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RUNNING HEAD: Effects of intubation on blood pressure in acute stroke patients

Effects of Intubation and Maintenance Sedation on Blood Pressure in Acute Stroke Patients  
Undergoing Mechanical Endovascular Thrombectomy

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## Effects of Intubation and Maintenance Sedation on Blood Pressure in Acute Stroke Patients Undergoing Mechanical Endovascular Thrombectomy

### I. Introduction

Acute stroke is the second leading cause of death in the United States, and the number one cause of disability in adults (Patel & Collins, 2009). Acute stroke can be divided into two categories: ischemic stroke and hemorrhagic stroke. Of the two, approximately 85% of strokes are ischemic (Patel & Collins, 2009). An ischemic stroke is primarily caused by an embolus obstructing the flow of arterial blood to an area of the brain. Not only is ischemic stroke the more common presentation, but the outcomes from an ischemic stroke are time dependent, due to the lack of blood flow to the affected area of the brain. The phrase, "time is brain," is often used to encourage the rapid restoration of perfusion.

There are many challenges presented to healthcare personnel when it comes to the rapid identification and treatment of acute stroke signs and symptoms. Treatment requires a highly specialized and well-trained team of providers in a facility equipped with the appropriate technology in order to offer the best patient outcomes.

Two primary goals in stroke treatment are to minimize the disability from the presenting stroke and to decrease the risk of recurrent stroke. Currently the most common treatment of acute stroke is a systemic thrombolytic medication called tissue plasminogen activator (t-PA), which must be administered within three hours from the onset of stroke symptoms (del Zoppo, Saver, Jauch, & Adams, 2009). One of the most sophisticated recent advancements in stroke treatment is an endovascular treatment called the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) device (Gobin et al., 2004). The MERCI procedure offers the benefit of directly targeting and removing the offending embolus from the patient and can be performed up to eight

hours after stroke symptoms first begin. Increasing the time window for treatment has made the MERCI device an incredible, live-saving medical breakthrough.

Key to the outcome of the MERCI procedure is the management of sedation, airway, and ventilation. This is primarily accomplished through general anesthesia with endotracheal intubation, which is the standard protocol for most facilities. The patient is sedated, chemically paralyzed, and placed on mechanical ventilation for the duration of the procedure (which has an average time of 1.9 hrs) (Devlin et al., 2012). Like any advanced procedure, endotracheal intubation carries its own set of potential complications, not the least of which are fluctuations in blood pressure. These fluctuations can be more pronounced in patients with airways that require multiple attempts before the intubation is successful. While intubation is standard for the MERCI procedure, some centers have been able to accomplish adequate conscious sedation without intubation.

According to Thomas Devlin, MD, PhD, director of the Southeastern Stroke Center, it has been noted in the national MERCI Registry Database that patients who undergo intubation for a mechanical embolectomy procedure have had worse outcomes than those who were not intubated (Devlin et al., 2012). The reason behind these findings is yet to be fully understood. Hence, Devlin and several others have set out to explore the possible explanations for these increased rates of morbidity and mortality.

One of the primary postulates is that the variations in blood pressure from the intubation are causing a negative effect on the already compromised cerebral tissue and could be causing further ischemia (Devlin et al., 2012). A plan was developed to closely monitor and observe the blood pressure of MERCI procedure patients during intubation. Additionally, a retrospective analysis was performed of each participant to evaluate for co-morbidities and other individual

factors potentially contributing to unfavorable outcomes. The purpose of this study is to evaluate the hemodynamic variables of intubated patients undergoing the MERCI procedure to better understand these complications in an effort to lay the groundwork for better management of the identified variables. The ultimate goal is to decrease the complications associated with the MERCI procedure as well as improve overall morbidity and mortality rates. This would result in shorter hospital length of stay, fewer days in the intensive care unit (ICU), and decreased lasting disability. This is a gateway study performed at a single center, which will then move into a multi-center format for a larger follow up study.

## II. Review of Literature

Intravenous thrombolytic treatment with t-Pa remains the only approved pharmacologic agent for the treatment of patients with acute ischemic stroke (del Zoppo et al., 2009). The National Institute of Neurological Disorders and Stroke (NINDS) study group demonstrated improved neurological outcome in patients treated within three hours of symptom onset (NINDS, 1995). In this study, patients treated with t-Pa were 30% more likely to have minimal or no disability at three months compared to patients that received the placebo. Subsequent subgroup analysis of the NINDS study and pooled analysis of six randomized trials investigating thrombolytic administration in ischemic stroke suggested a benefit in the three to four and a half hour time frame (Hacke, Kaste, & Bluhmki, 2008). Unfortunately, only a small proportion of patients with ischemic stroke are eligible for treatment with t-Pa, and of the patients treated with t-Pa that suffered a severe stroke, only 8% have clinically significant improvement (NINDS, 1997).

With this in mind, it was very apparent to the medical community that new advances must be made in the treatment of ischemic stroke in order to provide effective treatment to a greater number of stroke victims (Devlin, Baxter, Feintuch, & Desbiens, 2007). As noted in the introduction, these recent advances include the MERCI Retrieval System. In the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) Trial, 111 patients with large vessel ischemic stroke ineligible for intravenous alteplase (t-Pa) underwent an attempt at mechanical embolectomy with the MERCI Retrieval System (Gobin et al., 2004) within eight hours of symptom onset. Recanalization was achieved in 46% of patients. Patients with successful recanalization had significantly better neurological outcomes (modified Rankin score  $\leq 2$ ) at 90 days (46% vs 10%;  $P < 0.0001$ ) and decreased mortality (32% vs 54%;  $P = 0.01$ ) at 90 days as compared to patients with unsuccessful recanalization. In the subsequent Multi-MERCI trial, recanalization rates of 69% were achieved when the MERCI Retrieval System was utilized with adjunctive intra-arterial alteplase. It should be noted that there is not clear documentation in these initial studies to indicate whether or not a significant number of patients were sedated without the use of intubation to control the patient's airway.

The complications of airway management in the emergency setting are well documented and well known by any practitioners working in this type of environment. Sedation and airway management in the operating room is performed in a very controlled and calculated environment and is primarily an elective procedure. On the other hand, emergency endotracheal intubation can result in complications such as multiple attempts, esophageal intubation, and aspiration (Mort, 2007).

An additional known complication is an alteration in hemodynamics during the intubation procedure and continued throughout the patient's course on mechanical ventilation (Mort, 2007).

There has been much time and energy focused on preventing the marked increase in heart rate and blood pressure during airway manipulation in the operation room, as well as post-intubation hypotension and bradycardia. However, these items are only more recently being significantly spotlighted in the emergent setting. Other co-morbid conditions such as diabetes, renal impairment, congestive heart failure, and stroke can further complicate hemodynamic stability. When large amounts of induction medications are required for intubation, an even greater alteration in hemodynamics has been observed, with a common sharp decrease in systolic blood pressure regardless of existing co-morbidities (Mort, 2007).

As a theoretical framework for this study, the Neuman Systems Model was selected. The major goal of care in Neuman's model is to assist the client in achieving system stability through the attainment, retention, and maintenance of optimum health (Neuman, 2010). Neuman views both internal and external stressors as variables that affect the patient's optimum health state. There are a multitude of these variables that affect patients suffering from an acute ischemic stroke such as anxiety, respiratory compromise, neurosensory alterations, hemodynamic instability, possible traumatic injuries from falling, and even the fear of death. Stressors can also affect family members by increasing fear and anxiety about the potential outcome of their loved one. These stressors are further compounded by any variation from desired outcomes of successful reperfusion of ischemic brain tissue.

The Neuman Systems Model was chosen as a framework for this study because it portrays the client in a wholistic manner with the concepts and processes being applicable to many diverse areas of study. Healthcare providers serve as the advocates and implementers of new lines of defense to protect the patient's lines of defense from the many stressors the body is exposed to (Neuman, 2010). By participating in this study, the desired outcome is that the

information gathered will serve to prevent further complications and stressors on adult patients suffering an acute stroke in the future.

### III. Research Participation – Study Overview

The study design is a prospective observational study of the hemodynamic variations during intubation and airway management of identified MERCI procedure candidates and was reviewed and approved by the Institutional Review Board. The target number of subjects for this study is a total of 25, however there have only been nine cases included to date. Inclusion criteria are that the patient must be 18 years of age or older and must be diagnosed with an acute ischemic stroke with the plan of proceeding with attempted mechanical revascularization of an occluded cerebral vessel. Whether the procedure was successful or not is not part of the criteria. Exclusions include patients under age 18, patients that were not intubated, or patients that were intubated prior to arrival in the emergency department.

Whenever a patient suffering from an acute stroke presented to the emergency department and was identified as a candidate for a MERCI procedure, an arterial line was placed by a specially trained critical care nurse as per hospital protocols (which included a signed informed consent for the invasive procedure when a family member was available). This arterial line provided the ability for accurate, invasive, and real-time blood pressure monitoring. With the line in place, blood pressures were recorded every five minutes from the time period just prior to intubation up until one hour after the patient's arrival to the intensive care unit following the MERCI procedure. Additionally, blood pressure measurements were taken every two minutes during the first 10 minutes post intubation and more frequently if the patient's condition warranted. Finally, blood pressure measurements were recorded daily throughout the duration

of the admission. An integral part of the initial and on-going patient evaluation was the calculation of the National Institute of Health Stroke Scale (NIHSS), which is internationally recognized as a standard scale among neurologists, emergency medicine physicians, and stroke research nurses and is valid for predicting lesion size on brain CT scans (Brott, 1994).

Data collection relies mainly on nursing records for daily vital signs after the initial phase of collection. Patient demographics, initial NIHSS, risk factors for stroke as per the American Stroke Association (2012), electrocardiogram interpretation by the emergency department physician, baseline lab values, and arterial blood gases were all to be obtained and recorded on a standardized data collection form. Also recorded was the actual intervention performed (i.e. the specific vessel where embolectomy was performed) as well as the final diagnosis at the time of the patient's discharge from the hospital. All forms and other documents with patient identifiers were kept in a secure location, accessible only to study investigators. There will not be any protected health information included in this or any other publication regarding this study.

Another component of the study is retrospective analysis of other factors that may increase adverse outcomes of patients following an acute stroke such as hypertension, diabetes, and obesity. Respiratory failure and failure to wean from mechanical ventilation were also evaluated. Other factors investigated incorporate the development of nosocomial infections while in the hospital and the development of a hemorrhagic component in the patient's brain post MERCI procedure.

Statistical analysis of the data collected in this study has not yet been finalized as the primary investigators are awaiting a greater sample size. However, the initial data from the nine patients studied so far has been reviewed and shows a dramatic rise in mean arterial pressure (172% increase over the baseline), followed by a significant decrease (12%) in mean arterial

pressure (MAP) while in the emergency department awaiting transport to the endovascular lab. Sedation with various medications continued during the MERCI procedure on all patients and all nine had an average MAP that was 101% above the baseline pre-intubation measurement.

While these are still preliminary findings, early analysis supports there are significant variations in MAP during the airway manipulation of patients suffering an acute stroke. These variations place the cerebral tissue of already compromised patients at an even higher risk of ischemia (Devlin, 2012). It is the goal of the researchers that once completed, this study will prompt the careful design of new intubation and sedation protocols specifically tailored toward the acute stroke patient.

#### IV. Evaluation

Being a part of active research in a major health care facility is quite a challenge on many fronts. There is a large amount of groundwork even in a prospective study such as this where there is only one group being observed. If there were a control group and an intervention group being studied this would surely compound the difficulty of data collection and analysis. There was a sizable component of research ethics education required by the institution prior to being a part of any research activities which was actually very helpful in refreshing past things that had been learned in prior courses. This education was completed in an online continuing education format and provided by the institution at no extra cost to researchers.

Perhaps the most notable finding throughout this project is the time span and dedication required to complete a project of this depth. There was a great amount of time spent by the primary investigator (PI) and his assistants drafting the IRB proposal, identifying patients, obtaining consent for enrollment in the study, following the patients throughout their hospital

course, and performing data analysis. The PI plans to present this study at neurological conferences in the coming months with the objective of disseminating the findings and gathering momentum for continued research in this area. It is apparent that processes of mechanical embolectomy such as the MERCI are the future of aggressive and life saving stroke treatment and must continue to be revised and improved as further research is done.

There are several limitations noted in this study. The small sample size is suboptimal, however once the full enrollment of 25 cases is reached this will somewhat improve. Another limitation is the fact that this is solely an observational study without a group of non-intubated patients to compare outcomes, but this could become a suggestion for further studies.

Overall, this has been a very valuable, educational, and insightful journey into the realm of active, real-world research. A project such as this will be extremely applicable and practical in the critical care environment that I am preparing to enter as a nurse practitioner. As complicated and labor intensive as research can be, it is clear that the nursing and medical profession could not function and improve without it and the utilization and application of research has become an integral part of my professional practice.

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