from the acute hematoma. Patients with a GCS score below 5, posterior fossa hemorrhage, ICH secondary to an ischemic infarction or large vessel rupture, coagulopathy, significant prior disability, allergy to MR contrast agents, or active participation in another clinical trial were restricted from enrollment. Pregnant women were also excluded from this study. Informed consent was obtained from the patient or their legally authorized representative before randomization.

Patients were randomized to endoscopic and medical management or medical management in a 3:2 ratio. For all surgical patients, 1-mm-slice CT images were acquired and loaded into the BrainLab® (Chicago, IL) frameless neuronavigation software to enable identification of image-guided burr hole location, endoscopic trajectory, and depth of endoscope insertion. The patients were taken to the operative suite and underwent standard general anesthesia. The patient's head was appropriately positioned in a Mayfield headholder (Codman, Inc, Raynham, Mass), and the scalp was shaved and prepared in the routine sterile fashion. Cranial landmarks were registered with the BrainLab® navigation system, and a 4-cm incision was made in the scalp, consistent with the planned endoscopic trajectory. A 1.8-cm burr hole was created using a Midas Rex Instrument (Medtronic, Inc, Minneapolis, Minn). The dura was then coagulated and opened, and the pia was dissected to allow entrance of the endoscope sheath. The sheath was guided transcortically into

Download English Version:

<https://daneshyari.com/en/article/3093029>

Download Persian Version:

<https://daneshyari.com/article/3093029>

[Daneshyari.com](https://daneshyari.com)