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Advantages and Limitations of Anesthesia and Sedation Practices Used Among Acute Ischemic Stroke Patients during Endovascular Revascularization Therapy

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DNP Project

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Abstract

In order to safely and efficiently perform endovascular revascularization procedures among acute ischemic stroke (AIS) patients, general anesthesia or sedation is often required. However, anesthesia management during these procedures varies significantly worldwide and the procedural logistics have not been established yet. At some institutions AIS patients are intubated and paralyzed, while at other facilities, there is no routine protocol. In 2011 the University Hospital used “action nurses” (critical care float pool nurses) to provide pharmacological paralysis with sedation for intubated AIS patients under direct supervision of the neurointerventionalist. However, clinical outcomes among AIS patients undergoing endovascular procedures were poor. Exclusive utilization of the anesthesia team services for this patient population regardless of the anesthesia management modality chosen (sedation vs. general anesthesia) was introduced in November 2012. Implementation of this project helped to improve functional outcomes (as measured by a modified Rankin scale) among AIS patients undergoing endovascular revascularization therapy by 26.5% at 30-days follow up as compared to previous.

Keywords: acute ischemic stroke, general anesthesia, sedation, endovascular, revascularization, intra-arterial, thrombolysis, interventional neuroradiology, mechanical thrombectomy

Introduction

Background Knowledge

Stroke continues to be the leading cause of death and disability in the United States. Annually, approximately 800, 000 people experience a new or recurrent stroke with an estimated mortality rate of 53%-92% (Arnaout et al., 2012). Until recently, the only available treatment choice for acute ischemic stroke (AIS) has been intravenous (IV) tissue-type plasminogen activator (tPA) administration. Lately, new endovascular treatment options for AIS are evolving. Among them are intra-arterial (IA) thrombolysis with tPA and endovascular mechanical thrombectomy.

Endovascular treatment options for AIS are among the least common procedures that neurointerventionalists perform, with approximately eight procedures per year per stroke center (Meyers et al., 2011). Intra-arterial tPA administration continues to be an off-label procedure that must be delivered within six hours of symptoms onset. Moreover, it is associated with serious complications, such as intracranial hemorrhage and ischemic complications. Recently, there is an explosion of studies analyzing mechanical devices, that can be used beyond the six hour window (≤ 8 hours for anterior circulation vs. ≤ 24 hours for posterior circulation strokes) and promise improved patient outcomes (Soize et al., 2012).

As study of treatment options for AIS patients expands, it is important to evaluate the management of these patients during endovascular revascularization procedures. In order to safely perform these interventions, patients often require anesthesia or sedation; however, anesthesia management practices during intra-arterial revascularization procedures vary significantly. At some institutions, AIS patients are intubated and paralyzed, while at other facilities, there is no routine protocol (Nichols et al., 2010).

In most cases, the preference of the neurointerventionalist performing the procedure dictates the choice and this choice is usually based on his/her experience and comfort level (Abou-Chebl et al., 2010). There is a paucity of high-quality data in the medical and nursing literature regarding the most optimal anesthesia clinical practices that should be implemented during these procedures.

Local Problem

Endovascular revascularization procedures for AIS, especially off-label use of endovascular thrombolysis with tPA, continues to be rare and controversial due to the potential risk of intracranial hemorrhage and other procedure-related complications. At the same time, the logistics of the procedure delivery have not yet been established (Arnaout et al., 2012). The choice of conscious sedation versus general anesthesia (GA) must be considered carefully based on the knowledge of the procedure, the patient history, and limitations of each of the anesthesia techniques (Table 1). In some AIS patients, intubation is necessary due to severe agitation or for airway protection (Avitsian & Somal, 2012). However, “the role of an anesthesiologist in acute ischemic stroke management extends far beyond providing an immobile patient to minimize fluoroscopic artifacts” (Avitsian & Somal, 2012, p. 524). Regardless of the choice of anesthesia technique, intra-procedural management of the patient’s hemodynamics (blood pressure, cardiac arrhythmias), airway and procedural complications by the neuroanesthesia expert could be vital to the AIS patient’s outcomes and survival.

At the author’s institution, if an endovascular revascularization procedure is recommended for AIS, the patient is intubated in the Emergency Department (ED) and transferred to the Interventional Radiology (IR) suite. Pharmacological paralysis combined with sedation is provided by an ER or ICU float pool RN (“action nurse’) and supervised by the neurointerventionalist. Less frequently, general anesthesia is provided by an anesthesiologist.

Each of the anesthesia management techniques has its advantages and limitations Limitations specific to this facility's protocol include using an "action nurse," who is not an expert in handling this level of responsibility. Frequently, an action nurse has never participated in this type of procedure before; therefore, s/he might not be familiar with the routine and expectations of the interventional neuroradiologist performing the intervention. As a result, the nurse might not be comfortable with communicating unexpected procedure-specific complications (i.e. hemodynamic changes) with the neurointerventionalist effectively and in a timely manner. Moreover, s/he might not be aware of the potential complications or how to manage them, especially since these endovascular interventions are uncommon and there are no clear guidelines for hemodynamic management of AIS patients. Last year, there were nine endovascular revascularization procedures performed at the author's facility. This number is close to the national average.

Another concern is that ER/ICU float nurses are not always experts in managing optimal blood pressure among AIS patients, and appropriate management of blood pressure is crucial among this patient population. Blood pressure should not be higher than 185/105 with thrombolytic therapy (Shaikh, 2010). At the same time, "the rapid lowering of blood pressure could be detrimental" (Lee et al., 2004, p. S15). According to Leonardi-Bee et al. (2002), "for every 10 mmHg of systolic blood pressure below 150 mmHg, the risk of early death increased by 3.6% and the risk of late death and dependency increased by 17.9%" (Grise & Adeoye, 2012, p. 133). On the other hand, "for every 10 mmHg increase in systolic blood pressure above 150 mmHg the risk of early death increased by 3.8%" (Grise & Adeoye, 2012, p. 133). The target pressure (20-30% above the patient's baseline on admission to the emergency department) should be achieved gradually to maintain cerebral perfusion pressure (Lee et al., 2004). Therefore, continuous monitoring of blood pressure with an arterial line is ideal. However, in cases of sedation provided by an RN at the author's facility, a radial arterial line is usually absent. Instead a manual blood pressure measurement is taken every five minutes.

While the neurointerventionalist is fully focused on a time-sensitive procedure ("time is brain"), it would be helpful and safer for the patient to have an anesthesia expert be responsible for hemodynamic management rather than a sedation RN, who has to rely on verbal orders provided by the neurointerventionalist and does not always have up to date knowledge, especially when considering a paucity of data supporting blood pressure management in the early stages of AIS (Grise & Adeoye, 2012). Although endovascular revascularization procedures among AIS patients are still rare, there are other elective and emergency neuroendovascular procedures, such as intracranial aneurysm and arteriovenous malformation embolization, pre-operative embolization of vascular tumors, angioplasty and stenting of the intracranial vessels, that neurointerventionalists perform. All of the above neuroendovascular interventions, are always performed with the involvement of the anesthesia team at the author's institution. Moreover, the anesthesiologists/nurse anesthetists at the author's facility are responsible for managing the patients undergoing open vascular and neurovascular surgeries. Therefore, with no doubt the anesthesia team has a higher expertise in the anesthesia management of AIS patient population when compared to sedation nurses.

The above issue also applies to the management of cardiovascular complication encountered during an endovascular intervention, such as cardiac arrhythmias, cardiac ischemia, bradycardia and heart failure. “Myocardial injury can occur immediately preceding AIS (eg, causing cardioembolism), concurrent with AIS (eg, myocardial infarction), or as a result of sympathetic relative hyperactivity and catecholamine release caused by AIS” (Coplin, 2012, p. 552).

Moreover, the AIS patient population itself is a challenge as far as hemodynamic management is concerned. Most of these patients are elderly and have multiple medical comorbidities, such as atrial fibrillation, hypertension, hyperlipidemia, coronary artery disease, heart failure, diabetes mellitus and obesity (Coplin, 2012). The most frequent etiology of cardioembolic cerebral infarction includes “atrial fibrillation, recent myocardial infarction, mechanical prosthetic valve, dilated cardiomyopathy and mitral rheumatic stenosis” (Arboix, A. & Alio, J., 2012, p. 54). “In adults over 55 years of age, the lifetime risk for stroke is greater than 1 in 6” (Roger, V.L. et al., 2012, p. e101). In addition, there is often a scarcity of knowledge of the patient’s history and fasting status, as these procedures are typically performed on an emergent basis (Young, 2007). These factors raise the level of risk associated with anesthesia and justify the presence of an anesthesiologist during endovascular procedures. Due to the above cardiac risks among AIS patients, their fluid and electrolyte balance should be closely monitored during the procedure, especially in patients with a history of heart failure, fluid overload should be avoided. Because of their risk factors for coronary artery disease and stroke, a large percentage of these patients are managed at baseline with either single (aspirin) or dual antiplatelet prophylactic therapy (aspirin and plavix). A combined antiplatelet therapy with plavix and aspirin prior to the onset of AIS, increases significantly these patients’ risk for a symptomatic intracranial hemorrhage, especially if on the top of that they also receive either IV and/or intra-arterial tPA therapy for AIS treatment (Tarlov et al., 2012).

There is also evidence available that shows a correlation between hyperglycemia during the acute phase of stroke and poor outcome with endovascular revascularization therapy (Tarlov et al., 2012). Therefore, hyperglycemia should be avoided and blood glucose level checked routinely during the acute phase of ischemic stroke. The above points are additional reasons to have a member of the anesthesia or neurocritical care team to monitor and manage these patients during the endovascular revascularization procedures.

Probably the strongest contra-argument against using sedation nurses during AIS endovascular procedures is their ability to manage the airway in non-intubated patients. Despite the findings of a few retrospective studies revealing possible worse outcomes with intubation during AIS endovascular revascularization procedures, intubation is unavoidable in specific clinical situations, particularly when the patient is agitated or unable to protect his/her airway. Adding a prolonged supine position and unknown fasting status of these patients increases the risk of pulmonary aspiration and hypoxia during the procedures with conscious sedation. Sometimes, emergent intra-procedural intubation is required due to the patient's agitation, oversedation, or decline in the patient's neurological status (Froehler et al., 2012). The sedation provided by sedation nurses and supervised by a neurointerventionalist, usually is light or moderate, and not deep sedation; unless, the patient is intubated and pharmacologically paralyzed. Deep sedation without intubation requires skills in advanced airway management and intubation. Neither the sedation nurse nor neuroproceduralist, is adept at rapid intubation as it is outside their typical practice focus. "Emergent conversion to GA during the endovascular procedure could result in patient injury from endovascular devices, hypoxia, or aspiration and necessitates the presence of a practitioner skilled in endotracheal intubation" (McDonagh et al., 2010, p. 3).

In addition, a remote location of the Interventional Radiology suite, far from the main operating rooms, decreases the chances of a rapid response from the anesthesia team, especially when the procedure takes place during off hours (Froehler et al., 2012). Therefore, having the anesthesia team from the beginning of the endovascular procedure provides the patient and neurointerventionalist with the most optimal scenario, since the anesthesiologist can facilitate different levels of sedation and emergently intubate the patient, if necessary, without significantly delaying the opening of the occluded vessel. Having anesthesia experience and frequent practice in airway management clinical scenarios translates into faster revascularization treatment.

Making a decision regarding a request for anesthesia vs. a critical care float pool nurse takes additional time and "time is brain." Sometimes, while waiting for an action nurse, the patient's condition deteriorates, and an anesthesiologist is required to provide general anesthesia for this patient. Additional waiting lowers the patient's chances for a good outcome (Meyers et al., 2009).

Introduction of this protocol made a decision regarding the choice of anesthesia management easier and eliminated additional steps in the process allowing the institution to improve performance measures (eg. time from arrival to femoral puncture for intra-arterial thrombolytic infusion and/or mechanical recanalization therapy). Currently, a request for the anesthesia team is placed as soon as the Emergency Department knows about potential arrival of the patient with AIS.

Intended Improvement/Purpose of Change

The proposed change was the creation of a standard anesthesia management protocol for endovascular revascularization procedures among acute ischemic stroke patients that would always be provided by anesthesia services, but the type of anesthesia would be chosen based on the clinical presentation. This required classifying a revascularization procedure as a neurologic emergency; therefore, the anesthesia team had to be available within 15 minutes from the time request had been made.

By December 1, 2013 the University Hospital improved functional outcomes (as measured by a modified Rankin scale) among acute ischemic stroke patients undergoing endovascular revascularization procedures by 26.5% at 30-days follow up as compared to the outcomes from 2011. The chosen objective was as follows:

> Creation of a standard anesthesia management protocol (monitored anesthesia care vs. general anesthesia) for endovascular revascularization procedures among acute ischemic stroke patients, provided exclusively by a member of the anesthesia team. Anesthesia choice is based on a clinical presentation and determined by collaboration between the stroke neurologist, neurointerventionalist and anesthesiologist.

These were two available options:

Option #1

Status quo: continue current process. Unfortunately, the clinical outcomes of AIS patients who have undergone endovascular revascularization procedures at the University Hospital are poor, their length of stay is prolonged and the healthcare cost associated with providing care to these patients is high.

Option #2

Implement a standard anesthesia management protocol during endovascular revascularization procedures. This process would help to start these interventions in a timely-manner (“time is brain”), aim to improve the functional outcomes among AIS patients, decrease the length of hospital stay and lower the healthcare costs.

Review of the Evidence

Findings from a few recent retrospective studies have suggested a correlation between general anesthesia (GA) and poor clinical outcomes among AIS patients undergoing endovascular revascularization therapy (Davis et al., 2012). This data, however, must be analyzed carefully as patients with more severe stroke (higher National Institutes of Health Stroke Scale [NIHSS] score) were more likely to be included in the general anesthesia group (Nichols et al., 2010). Also, while reviewing these findings, one can notice a chronological trend toward more detailed description of the anesthesia management logistics. The newer studies, although still retrospective, provide a clear definition of conscious sedation, including the type of medications used and their dosages, as well as specify who administered conscious sedation (anesthesia team vs. non-anesthesiologist). So far, however, there is no research available analyzing the outcomes between two groups of AIS patients; those who have been managed by the anesthesia team vs. those who have been managed by the non-anesthesiologist (eg. sedation RN with supervision of a neurointerventionalist).

In a restrospective study by Jumaa et al. (2010), the authors compared the outcomes of endovascular revascularization therapy in two groups of consecutive AIS patients. One group underwent the above procedure with conscious sedation without intubation (non-intubated state-NIS), while the other group of patients was intubated (intubated state-IS) with general anesthesia. The authors found that length of stay in the intensive care unit was longer for the general anesthesia group (6.5 vs. 3.2 days, p=0.0008). Moreover, the rate of intraprocedural complications was lower among nonintubated patients as compared to the intubated group (6% vs. 15% respectively, p= 0.13); however, the difference was not statistically significant. Also, there were no significant discrepancies found in clinical outcomes and final infarct volumes on follow up imaging between the two anesthesia management techniques. Regardless of the anesthesia management modality (intubated state vs. nonintubated state), all procedures in this study were performed with the involvement of an anesthesiologist.

Another retrospective study by Davis et al. (2012) attempted to identify possible causes of poor outcome among AIS patients who had undergone endovascular revascularization procedure with general anesthesia vs. local anesthesia/sedation. The authors reviewed the medical records of 129 patients, who had received treatment between January 2003 and September 2009. The study group included 96 out of 129 patients for whom 3 months post-stroke outcome scores measured with the modified Rankin Scale (mRS) were available. The choice of anesthesia modality was a result of collaboration between the neurologist, radiologist and anesthesiologist. In cases of local anesthesia, light conscious sedation with IV midazolam and fentanyl was provided by the stroke neurologist. As soon as deep sedation was needed, the patient was intubated and light general anesthesia was delivered by an anesthesiologist. Some of the reasons for intubation were pre-intervention aspiration, airway obstruction, or worsening in the patient's level of consciousness.

In addition to anesthetic technique, Davis et al. (2012) analyzed other functional outcome predicting variables, such as patient's age, comorbidities, the baseline stroke severity (NIHSS score), blood pressure, blood glucose concentration, and time interval from stroke onset to endovascular treatment. At three months post-stroke follow up, twenty two patients (23%) had no or minimal neurologic deficits (mRS 0-1), 37 patients (39%) were functionally independent (mRS 0-2), and 25 patients (26%) died. Mortality rate was higher in the general anesthesia group. After adjusting for baseline stroke severity, sedation and no incidence of hypotension (blood pressure ≤ 140 mmHg) were predictors of a good functional outcome. The authors reported a good functional outcome in fifteen percent of patients managed with general anesthesia, as opposed to sixty percent of patients who were managed with sedation ($p < 0.001$).

In a prospective, small size sample (36 patients) study by Soize et al. (2012), the investigators attempted to analyze the feasibility, safety and efficacy of endovascular mechanical thrombectomy with a Solitaire FR device under conscious sedation among AIS patients, who presented with NIHSS score ≥ 8. The study sample included consecutive patients with AIS caused by occlusion of a large artery (≤ 6 hours for anterior and ≤ 24 hours for posterior circulation). The primary outcomes measured at 3-months follow up were mortality rate and functional outcome. Twenty two patients (61.1%) presented at 3-months follow up with good functional outcomes and ten patients (27.8%) had a poor outcome or died. Successful revascularization was accomplished in twenty eight (77.8%) patients. The anesthesia team was used only in “severe cases,” the definition of which was not provided; whereas conscious sedation with IV midazolam was administered by the stroke neurologist.

McDonagh et al. (2010) studied anesthesia preference for endovascular revascularization therapy among AIS patients by surveying members of the Society of Vascular and Interventional Neurology (SVIN) with a 12-question review. Response rate was high at 72% (n= 49/68). As reported by survey respondents, the most frequently used anesthesia type was general anesthesia (GA), followed by conscious sedation (nurse administered), then monitored anesthesia care (MAC) administered by the anesthesia team, and finally local analgesia alone. Preference for GA was associated with a type of endovascular procedure. Mechanical thrombectomy was most frequently associated with a request for GA (55% of respondents). General anesthesia was a preferred practice for patients with a NIHSS score >15 (53% of respondents) and patients with brainstem stroke (51% of respondents). More than half (50.3%) of respondents felt strongly than any mechanical manipulation, such as angioplasty and/or stenting required GA. Eliminating patient's movement, perceived procedural safety and improved procedural efficacy were additional reasons for choosing GA. Limitations of GA included: time delay, cerebral ischemia as a result of hypoperfusion, and lack of adequate anesthesia workforce.

Nichols and colleagues (2010) retrospectively analyzed procedural sedation among patients from the Interventional Management of Stroke (IMS) II trial. Patients with moderate to severe (NIHSS >10) anterior circulation strokes, who underwent conventional cerebral angiogram and/or intra-arterial revascularization were included in this study. While conducting IMS pilot trials I and II, the authors noticed a high level of variation in use of peri-procedural sedation. In addition, they observed an absence of a standard anesthesia/sedation protocol for AIS endovascular procedures. Therefore, the emphasis of this retrospective study was the level of sedation used during the endovascular procedures, its association with patient outcomes and factors that influenced the level of sedation. Out of 75 patients who met the inclusion criteria, 40 (53%) received no sedation and 17 (23%) were pharmacologically paralyzed. A higher sedation level was used for patients with aphasia, internal carotid artery occlusion and in patients with longer procedure times. Baseline NIHSS score varied widely between the different levels of sedation ($p = 0.03$). Lower levels of sedation and male gender were correlated with good clinical outcome. The highest level of sedation, including pharmacological paralysis, was an independent predictor of death. Mild or no sedation, and no internal carotid artery occlusion were predictors of successful reperfusion. The study found a significantly higher level of infection (pneumonia and/or sepsis) in patients who received heavy sedation ($p = 0.02$). High sedation level remained a predictor of poor clinical outcome and death even after baseline NIHSS score was accounted for in multivariable analysis. Besides a retrospective design and small sample size, Nichols and colleagues (2010) were not able to precisely identify the types of anesthesia medications used, the duration of the treatment, the times of administration in relation to the angiographic procedure, and the route of administration. The authors did not specify who provided the anesthesia management during the procedure.

Abou-Chebl and colleagues (2010) sought to examine the relationship between the type of anesthesia used during endovascular therapy for AIS involving anterior circulation, and patient safety and outcomes. The authors studied retrospectively a group of 980 patients at twelve stroke centers in the United States, who underwent endovascular therapy for AIS between 2005-2009. A total of 428 (44%) patients were placed under GA before the procedure started. The general anesthesia group was more likely to have distal carotid occlusion (25% vs. 15%, $p < 0.01$) and higher NIHSS scores on admission (17 ± 5 vs. 16 ± 6, $p < 0.01$) compared to the conscious sedation group. Even after the study results were adjusted for age, initial NIHSS score, time to femoral artery puncture, time to vessel opening, recanalization outcome, and intracerebral bleeding complication, patients placed under GA were at significantly higher risk of a poor outcome. This study concluded that conscious sedation seemed to be as safe as GA with respect to the procedural complication of intracranial hemorrhage (Abou-Chebl et al., 2010). However, not controlling for comorbidities, patient clinical status and endovascular techniques, are some of the limitations of the study. Furthermore, the investigators did not address the issue of emergency intubation since they could not differentiate between the group of patients who were intubated before the procedure and those who were intubated emergently during the procedure. A clear definition of conscious sedation and who managed it was not provided in the study methodology.

In the most recent study by Li et al. (2013), the researchers were attempting to analyze the impact of the anesthesia technique on mortality rate among AIS undergoing endovascular revascularization therapy between December 2006 and October 2012. In their retrospective investigation they compared two groups of patients: general anesthesia group (N= 35) vs. conscious sedation group (N= 74). They found that general anesthesia and post-procedural hyperglycemia (blood glucose > 200 mg/dL) were the most important predictors of mortality (mortality rate 40% vs. 22% when comparing general anesthesia vs. conscious sedation group, p= 0.045). The time from AIS symptoms onset to recanalization and the length of endovascular revascularization procedure were longer in the general anesthesia group. There were no statistically significant differences between general anesthesia and conscious sedation groups as far as procedure-related complications (p= 0.997) and the patients' functional outcome at discharge (p= 0.631). However, a 90-day clinical follow up could provide more information regarding a long-term outcomes. Although the rate of pneumonia was higher in general anesthesia group (21% vs. 16% in conscious sedation group), it had not been associated with a higher morbidity or mortality based on this study findings. Only patients treated with Merci retriever and Penumbra thrombectomy devices were included in this study. The procedures performed with the latest generation of stent-retriever technology, which are superior in performance when compared to the old generation devices (eg. Merci retriever), were not included in this study. Before 2011, general anesthesia was used at this institution routinely for all patients undergoing endovascular treatment for AIS. It has changed after 2011as neurointerventionalists had become more familiar and comfortable with using conscious sedation for AIS patients during endovascular therapy procedures. The retrospective study design, lack of randomization and small sample size are the major limitations of this study.

Conceptual/Theoretical Framework

The healthcare environment is a chaotic, complex adaptive system, made up of multiple diverse, but interconnected elements. Therefore, a Chaos Leadership Theory was chosen as a conceptual framework to help guide the author of this project in achieving set goals.

The first step to success according to this theory is a leadership style that “focuses less on prediction and control and more on fostering relationships and creating conditions in which complex adaptive systems can evolve to produce creative outcomes” (Burns, J., 2001, p. 474). A complexity-based leadership approach is found on the assumption that employees of a healthcare organization have the ability to self-organize and to produce desired outcomes despite providing an impression of chaos. The relationships among the employees are more important than the employees themselves in order to achieve expected results. The author of this project created a general vision of the process change while providing reasons for it, without planning every detail of the change. According to complexity theory, leaders who raise questions that have no obvious answers (like the one in this project: *What is better, general anesthesia vs. sedation for endovascular revascularization procedures among AIS patients*), create tension and anxiety, which may lead to increased creativity and innovation (Burns, 2001). Publishing a manuscript by the author on the same topic started a public discussion and motivated researchers and healthcare organizations to study this issue even further.

According to complexity theory, “organizations that are learning should start small, experiment to find the small things that work, and then link the successful pieces together into more complex systems” (Burns, J., 2001. p. 479). The clinical outcome of an AIS patient, who undergoes endovascular revascularization therapy might be affected by a multitude of factors, type of anesthesia being just one of them. However, if we control for some of these confounding variables by providing the highest currently available standards of care (anesthesia team for all AIS patients regardless of the anesthesia management technique chosen), we will be able to establish procedural logistics sooner.

Methods

Ethical Issues

Claiming that nursing colleagues do not have enough skills and knowledge to provide procedural sedation to AIS patients during endovascular revascularization procedures was the main ethical dilemma that the author had to face as a result of this project implementation. It created some tension and animosity among staff nurses. On the other hand, it helped other nurses who shared the author’s point of view with their moral distress. According to complexity theory, however, whenever there is a controversy, it creates a tension that leads to increased creativity and self-organization.

A further ethical issue associated with this project pertained to allocation of resources. Reclassification of endovascular procedures for AIS as a neurological emergency takes the anesthesia team away from the patients who were scheduled for elective procedures. There were times that elective procedures had to be rescheduled and postponed. The question of who should explain the reason for procedure/surgery cancellation to the patients was also raised. However, maintaining the status quo also produced an ethical dilemma. There is a close association between nursing goals and ethics. Underlying nursing practice is the intention to do good, avoid harm, commit to and protect the patient, and advance social policy for the greater good (Grace, 2009). Being inadequately skilled in an intervention (incompetence), such as providing anesthesia management to patients with AIS during endovascular revascularization procedures creates an ethical dilemma that is against the American Nurses Association (ANA) Code of Ethics (Grace, 2009). It violates the principles of fidelity, patient advocacy, and protection of the patient's welfare, especially since this particular patient population is vulnerable and defenseless.

An additional ethical issue related to AIS revascularization therapy is that the procedures are costly (~$30,000-40,000), not FDA approved (off-label intra-arterial tPA administration), and currently associated with a potential serious complications (eg. intracranial bleeding). At the same time, the presence of numerous variables affecting the outcome of AIS (time to treatment, thrombus type, location and size of thrombus, proceduralist's skills, and the individual patient's characteristics, such as collateral circulation, comorbidities, age) makes the research investigation more difficult. These procedures are still rare due to lack of sufficient infrastructure supporting the rapid triage and transport of patients with AIS to stroke centers (Blackham et al., 2012). Availability of additional and stronger scientific evidence in the future could lead us to conclude that AIS patients have been undergoing low efficacy procedures with risks outweighing the benefits, and the society has been exposed to wasteful spending (the justifiable distribution of resources theory).

A separate complex ethical concept associated with this problematic clinical practice is the issue of informed consent for an endovascular revascularization therapy.

As described previously, it can be overwhelming to healthcare experts to make a decision to proceed with an endovascular revascularization procedure for AIS treatment. However, it is even more challenging to explain this procedure to a lay person, especially when it has to be done urgently and via phone. In order to do it efficiently, “we need to understand the patient’s beliefs, values, and goals; the patient’s/family’s ability to process information; and psychological, physiological, or environmental factors that might interfere with or facilitate processing of information” (Grace, 2009, p. 84). As far as religious values discussion, a potential for blood transfusion option in case of a vessel rupture would have to be disclosed to Jehovah’s Witness patient/family when obtaining an informed consent.

Despite available treatment options for AIS, only 4.3% of AIS patients receive IV tPA within the narrow treatment window, and the percentage is even smaller in regards to intra-arterial treatment options (Jauch et al., 2013). The concept of distributive justice in relation to AIS medical management could be related to limited public and healthcare provider recognition of early stroke symptoms, and limited access to stroke centers. One of the studies revealed a delay in initiation of endovascular therapy among patients who were transported from a community hospital, as opposed to those who were transferred directly to a comprehensive stroke center (El Khoury et al., 2012).

Setting

The project implementation took place at the University Hospital, a major academic health center, which is an approximately 630-bed level I trauma center for both adults and pediatric patients, and an advanced primary stroke center certified by the Joint Commission in July 2009. The facility provides 24/7 access to the Interventional Neuroradiology suite, where endovascular revascularization procedures for AIS can be performed. It has two neurointerventionalists on staff, who rotate taking calls. One of them obtained training in Diagnostic and Interventional Neuroradiology; the other is a neurosurgeon with additional preparation in minimally invasive neuroendovascular procedures. This facility has been characterized by satisfactory nursing staffing ratios protected by union rules. The institution's radiology nurses and angiography technologists take call during off-shifts and are available continuously, if needed for a variety of emergency cases. At the same time, there is a shortage of anesthesiologists, which initially posed a threat to a success of this project.

There were multiple stakeholders involved in this project including the Emergency Department, Neurology, Radiology (CT, MRI), Interventional Neuroradiology, Anesthesia, and the Quality Management Departments. These are separate and semi-autonomous work units that are loosely coupled and specialize in different areas of care delivery. Organizational loose coupling can limit the flow of information and make it difficult to coordinate services for AIS patients (Pinelle & Gutwin, 2006). For this reason, the facility organized the stroke committee with regular meetings taking place every three months and led by the Stroke Program Director for periodic evaluation of care provided to AIS patients and their outcomes. During each meeting the hospital stroke committee made recommendations for future improvement of processes based on the available outcomes of AIS patients.

Planning for this project took place at the same time as the hospital's submission processes for Magnet status. Therefore, the timing for it could not have been better since every administrator, manager and staff nurse was actively involved in a variety of the evidence-based projects. This project and a manuscript published on the same topic were also used to help the facility to obtain Magnet recognition.

Planning the Intervention

In 2011, nine endovascular revascularization procedures for AIS were performed at the author's institution. Only one of these patients had an improvement in functional outcomes. The statistics nationwide are not more encouraging, and the average cost of the endovascular procedure is high (approximately $30,000-40,000), not including the costs of the hospital stay. Moreover, neither IV tPA, nor endovascular therapy have been found to reduce mortality from stroke (Lackland et al., 2014). After reviewing available literature, there was not enough strong evidence to support one method of anesthesia management vs. another. There are few restrospective studies, which compare the outcomes of endovascular revascularization therapy based on the method of anesthesia management. Current evidence is not sufficient to guide the choice of anesthesia for endovascular revascularization interventions in patients with AIS (Flexman, Donovan & Gelb, 2013).

In one of the recent studies, Jumaa et al. (2010) found that length of stay in the intensive care unit was longer in the intubated patient group (6.5 vs. 3.2 days, $p = 0.0008$). Moreover, the rate of intraprocedural complications was lower among nonintubated patients as compared to the intubated group (6% vs. 15% respectively); however, the difference was not statistically significant ($p = 0.13$). Also, there were no significant discrepancies found in clinical outcomes and final infarct volumes on follow up imaging between the two anesthesia management techniques. Worth noticing is the fact that all procedures in this study were performed with the involvement of an anesthesiologist.

If prospective randomized trials continue to support moderate sedation as the anesthesia of choice for endovascular procedures, the current use of “action nurses” at the author’s institution would remain problematic as they are not the experts in airway management and hemodynamic stabilization. These situations require the presence of an expert anesthesiologist for airway protection, emergent intubation, optimal hemodynamic control, and prompt management of intra-procedural adverse events, such as reperfusion injury, acute cerebral ischemia, ventricular arrhythmias, bradycardia, myocardial ischemia, and pulmonary aspiration (Lee et al., 2004).

Although anesthesia resources are scarce at the author's institution, AIS patients deserve the same attention as trauma surgery patients do, since delay in intervention could result in the patient's death or severe disability. Therefore, the same process for the anesthesia team request should apply to both trauma surgery as well as acute ischemic stroke, even if elective surgeries/procedures have to be postponed.

Based on above market analysis, outcome results of the endovascular revascularization procedures among AIS patients at the author's institution, and a review of the related literature, there was an obvious need for a change and process improvement. The proposed change was the exclusive utilization of anesthesia services for endovascular revascularization procedures among AIS patients regardless of the used anesthesia management modality (sedation vs. general anesthesia). Anesthesia choice would be based on clinical presentation and determined by collaboration between the stroke neurologist, neurointerventionalist and anesthesiologist. Once endovascular revascularization was recommended, the anesthesia and Interventional Radiology staff would be notified, so they could start preparation for the procedure.

The leadership of this project had hopes that implementation of this new anesthesia protocol would improve the outcomes of the AIS patients undergoing endovascular treatment, decrease the length of hospital stay, and result in financial savings to the facility as illustrated in *Appendix B*. The costs associated with the proposed project were related solely to anesthesia professional and technical fees. These expenses vary depending on the type of anesthesia modality used (monitored anesthesia care vs. general anesthesia). Any surgery/procedure over four hours, where a general anesthetic is used costs approximately $7,300; whereas, monitored anesthesia care costs are approximately $3,530 for the same length of time. Placement of an arterial line (recommended for this procedure) or central line during a procedure also raises costs. In comparison, costs for one day of stay in a Neurosurgical Intensive Care Unit (room rate) are approximately $17,000. Therefore, if the length of stay in the Neurosurgical Intensive Care Unit was reduced by one day only, the cost of anesthesia would be covered, and the hospital could even save money ($17,000- $7,300= $9,700 per procedure). Multiplying $9,700 times 9 (number of endovascular revascularization procedures performed at the University Hospital in 2011), would bring $87,300 in savings annually.

The process of a 30-day follow up for the functional outcome evaluation among AIS patients and monitoring of endovascular revascularization procedures complications has not changed as a result of this project implementation. A follow up has been performed by the Neurology service in collaboration with the Quality Management department. Therefore, there was no change to this process and no additional costs associated with it. The project implementation took approximately one year (November 1, 2012 to December 1, 2013). A detailed work breakdown structure is presented in *Appendix C*. The evaluation process of the project still takes place, and improvements are being made. It is a constant work in progress.

Implementation of the Project

The implementation of the above process change started on November 1, 2012, after approval by the hospital administration. Before its initiation, the project plan proposal was presented to all stakeholders (Interventional Neuroradiology faculty, Interventional Radiology management, Stroke Program Director, Chair of Anesthesia Department, Emergency Department management, Quality Management Department and Stroke Committee). Stroke Committee meetings were the main source of communication between all stakeholder. The patient's follow up and outcome evaluation at 30 days (either in person or as a telephone interview) has been conducted by the Neurology service (similarly to 2011) and data for the study period between 11/01/2012 and 11/01/2013 was presented to all stakeholders at the end of the project implementation (December 2013).

Project implementation was discussed at each Stroke Committee meeting (on average meets every three months). Suggestions from Stroke Committee members were carefully analyzed and if appropriate, adjustments to the project proposal were made. The Anesthesia Chair was updated at three month intervals (more often, if needed) regarding the project progress and anesthesia issues (i.e. anesthesia delays). The Interventional Neuroradiology Nurse Practitioner (NP) presented the project proposal and its implementation date to the Interventional Radiology staff (nurses and techs). Before the project implementation, there were multiple presentations provided to the Emergency Department and critical care float pool nurses ("action nurses"), who were previously responsible for providing a sedation to already intubated and pharmacologically paralyzed AIS patients during their endovascaular stroke therapy. A detailed statement of work with scheduling plans (GANTT chart) can be found in *Appendix C*.

Planning the Study of the Intervention

A neurologist, who is the Stroke Program Director, was the leader of this project.

An administrative nurse researcher, who is accountable for the Stroke Program Clinical Operations, was responsible for collecting and presenting a summary of all stroke (ischemic and hemorrhagic) performance measures and areas for improvement at each committee meeting.

To assess how effectively the intervention was implemented, the Neuroradiology NP was assigned to monitor the following performance measures: times of patients' admission to ED or stroke symptoms onset if inpatient, start and completion times of a CT Head and/or MRI Brain diagnostic studies, time to femoral artery puncture, and time to intra-arterial tPA administration and/or time of clot crossing with a mechanical thrombectomy device. These performance measures were not documented prior to this project implementation.

A Neurology resident was responsible for monitoring the AIS patients' response to IV tPA, intra-arterial tPA and /or mechanical thrombectomy, their clinical outcomes at 30-days follow up either via phone or in person (with the assessment of a modified Rankin scale), and complications (death, symptomatic intracranial hemorrhage or ischemic stroke). Although the author's facility has the advanced primary stroke certification, the hospital is in the process of pursuing comprehensive stroke certification. Therefore, the hospital's stroke committee decided to use comprehensive stroke measures to evaluate the clinical outcomes of AIS patients.

The baseline data prior to the project implementation is very raw (does not include a clinical outcome assessment with a modified Rankin scale) and is presented in *Table 2*. In comparison, the data for the study period between 01/01/2013 and 11/01/2013 can be found in *Table 3* and reveals higher (26.5%) than the anticipated 25% improvement in clinical outcomes at 30-day follow up among AIS patients undergoing endovascular intervention after the project implementation. There was also decrease in mortality rate between 2011 and the time of project implementation (33.3 % vs. 12.5% respectively). At 30-days post-stroke follow up, three patients (37.5%) were functionally independent (mRS ≤ 2). However, the number of AIS patient undergoing endovascular revascularization therapy has decreased from 9 patients in 2011 to 8 patients during study period.

Methods of Evaluation

The primary outcome of this project implementation was the clinical results as measured with a modified Rankin scale at 30-days follow up. Neurology service performed the assessment either in-person or via phone among AIS patients who had undergone an endovascular revascularization therapy with intra-arterial tPA and/or mechanical thrombectomy with the assistance of the anesthesia team.

The following were the secondary outcomes: time from the patient's hospital arrival to femoral puncture, time from hospital arrival to the first clot crossing with a mechanical thrombectomy device or intra-arterial tPA administration, incidence of serious complications (death, symptomatic intra-cranial hemorrhage, ischemic stroke), and cost of the hospitalization. The hospital's billing department was not willing to provide the actual costs accrued during the patient's admission for AIS; therefore, the cost was roughly estimated based on the length of the hospital stay.

Analysis

Project implementation resulted in better than expected findings as there was 26.5% actual improvement vs. 25% expected improvement in clinical outcomes among the AIS patients undergoing endovascular revascularization procedures. There was no clearly reported baseline for the secondary outcomes since most of the performance measures had not been previously reported prior to this project implementation. Based on the available documentation, these were the outcomes for nine AIS patients who had undergone endovascular revascularization in 2011: three patients died, six patients had no improvement after the endovascular procedure, and one patient had a major improvement and was discharged to the Extended Care Facility in a good condition. The following were the post-endovascular procedure complications in 2011: two patients developed hemorrhagic conversion of stroke, one patient had a myocardial infarction, one patient developed nosocomial pneumonia, and one patient developed pulmonary edema and respiratory failure as a result of exacerbation of diastolic heart failure (see *Table 2*).

Between November 1, 2012 and November 1, 2013 (study implementation period) eight patients with AIS had undergone endovascular revascularization treatment. One patient died (family withdrew care due to poor neurological prognosis), three patients had good functional outcome (mRs ≤2), four patients had little or no improvement, one patient had a complication of pneumonia and sepsis, and one patient had a complication of a small hemorrhagic conversion within the left cerebellar hemisphere. *Table 3* illustrates the data and clinical outcomes after the project implementation.

Results

Program Evaluation/Outcomes

Before this project implementation, “an action nurse” (ED or critical care float pool nurse) provided sedation under the supervision of the neurointerventionalist to AIS patients during endovascular revascularization procedures. According to the institutional protocol, most of these patients were intubated in the ED and pharmacologically paralyzed during the procedure for airway protection since the “action nurses” do not have the skills to intubate the patient in cases of airway compromise. There were legitimate concerns regarding this practice expressed by radiology staff nurses as well as by the critical care float pool nurses themselves. Some of the action nurses had never previously participated in this type of procedure and felt uncomfortable managing the airway compromise and need for emergency intubation scenarios, hemodynamics of blood pressure (there are no clear guidelines available), cardiac issues (arrhythmias, ischemic changes on ECG), and potential serious procedure-related complications (intra-cranial hemorrhage, additional ischemic stroke, pulmonary edema, brain edema).

Moreover, before the project implementation there were few retrospective studies available that favored local anesthesia with light sedation over general anesthesia or heavy sedation for these procedures. These studies proclaim that patients who undergo endovascular revascularization treatment for AIS with use of light sedation have better clinical outcomes as opposed to patients managed with general anesthesia or heavy sedation. Although these studies have limitations (retrospective design and small sample size), if validated with prospective randomized trials, could have questioned in the future the utilization of the action nurses at the author's institution due to mentioned previously nursing scope of practice and skills restrictions.

Moreover, the clinical outcomes among AIS patients treated with intra-arterial tPA and/or mechanical thrombectomy have been poor, especially when a high cost of the procedure is taken under consideration ($30,000-40,000). Among nine AIS patients, who had undergone endovascular treatment in 2011, only one patient showed improved clinical status. There were times, when the procedure had to be cancelled in those managed with a light/moderate sedation by an "action nurse" due to the patient's agitation, worsening neurological status, cardiac or airway compromise with subsequent waste of already open supplies and time/cost of involved workforce (nurses, techs, anesthesia, proceduralist).

There was an obvious need for change of this questionable clinical practice of utilizing “action nurses” for procedural sedation during endovascular revascularization therapy. The change in practice was initially proposed by the Interventional Neuroradiology NP at one of the facility’s stroke committee meetings. It was supported by the Stroke Program director and the rest of the committee. The Stroke Program Director issued an official letter to the hospital administration and the anesthesia department chair. At first, there was no response. Later, concerns about an insufficient anesthesia workforce were raised. Publishing a manuscript in the “Journal of Radiology Nursing,” which described this controversial clinical issue, and sharing a copy of this article with all involved stakeholders increased their level of engagement in this project. It also started a public discussion regarding the endovascular revascularization procedures logistics. The author, who published this manuscript received a positive responses from a nationwide interventional radiology community, as well as invitations for presentations and further publishing, even from anesthesiology journals. This project also helped to improve the process of stroke performance measures documentation at the author’s facility. Moreover, it motivated the project stakeholders to proceed towards obtaining a comprehensive stroke certification. The author and Neuroradiology NP played a significant role during this project implementation. She was the initiator of this idea and worked closely with both of her neurointerventionalists, who were very supportive and wanted this project to succeed.

Having anesthesia expertise and excellent collaboration among all stakeholders through their active participation in the Stroke Committee was the strength of this project. Its weakness was a lack of adequate anesthesia workforce at the author’s institution and additional costs associated with the use of the anesthesiologists. Currently, AIS revascularization cases are considered a "neurologic emergency" at the University Hospita.l. As a result, anesthesia is readily available, even if an elective procedure has to be rescheduled/postponed. On the other hand, endovascular ischemic stroke procedures remain among the least common procedures that neurointerventionalists perform (nine procedures in 2011). Therefore, this number should not be too overwhelming to the anesthesia workforce at the author's facility. As the number of endovascular revascularization procedures grows, it might necessitate opening of an additional anesthesia position. However, it should be financially justified by the savings this project could bring to the institution. Success of this project could help create new protocols for anesthesia management for AIS during endovascular revascularization procedures, not only at the author's institution, but nationwide, and motivate researchers to conduct prospective, randomized studies on the efficacy of these costly ($30,000-40,000 per procedure) interventions (*Appendix A*, SWOT Analysis).

Despite a successful project implementation, there are still times when procedural sedation is provided by a critical care float pool nurses, if anesthesia is not immediately available. Most frequently, however, it applies to the inpatients who developed stroke symptoms while in the hospital due to different health problems. Therefore, the hospital staff directly involved in care of these patients is familiar with their past medical, surgical history, the time of stroke symptoms onset, and the patients' fasting status.

Discussion

Summary

This project implementation changed a controversial clinical practice and provided the AIS patients at the author's institution with the highest standards of care available based on current knowledge. It also helped to improve the clinical outcomes of the endovascular revascularization procedures for AIS by 26.5% within 1 year of the project implementation. Secondary gain of this project was an initiation of monitoring of the endovascular procedures outcomes and performance measures. Unfortunately, the project implementation had not decreased the length of hospital stay among AIS patients as expected. The average length of hospital stay increased during the study period as compared to 2011 (16.75 days vs. 14.9 days, respectively). However, the mortality rate was higher in 2011, and three patients from the project group developed ischemic stroke as inpatients during their hospitalization due to different reasons (cardiac surgery, renal transplant and trauma patient), which could affect their length of hospital stay.

Shortage of the anesthesia workforce at the author's facility and controversy about whether it is a "neurological emergency" were the main obstacles to this project implementation. Lack of adequate anesthesia force and associated time delays were additional constrains of this project. Having more research supporting intra-arterial tPA revascularization therapy and subsequent FDA approval would make this approach more convincing to all stakeholders worldwide. An additional anticipated threat to the project success was the patient population the author's facility serves. A significant percentage of patients admitted to the University Hospital are low income, uninsured and/or homeless. This group of patients can be easily lost to follow up. Moreover, uninsured patients can create additional financial burdens for the institution and not participate in bringing in funds to cover additional anesthesia costs.

The driving force of this project was the explosion of studies analyzing mechanical thrombectomy devices that could be used beyond the 6-hr window. Intra-arterial tPA administration continues to be an off-label procedure due to lack of sufficient scientific evidence supporting its use and it has to be delivered within 6 hours of symptoms onset. This makes an implementation of intra-arterial thrombolytic therapy more difficult.

The topic of this project is controversial and has never been analyzed from this point of view in the nursing or medical literature before. It is one of many healthcare practice issues that the author has questioned during her nursing career based on observations and experiences, in order to improve the standards of care and patient outcomes. The uniqueness of this project is its originality. While others have compared outcomes of AIS patients undergoing endovascular revascularization with sedation versus general anesthesia, no one had analyzed the differences in outcomes between two groups of patients; those managed by the anesthesia team versus those managed by the non-anesthesiologist team. Providing anesthesia management to a group of patients with a complex medical or unknown history, such as AIS patients, without being adequately skilled and familiar with Interventional Radiology, during an off-shift creates an ethical dilemma, and it is against the American Nurses Association Code of Ethics (Grace, 2009). Implementation of this project hopefully helped nurses with their moral distress and increased the patients' safety.

The author anticipates that publishing a manuscript on this topic will start a public discussion of this problematic clinical practice with the involvement of the other stakeholders and professional organizations that share the same concerns (e.g. American Heart Association). The author hopes that the positive changes this project brings will improve the AIS patients' outcomes, decrease the length of hospital stay, and finally result in reduction of total healthcare costs. Beyond the financial objectives, this project could improve the outcomes of stroke patients, and increase their independence and quality of life. The same changes could eventually be adopted by the other institutions nationwide, and perhaps worldwide.

The author believes that nurses who are educated and knowledgeable, and possess leadership skills, can increase collaboration with physicians and other healthcare providers to positively affect patients' outcomes. Moreover, nurses, who share their knowledge by publishing their findings are given credit for it. This project is an example.

Relation to Other Evidence

As mentioned previously, there are few retrospective studies (see *Appendix D*) that discuss the advantages and limitations of the anesthesia and sedation practices used for AIS patients during endovascular revascularization procedures. They attempt to convey that patients who undergo these procedures with general anesthesia, have worse clinical outcomes. However, the available evidence has its limitations such as retrospective design and small sample sizes, and should be analyzed with caution. There was a similar attempt undertaken in the past regarding patients undergoing elective carotid endarterectomy for carotid stenosis. While the initial retrospective studies favored local anesthesia, this was not validated with a prospective randomized trial, which showed no difference in outcomes between two groups of patients (Vaniyapong et al., 2013).

Conclusions

There are but a few retrospective studies that attempt to show superiority of local anesthesia with conscious sedation as compared to general anesthesia during endovascular revascularization procedures among AIS patients. Until higher quality evidence is available, monitored anesthesia care with intravenous sedation or general anesthesia (both provided by the anesthesia team), depending on the clinical situation, seems to be the safest anesthesia management plan during endovascular procedures for AIS. The anesthesia team is best equipped to handle procedural complications, if they occur. In addition, in light of controversy surrounding endovascular revascularization procedures, it is imperative to provide optimal hemodynamic management and monitoring of these patients for possible complications such as reperfusion bleeding (Leifer et al., 2011). There are so many potential contributing factors (type of anesthesia being one of them) affecting the outcomes of these patients; however, if we control for some of them, we will be able to establish procedural logistics sooner.

Further prospective research studies are needed to determine what anesthesia management is optimal for patient safety and functional outcomes, and to create standard anesthesia/sedation protocols. Also, future prospective studies are desired to compare the outcomes between two groups of AIS patients; those who have been managed by the anesthesia team vs. those who have been managed by the non-anesthesiologist.

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General Anesthesia	
Advantages: • Patient immobility • Perceived procedural safety with mechanical manipulation • Improved procedural efficacy • Better imaging (no motion artifact) • Optimal management of procedure-related complications	**Limitations:** • Time delay • Lack of adequate anesthesia workforce • Inability to monitor the patient's neurological status • Higher risk of stroke as a result of hypotension during anesthesia induction • Higher risk of cardiovascular complications
Sedation & local anesthesia	
Advantages: • Ability to start the procedure in a timely manner ("Time is brain") • Ability to monitor the patient's neurological status during the procedure and adjust the approach, if necessary • No risks of general anesthesia • Lower procedure costs	**Limitations:** • Neurointerventionalist cannot fully concentrate on the procedure • Risk of aspiration and emergency intubation • Risk of not being able to control blood pressure adequately • Risk of not being able to manage cardiac complications adequately • Higher risk of aborting the procedure and costs associated with it • Patient factor: - Patient's mobility - Non-English speaking - Hard of hearing - Severe anxiety, agitation - Aphasia, dementia - Not able to tolerate prolonged supine position (back pain, heart failure, etc.) - Inability to follow commands

Table 1. Advantages and limitations of different anesthesia management modalities

Date	**Response to endovascular therapy**	**Complications**	**Outcome**	**Length of Hospital Stay**

01/24/2011	Mercy retriever only. No recanalization. No improvement.	No complications	DC to SNF hemiplegic and aphasia	10 days
01/26/2011	Combined IV and IA tPA. Major improvement.	No complications	DC to SNF (but in very good shape)	8 days
02/24/2011	IA tPA and Mercy retriever, Unable to recanalize MCA. No improvement.	NSTEMI Exacerbation of dHF Pulmonary edema Respiratory failure Hemorrhagic conversion	DC to subacute care facility on a ventilator G-tube Tracheostomy	35 days
04/13/2011	IA tPA only. No improvement.	No complications	Died of massive stroke. Family withdrew care on 04/25/2011	12 days
06/06/2011	IA tPA only. No improvement.	No complications	DC home. Died on 07/01/2011.	21 days
06/24/2011	Received bridging dose IV tPA and IA tPA plus Mercy retriever. No recanalization. No improvement.	Nosocomial pneumonia	Transferred to Kaiser with global aphasia and dense right hemiplegia.	5 days
09/26/2011	Mechanical thrombectomy only. No recanalization. No improvement.	No complications	Left hemiplegia, dysarthria	18 days
12/07/2011	Full dose IV tPA plus mechanical thrombectomy	Hemorrhagic conversion	Patient expired on 12/11/2011	4 days
11/09/2011	IV tPA plus mechanical thrombectomy. No recanalization. No improvement.	No complication	DC to SNF with global aphasia and G-tube. Regained right upper and lower extremity movement.	21 days

Table 2. Endovascular revascularization therapy for acute ischemic stroke at the University Hospital in 2011.

Date	**Response to Endovascular Therapy**	**Complications**	**Outcome**	**Length of Hospital Stay**
11/05/2012	Mechanical thrombectomy with Trevo device Successful recanalization.	None	Full recovery. Neurologically intact. mRS≤ 1	58 days
11/15/2012	Mechanical thrombectomy with Trevo device with complete recanalization of	Small hemorrhagic conversion within the left cerebellar	DC to SNF. Oriented to self, ability to follow simple commands,	14 days

	basilar artery.	hemisphere	improved right hemiparesis. mRS= 3	
12/31/2012	Full dose of IV tPA plus mechanical thrombectomy with Trevo device. Technically successful recanalization of the basilar and right vertebral arteries.	Large right cerebellar, occipital, and thalamic strokes.	Family withdrew care due to poor neurological prognosis. Patient expired. mRS= 6	3 days
03/26/2013	IV tPA plus IA tPA administration (2 mg). Partial recanalization of basilar artery.	Pneumonia, sepsis	Transferred to Kaiser. Able to withdraw extremities to pain; opens eyes to name and light mRS= 5	2 days
04/30/2013	IA tPA administration (2 mg). No recanalization. No improvement.	None	Remained aphasic. mRS= 4	18 days
05/23/2013	IV tPA; no endovascular treatment. Recanalization of left ICA after IV tPA treatment	None	DC to SNF with right hemiplegia, dysarthria and dysphagia. G-tube placement mRS= 5	15 days
05/24/2013	IA tPA (2 mg) plus mechanical thrombectomy with Trevo device. Recanalization of left MCA M1 segment.	None	DC to assisted living facility with proximal right arm weakness; otherwise neuro exam WNL. mRS≤ 2	10 days

08/16/2013	IA tPA (2 mg) and mechanical thrombectomy with Trevo device. Recanalization of left MCA M1 segment	None	Some expressive aphasia, but no other neurological deficits. mRS≤ 2	14 days

Table 4. Endovascular revascularization therapy for acute ischemic stroke at the University Hospital between November 1, 2012 and November 1, 2013.

Appendix A (SWOT Analysis)

<u>Strengths</u>	*<u>Weaknesses</u>*
• Improved AIS patient outcomes • Higher quality of life among AIS patients (more independent, lower burden to the society) • Decreased length of hospital stay (lower costs due to shorter stay) • Rare procedures (not too	• Lack of adequate anesthesia workforce • Additional costs due to anesthesia expenses • Lengthy endovascular procedures (4-5 hours) taking more anesthesia time

overwhelming to anesthesia; 8-10 procedures/year) • Having procedure protocol and structure could decrease the time from the patient admission to femoral puncture/revascularization	• Not enough strong evidence supporting change • Rare procedures (hard to conduct randomized trials and not enough practice for NI) • Noninsured patients (additional expense to the institution)
<u>Opportunities</u> • Justification for another anesthesia position opening • Good collaboration among stakeholders (practice for future projects) • Decreased length of hospital stay (more ICU beds available) • Creation of new anesthesia protocols nationwide/worldwide • Motivation for researchers to investigate this issue thoroughly with prospective studies (would provide better evidence about efficacy of the procedure)	***<u>Threats</u>*** • Delayed procedure start due to inadequate anesthesia workforce • Loss of patients to follow up (low income, homeless patient population) • Availability of stronger evidence could prove low efficacy of the procedure (risks outweigh the benefits) and demonstrate wasteful spending ($30,000-40,000 per procedure)

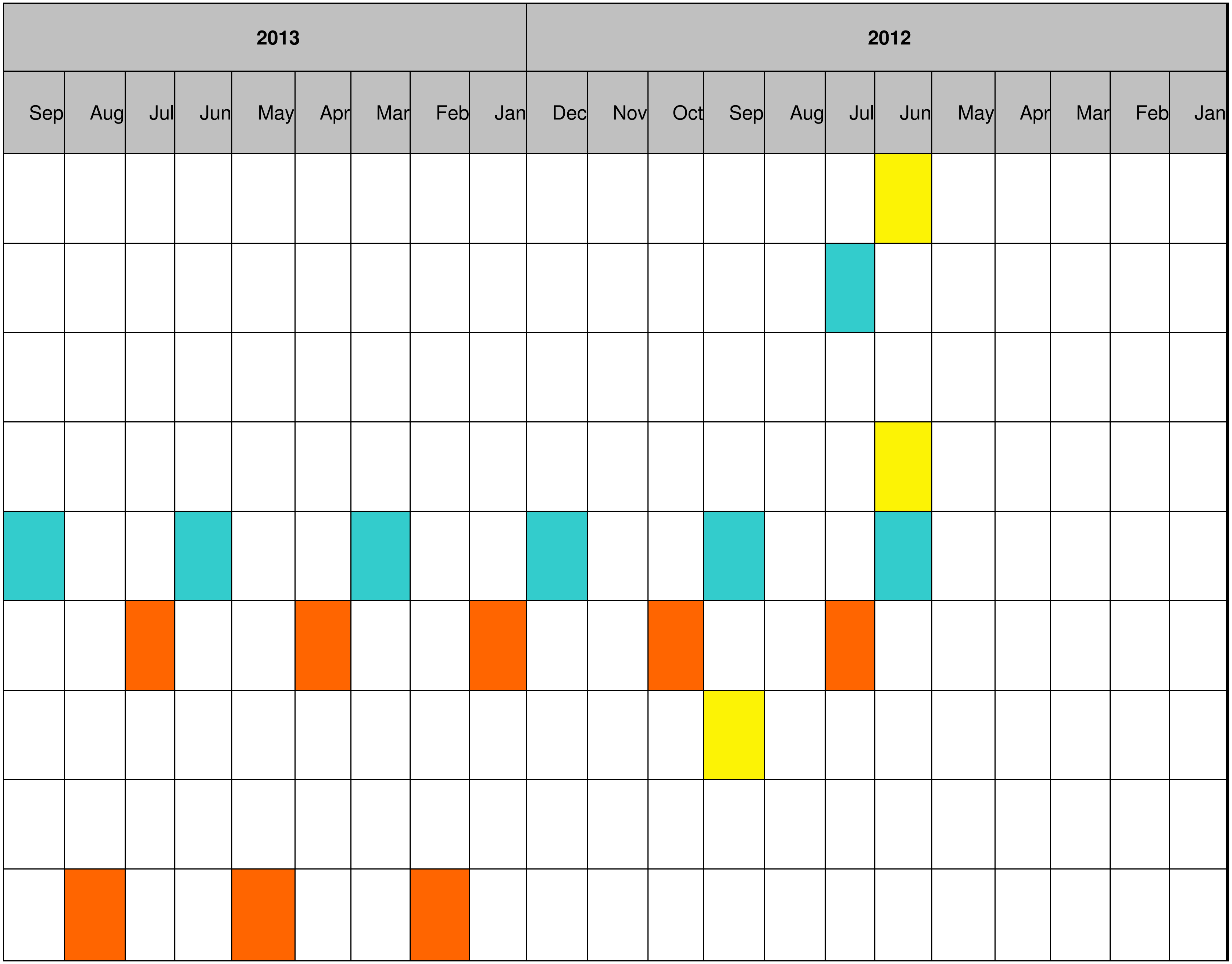
Appendix B (Proposed Budget)

Cost of hospital services	Cost of AIS revascularization procedure with anesthesia team	Cost of AIS revascularization procedure with RN sedation
Procedure cost per patient	$30,000	$30,000
Anesthesia cost per patient	$7,300	$0.00
Cost of nursing (action nurse & Radiology RN) per patient	$700.00	$700.00
Cost of stay in NeuroICU	$17,000 x 1 day= $17,000	$17,000 x 2days= $34,000

($17,000/day/patient)			
Total cost of hospitalization per patient	$55,000	$64,700	
Total cost of hospitalization x 9 patients/year	$495,000	$582,300	
Hospital savings per year			$87,300

Appendix C (GANTT chart)

Year
Project Milestones and Evaluation
Project proposalpresentation to the Interventional Neuroradiology (INR) faculty and IR management
Project proposal presentation to a Chair of Anesthesia Department and Stroke Program Director
Project implementation after approval and changes to a stroke protocol
Project proposal presentation to a hospital Stroke Committee and Quality Management representatives
Project updates presentation at Stroke Committee meetings
Project updates presentation to Anesthesia Chair/Department
Project proposal presentation to IR staff and action nurses
Presentation of 1 year project results/outcomes to all stakehoders (Stroke Committee, anesthesia, INR, Neurology, Quality Management)
Project evaluation


2013
2012
Sep
Aug
Jul
Jun
May
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Dec
Nov
Oct
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Feb
Jan

	Oct									
	Nov									
	Dec									

Appendix D (JHNEBP Research Evidence Appraisal)

Author (year)	**Study Design/Randomization/Sample Size**	**Study Conclusions**	**Study Limitations**	**Evidence Rating**
Abou-Chebl et al. (2010)	Retrospective No randomization N= 980	After the study results were adjusted for age, initial NIHSS score, time to femoral artery puncture, time to vessel opening, recanalization outcome, and intracerebral bleeding complication, patients placed under GA were at significantly higher risk of a poor outcome. Conscious sedation seemed to be as safe as GA with respect to the procedural complication of intracranial hemorrhage.	Higher NIHSS scores on admission (17±5 vs. 16±6, $p<0.01$) GA vs. conscious sedation group respectively. Not controlling for comorbidities, patient clinical status and endovascular techniques. The investigators did not address the issue of emergency intubation since they could not differentiate between the group of patients who were intubated before the procedure and those who were intubated emergently during the procedure. A clear definition of conscious sedation and who managed it was not provided in the study methodology.	3C
Jumaa et al. (2010)	Retrospective No randomization N= 126	The length of stay in the ICU was longer for the general anesthesia group (6.5 vs. 3.2 days, p=0.0008). The intraprocedural complications rate was lower among nonintubated patients as compared to the intubated group (6% vs. 15% respectively, p=0.13); however, the difference was not statistically significant. There were no significant discrepancies found in clinical outcomes and final infarct volumes on follow up imaging between the two anesthesia	Small sample size. Difference in baseline NIHSS score (17.6 [14-22] vs. 15.1 [12-18]) between two groups of patients (intubated state vs. non-intubated state, respectively). Missing data regarding time from decision to intervene to groin puncture, intra-procedural blood pressure variations and PCO2 values (acute	3C

		management techniques. Regardless of the anesthesia management modality (intubated state vs. nonintubated state), all procedures in this study were performed with the involvement of an anesthesiologist.	hypocapnia-vasodilation).	
McDonagh (2010)	Retrospective survey No randomization N= 49/68 respondents (72% response rate)	The most frequently used anesthesia type was general anesthesia, followed by conscious sedation (nurse administered), then monitored anesthesia care (MAC) administered by the anesthesia team, and finally local analgesia alone. Preference for GA was associated with a type of endovascular procedure. Mechanical thrombectomy was most frequently associated with a request for GA (55% of respondents). General anesthesia was a preferred practice for patients with a NIHSS score >15 (53% of respondents) and patients with brainstem stroke (51% of respondents).	Small sample size. Recall bias (self-reported perceptions of 49 NI's from the SVIN). Poor external validity (only SVIN members were surveyed). Missing data regarding the NI's involvement in choosing anesthesia type, the ventilator/critical care management during the case, and specific criteria for requesting GA.	3C
Nichols et al. (2010)	Retrospective No randomization N= 75	Lower levels of sedation and male gender were correlated with good clinical outcome. The highest levels of sedation, including pharmacological paralysis, were the only independent predictors of death. Mild or no sedation, and no internal carotid artery occlusion were the predictors of successful reperfusion. The study found a significantly higher level of infection (pneumonia and/or sepsis) in patients who received heavy sedation (p= 0.02). High sedation level remained a predictor of poor clinical outcome and death even after baseline NIHSS score was accounted for in multivariable analysis.	Small sample size. Baseline NIHSS score varied widely between the different levels of sedation (p= 0.03). The researchers were not able to precisely identify the types of anesthesia medications used, the duration of the treatment, the times of administration in relation to the angiographic procedure, and the route of administration. The authors did not specify who provided the anesthesia management during the procedure.	3C
Davis et al. (2012)	Retrospective No randomization N= 96	Mortality rate was higher in the general anesthesia group. After adjusting for baseline stroke severity, sedation and no incidence of	Small sample size. No clear definition of baseline blood pressure value available. The	3C

		hypotension (blood pressure ≤ 140 mmHg) were predictors of a good functional outcome. The authors reported a good functional outcome in fifteen percent of patients managed with general anesthesia, as opposed to sixty percent of patients who were managed with sedation ($p < 0.001$).	NIHSS score was higher in patients who received GA.	
Soize et al. (2012)	Prospective, single center No randomization, no control group N= 36 (consecutive patients)	The primary outcomes measured at 3-months follow up were mortality rate and functional outcome. Twenty two patients (61.1%) presented at three months follow up with good functional outcomes and ten patients (27.8%) had a poor outcome or died. Successful revascularization was accomplished in twenty eight (77.8%) patients. The anesthesia team was used only in "severe cases," the definition of which was not provided; whereas conscious sedation with IV midazolam was administered by the stroke neurologist.	Small sample size. No control group, no randomization. High complication rate:	3 C
Li et al. (2013)	Retrospective No randomization N= 109	General anesthesia and post-procedural hyperglycemia (blood glucose > 200 mg/dL) were the most important predictors of mortality (mortality rate 40% vs. 22% when comparing general anesthesia vs. conscious sedation group, p= 0.045). The time from AIS symptoms onset to recanalization and the length of endovascular revascularization procedure were longer in the general anesthesia group. There were no statistically significant differences between general anesthesia and conscious sedation groups as far as procedure-related complications (p= 0.997) and the patients' functional outcome at discharge (p= 0.631).	Small sample size. Higher incidence of posterior circulation stroke among the GA group patients (20% vs. 4% in CS group). Only patients treated with Merci retriever and Penumbra thrombectomy devices were included in this study (no cases with the latest generation of stent-retriever technology). Before 2011, general anesthesia was used routinely for all patients undergoing endovascular treatment for AIS. Serial glucose levels could not be consistently collected retrospectively; therefore, definite conclusions cannot be made. Lack of long-term	3C

			90-day clinical follow up. Absence of detailed information regarding stroke severity, size and location.	