SLEUTH
Safety of Lysis with EKOS Ultrasound in the Treatment of Intracerebral and Intraventricular Hemorrhage

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Background

Intracerebral hemorrhage (ICH) occurs in over 100,000 Americans each year and has no effective treatment. It is fatal in 30% to 50% of all occurrences and the majority of survivors have significant motor and cognitive disability. The severity of brain injury is related to the volume of blood clot and the exposure time. ICH is easily and rapidly identified. It occurs in younger patients, and it initially produces a smaller injury to the central lesion, suggesting that amelioration is possible with the right intervention that promotes effective blood clot removal.

ICH is frequently complicated by intraventricular hemorrhage (IVH). IVH increases mortality to as high as 85%. IVH obstructs cerebrospinal fluid (CSF) flow and leads to hydrocephalus. Re-establishing CSF flow is considered a neurosurgical emergency requiring ventricular catheter placement. These catheters control ICP but do not enhance blood removal. Research demonstrating the value of blood removal suggests that rapid and complete removal is desirable, but rarely achieved with current technology. It has been recently demonstrated that ultrasound markedly increases the rate of blood clot lysis produced by the thrombolytic substance recombinant tissue plasminogen activator (r-PA).

Current surgical care for ICH is open craniotomy, with a small, 4% benefit that remains controversial. Craniotomy is associated with poor patient stability, substantial brain tissue injury, and frequent rebleeding. In ICH, a ventriculostomy is placed blindly into the contra lateral ventricle. This technique is complicated by inaccurate placement of the catheter, progression of bleeding and injury to normal brain tissue. In contrast, data from human and animal models demonstrate that minimally invasive surgery (MIS) techniques and thrombolitics can substantially reduce blood clot size and the area of brain tissue in direct contact with blood, resulting in better patient stability, substantially decreased tissue injury, and minimal bleeding or infection.

The long-term goal of this research is to change the way ICH and IVH are treated, reducing brain injury with catheter based surgical and clinical management. This innovative approach combines local delivery of r-PA with ultrasound enhancement to provide effective hematoma removal.

Methods

Thirty five patients with spontaneous intracerebral hemorrhage were screened for inclusion into the study. A total of 9 patients were entered into the study and completed treatment. Treatment was conducted in the operating room and included placement of a burr hole, and navigation of the ultrasound and drainage catheter into the hematoma using a GPS-like system (STEALTH) for optimal catheter placement. Ultrasound was then delivered to the hemisphere in addition to the thrombolytic drug tissue plasminogen activator (t-PA) for 24 hours. Drainage was continued for a total of 48 hours in most patients.

Results

Figure 2 illustrates (left) the initial hematoma, (center) catheter placement, and (right) the disappearance of blood clot within the cerebral ventricle within 24 hours after initiation of treatment.

Figure 3 is a table illustrating the results of treatment in 9 patients treated for their hemorrhage using the SLEUTH protocol. There was one death within 30 days due to the severity of the hemorrhage, no catheter infections, and no bleeding episodes or other significant adverse events.

Conclusions

Minimally invasive surgery using neuro-navigation techniques for catheter placement combined with ultrasound aided thrombolytic treatment and drainage appears to be well tolerated and safe. The procedure is very effective for blood clot removal and relief of mass effect in the brain following intracranial hemorrhage. This procedure may play a major role in the future treatment of intracranial hemorrhage. A larger multi-center trial for safety and efficacy with a redesigned catheter is warranted.

References


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