STROKE RELATED DISABILITY AND TREATMENT OUTCOME: A RETROSPECTIVE COMPARISON OF IV ALTEPLASE AND ENDOVASCULAR INTERVENTION FOR ACUTE ISCHEMIC STROKE (AIS)

by

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DNP Project Approval Form

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Stroke-Related Disability and Treatment Outcome: A retrospective comparison of IV Alteplase and Endovascular Intervention for Acute Ischemic Stroke (AIS)

on __________________________, 2019.
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Abstract

Problem: Stroke is a leading cause of death. Stroke is also the leading cause of adult disability in the USA. It is continuously rising in the middle-aged population.

Purpose/objective: The objective of this study was to compare the treatment outcomes for two stroke interventions - intravenous Alteplase and intra-arterial thrombectomy in patients with acute ischemic stroke. Patients’ disability level at 90 days was compared.

Background/Literature/Theoretical Framework: Intravenous Alteplase and intra-arterial thrombectomy are the current treatment options for ischemic stroke. Although the two treatments are safe and effective, outcomes are unclear. The Plan-Do-Study-Act (PDSA) framework for quality improvement underscored the evaluation of the two treatments’ outcomes.

Methods: Retrospective review of charts of patients treated with IV Alteplase/IA thrombectomy for acute ischemic stroke were obtained from the stroke database of a comprehensive stroke center. The 90 days modified Rankin Scale (mRS) scores for the two groups were compared. Baseline data on demographics and known comorbidities were analyzed using descriptive statistics. A one-way ANOVA compared the treatment groups by disability scores.

Results: A statistically significant difference was noted between the two treatments. The intravenous Alteplase group (170 of 174) had mean = 2.65 and intra-arterial thrombectomy group (78 of 108) had mean = 4.12. Both intervention groups had ideal mRS of 37.6% and 12.8% for Alteplase and thrombectomy groups respectfully.

Conclusion: Patients who received the IV Alteplase intervention were found to have better outcomes than those in IA thrombectomy group [F(1,246) = 15.62; p = .000].

Keywords: acute ischemic stroke treatment, stroke treatment outcomes, disability level after stroke.
Acknowledgements

First and foremost, I thank the Almighty God for giving me the idea and strength for the successful completion of this capstone project.

I would like to thank Dr. Nancy Campbell, my capstone advisor for the guidance in the successful completion of this capstone project. In fact, words cannot describe my gratitude for the time and effort she put into the completion of this milestone achievement of completing my capstone project.

I would also like to thank Dr. Robert N. Sawyer Jr., MD (Co-Medical director of the Stroke program), and the nursing director and all staff of the neurosciences for granting me the permission and also assisting me to use the stroke database to obtain the data needed for my capstone project.

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I would also like to thank the entire school of nursing staff and faculty not forgetting Sharon Murphy for helping me with the literature review search.

Last but not the least, my sincere gratitude to my family and friends for their support and encouragement and all who in one way or the other contributed to the successful completion of this capstone project, I say Ayikoo (meaning well-done)!
The interest in this study originated four years ago when I started to work in the neuroscience and neurology department. While reviewing the treatment protocol data, I incidentally found that the incidence of acute ischemic stroke (which accounts for about 87% of all strokes) was continuously rising in the middle-aged population. Since strokes remain a leading cause of adult disability and death, I started thinking about how to improve treatment outcomes and reduce the devastating effects of disease. This situation led to reviewing the treatment options and their outcomes from where I noted that the outcomes related to the two common treatments were not clear.

**Background, Purpose, and Significance of the study**

Strokes (ischemic and hemorrhagic) are the 5th leading cause of death in the United States with acute ischemic stroke (AIS) having the highest incidence rate (American Stroke Association/American Heart Association, ASA/AHA, 2017). Strokes are also the leading cause of disability in adult patients in the United States. Strokes reduce mobility and function in more than 50% of stroke survivors according to the Centers for Disease Control and Prevention (CDC, 2016). The disabilities after a stroke also reduce the independence level of the patient which may result in impairment in the performance of basic activities of daily living. In addition to the disabilities caused by AIS, the cost of treating strokes is very high (CDC, 2016). The CDC posits that AIS costs the United States about 33 billion dollars each year, including but not limited to, the cost of health care services, medications to treat stroke, missed days of work, and the amount of time taken for rehabilitation (CDC, 2016). AIS alone accounts for about 87% of all strokes (CDC, 2016; ASA, 2017). Along with these overall high incidence rate and cost of AIS is the continuous and steadily rising among the young adult and the middle-age populations who represent the majority of the nation’s workforce. In fact, according to Kissela et al. (2012), the
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rate of first-time strokes among patients aged 20 to 54 jumped from 12.9% (in 1993-1994) to 18.6% (in 2005 \( P=0.002 \)). These findings predict that the stroke incidence will rise over approximately 6% by the year 2029 even though treatment and management outcomes for the two current treatments remains understudied (Wardlaw, Koumellis, Liu, 2013). Additionally, 34% of people hospitalized for strokes were less than 65 years old in 2009 (CDC, 2017).

The purpose of this retrospective review was to compare the disability levels at 90 days after treatment of AIS with either intravenous (IV) Alteplase or intra-arterial (IA) thrombectomy by measuring and comparing the modified Ranking Scale (mRS) scores. This study was looking to answer the question “In patients suspected of having AIS, what will be the disability level at 90 days when treated with IV Alteplase compared to IA thrombectomy? A comparison of the outcomes for these two treatment protocols will strengthen the evidence of treatment outcomes (Buijs, Uyttenboogaart, Brouns, de Keyser, Kamphuisen, & Luijckx, 2016; Bendszus et al. 2015; Badhiwala et al. 2015; Jiang et al. 2016).

**Literature Review**

There was no mainstay of a treatment and management protocol with proven efficacy for treating an AIS until 1996 when the Food and Drug Administration (FDA) approved the use of IV Alteplase. However, the use of IV Alteplase as the first line treatment and management of AIS requires administration within 3 hours of the patient’s onset of stroke signs and symptoms. This short time frame limits the use of IV Alteplase as the main treatment and management protocol. Although the AHA/ASA has extended the time frame from 3 hours up to 4.5 hours from the onset of disabling stroke signs and symptoms, many patients still miss the time frame for this drug. Another treatment protocol is the use of a neuro-endovascular surgical procedure called intra-arterial mechanical thrombectomy (IA thrombectomy) which can be undertaken in a
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much longer time frame up to 24 hours after symptom development (AHA/ASA, 2017). The two
current treatment and management protocols are such that patients who suffer an AIS can receive
either IV Alteplase or IA thrombectomy or both depending upon the time of presentation, the
National Institute of Health Stroke Scale (NIHSS) score and the presenting signs and symptoms
as well as diagnostic imaging and laboratory testing results.

Even though several studies have demonstrated the safety and efficacy of IV Alteplase
and IA thrombectomy, there has not been a comparison of the outcomes of these treatments. In a
study by Bendszus, Thomalla, Knauth, Hacke, Bonekamp & Fiehler (2015), the researchers
concluded that although the use of IA thrombectomy does provide evidence of a safe and
effective treatment for patients who are not eligible for IV Alteplase, it was unclear as to whether
mechanical thrombectomy improved clinical outcomes. Another recent study found that more
than 50% of patients treated with IV Alteplase had good outcomes at 90 days with men having a
higher outcome than women with a P value < .001 (Buijs, Uyttenboogart, Brouns, de Keyser,
Kamphuisen & Luijckx, 2016). The researchers also found that certain secondary conditions
impacted the treatment outcome. In a multivariate analysis using the modified Ranking Scale
(mRS) scores, risk factors such as hypertension, obesity, diabetes and atrial fibrillation did
impact treatment outcomes (Buijs et al., 2016). In another study, the researchers noted that IV
Alteplase treatment in the young and older populations (higher than or less than 80 years)
yielded similar results in their quality of life on the Stroke Impact Scale (Diard-Detoeuf, Debiais,
Imert, Musikas, Gaudron, Laurent, De Toffol, Hommet & Mondon, 2015). The researchers
concluded that there were promising results which postulated the importance of systematic
screening of outcomes for post-stroke cognitive impairment (Diard-Detoeuf et al., 2015). This
finding from Diard-Detoeuf et al. (2015) showed that treatment outcomes can be the same for all
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age groups when considering a treatment plan for AIS. Nevertheless, whether the level of
disability at 90 days will be the same after treatment for IV Alteplase and IA thrombectomy was
yet to be studied in detail. More also, considering that IV Alteplase at a dose of 0.9 mg/kg or IA
thrombectomy procedure is the current best practice for treating AIS which is a leading cause of
death (Wardlaw et al., 2013), a comparison of outcomes was imperative in determining
functional and disability level after each of these treatments. The outcome of this study also
clarified the outcome of disability after treatment and demonstrated the treatment with better
outcomes at 90 days (AHA/ASA, 2013; CDC, 2017).

Analysis of Evidence

The literature review demonstrated that IV Alteplase and IA thrombectomy are both safe
and effective in the treatment of AIS (Diard-Detoeuf et al. 2015; Wardlaw et al. 2013; Badhiwala
et al. 2015). However, there have been several trials with interest in IA thrombectomy since IV
Alteplase has a very limited treatment time window (3 hours approved by the Food and drug
administration but up to 4.5 hours according to evidence by the American Heart/Stroke
Association (Bendszus et al. 2015, Buijs et al. 2016; Jiang et al. 2016& Wardlaw et al. 2013)).
According to the literature, Buijs et al. (2016) noted that a little over 50% of patients had a good
outcome at 90 days when treated with IV Alteplase. However, Bendszus et al. (2015) concluded
that thrombectomy for patients who were ineligible for IV Alteplase though safe and effective, it
was unclear as to whether thrombectomy improved outcomes.

Regarding complications, intracerebral hemorrhage (ICH) and angioedema are the two
most common (AHA/ASA, 2017). Badhiwala et al. (2015) noted that IA thrombectomy
performed 24 hours after symptoms onset had no significant symptomatic ICH similar to IV
Alteplase given within 4.5 hours even though thrombectomy did achieve significant
revascularization of the occluded brain. Although all the six final articles show that IV Alteplase and IA thrombectomy are both safe and effective in treating AIS, the outcomes are unclear (Bendszus et al. 2015). Again, Jiang et al. (2016) noted that an IA thrombectomy performed with solitaire stent device had a higher recanalization rate, but the outcome was not determined. Also, Wardlaw et al. (2013) found that there is limited evidence that higher doses of IV Alteplase led to higher rates of fatal ICH but did assert that thrombectomy therapy may have a better outcome than IV Alteplase. This assertion may be substantiated by a comparison of the two treatment protocols. Although there are many studies about the safety and effectiveness of the two treatment protocols, not many studies have been done on the outcome of these two treatment protocols. Hence, given that stroke remains the leading cause of adult disability in the United States, treatment options should target improving the disabilities caused by strokes since the goal of stroke treatment is to improve outcomes at 90 days (AHA/ASA). Therefore, a comparison of the outcome of these two treatment protocols (IV Alteplase and IA thrombectomy) will demonstrate the treatment with a better outcome. This information will improve the quality of the evidence for treatment decision making which could affect outcomes and functioning after treatment of AIS.

The review of the literature demonstrated that several studies had explored the safety and efficacy of IV Alteplase and IA thrombectomy. Also, both treatments are currently being performed depending on the patients’ presentation, evaluation, time the patient was known to be at their baseline of health and time of presentation to the hospital after the onset of stroke signs and symptoms or the time of discovery of the signs and symptoms. An analysis of the treatment outcomes in terms of the disability level is imperative for efficient and improved treatment of
AIS that will potentially result in the least possible disability, providing high functional level of independence, improved treatment outcome and improved quality of life after suffering an AIS.

**Theoretical/Conceptual Framework (PDSA)**

The conceptual framework that guided this study is the Plan-Do-Study-Act (PDSA) template for quality improvement by the Institute for Healthcare Improvement (IHI). The PDSA cycle is part of the IHI’s Model for quality improvement. This model is a simple yet powerful tool for designing a quality improvement project (Agency for Healthcare Research & Quality, 2013). This study was looking to improve treatment outcomes by knowing the level of disability at 90 days for the two treatment protocols; either IV Alteplase or IA thrombectomy. Hence, using the PDSA template, the modified Ranking Scale (mRS) scores at 90 days for patients who were treated with IV Alteplase and IA thrombectomy were obtained from the stroke database of a stroke treatment hospital (Plan). A review of the records of patients that were treated for AIS with either IV Alteplase or IA thrombectomy to determine the results of the outcome of the type of treatment at 90 days post discharge was conducted (Do). In this study, the level of disability at 90 days was analyzed using the disability scores of the two treatments (Study). The study results can be used in making decisions about future treatment approaches (Act).

**Methodology**

**Study design and setting**

Medical records of patients treated with either IV Alteplase or IA thrombectomy for AIS were retrospectively collected from the stroke database of a comprehensive stroke treatment center in upstate New York.

**Study Sample**
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An initial total sample of 2075 patients with 129 different variables were obtained from the stroke database. A total of 342 patients was obtained that were for all patients who received treatment for suspected ischemic stroke. A further 60 patients (patients received a combination of the two) were removed to obtain a final sample of 282 patients representing patients treated with either IV Alteplase or IA thrombectomy for AIS between January 2017 to December 2017.

Inclusion

All patients who received treatment with either IV Alteplase or IA thrombectomy for the treatment of suspected AIS between January and December 2017 were included in the review.

Exclusion

Patients who were ineligible for either IV Alteplase or IA thrombectomy were excluded since the study is looking at the outcome for patients who receive one of the two treatment protocols. Patients who received a combination of the two treatments were also excluded as they could not be classified into one of the two treatments under comparison.

Data collection

Data were obtained by running the configurable measures report of the stroke database of a comprehensive stroke care center in New York State. The configurable measures report consists of several stroke treatment target measures and can provide data reports for specific report that is needed. The first report for patients treated for suspected AIS was run to obtain the first data set. The data were pulled into an Excel spreadsheet and labeled as the raw dataset 1. The configurable measures report was re-run for the modified Rankin scale (mRS) scores at 90 days known in the stroke database as the post discharge mRS (measure CSTK-02) with 29 variables. Both datasets were imported into the Statistical Package for the Social Sciences (SPSS). The two datasets were cleaned and then merged for analysis (Polit, 2010).
Validity/reliability of instrument

The mRS is the tool/instrument that was used to measure the level of disability at 90 days. This tool is the most widely and accepted tool used in stroke clinical trials in determining the patient’s functional level after a stroke (Banks & Moratta, 2007). The mRS is a 6-point disability scale with possible scores ranging from 0 to 5, but a separate category of 6 is usually added for patients who have expired after suffering a stroke (The Joint Commission, 2016). The mRS is a valid and reliable tool for evaluating post-stroke treatment in patients regarding their level of disability (AHA/ASA, 2017). The tool grades the patient’s level of functioning into a numeric value from 0 (which means no symptoms of disability) up to 5 (which indicates severe disability such as bedridden) and a score of 6 is for patients who have expired at the 90 days after any of the treatments. A score of 7 and 8 are used when a patient refused to have the mRS done or unable to reach the patient for a score respectively.

Analysis of Data

The data set used for analysis included the independent variable, which was the type of stroke treatment (either intravenous alteplase (IV Alteplase) or intraarterial endovascular intervention (IA thrombectomy)), and the dependent variable, which was the 90-day post discharge mRS scores between January 1 to December 31 for the year 2017. The data were imported into SPSS and checked for errors. Data variables that were provided in a text format were changed to numeric values and labeled; for example, “male” and “female” values were converted to 1 and 2 respectively and labeled appropriately. The data set contained all patients that were treated at the stroke center, so the patients who did not receive either the IV Alteplase or IA thrombectomy were removed from the sample as well as those who received combination of the two treatment under comparison.
Preliminary Assessments:

Because of well-known and documented risk factors (such as hypertension, dyslipidemia, obesity and diabetes mellitus) of stroke, these variables were assessed to determine if they warranted being included as potential covariates in an initial analysis. In the preliminary assessments, these variables did not have significant relationships with the independent and dependent variables in an analysis of covariates and therefore were not necessary to include in the primary analyses. A One-way analysis of variance (ANOVA) was selected to analyze the significance of group differences using IV Alteplase and IA thrombectomy as the independent (factor) variable and the post-discharge mRS at 90-days as the dependent variable.

Results

Descriptive frequency statistics for the two groups (n=282)

There were four (1.4%) patients who were of Hispanic ethnicity compared to 278 (98.6%) patients who were of non-Hispanic ethnicity in the final sample of which 137 (48.6%) were males and 145 (51.4%) were females. Again, of the final sample size of 282, the rate of stroke among the different races were as follows: Whites=239 (84.8); Blacks/African Americans=36 (12.8%); Asians=2 (0.7%); Native Americans=3 (1.1%) and 2 (0.7%) did not have the race documented. The diagnosis of acute ischemic stroke accounted for 267 (94.7%) of the final sample and 4 (1.4%) were diagnosed with a transient ischemic attack often described as mini stroke. The remaining 11 (3.9%) ended up having no stroke related diagnosis. The etiology of stroke showed that 46 (18%) were by large-artery atherosclerosis (e.g., carotid or basilar artery stenosis); 110 (43.1%) by a cardioembolic source (e.g., atrial fibrillation/flutter, prosthetic heart valve or recent myocardial infarction); 21 (8.2%) by a small-vessel disease (e.g., subcortical or brain stem lacunar infarction <1.5 cm); 2 (0.8%) by a stroke of other
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determine etiology (e.g., post-surgery) and 76 (29.8%) were cryptogenic stroke (undetermined or
unspecified cause) i.e. stroke of unknown cause. The presenting disability level was measured
with the National Institute of Health Stroke Scale (NIHSS). The NIHSS scores which were 6 or
less were 44.5% and those greater than 6 (which will make the patient eligible for IA
Thrombectomy) 55.5%.

The post discharged mRS scores showed that 74 (29.8%) had a mRS of 0; 29 (11.7%)
had 1; 19 (7.7%) had 2; 18 (7.3%) had 3; another 18 (7.3%) had 4; 6 (2.4%) had 5; 41 (16.5%)
had 6 (expired); another 41 (16.5%) had 7 and 2 (0.8%) had 8. The last two scores of 7 and 8
means the patient refused or was not reachable respectively and that the mRS was not done.

Comparison of IV Alteplase versus IA thrombectomy using One-way ANOVA

The total sample for IV Alteplase was 174 (61.7%) in comparison to IA thrombectomy
which had 108 (38.3%). The admission NIHSS ranged from 0 to a highest of 29 for both the IV
Alteplase and the IA thrombectomy groups. Tables 1 and 2 shows a comparison of the
demographic data of the two groups and well-known documented comorbidities:
<table>
<thead>
<tr>
<th>Variables</th>
<th>IV Alteplase (n=174)</th>
<th>IA thrombectomy (n=108)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>88 (50.6%)</td>
<td>49 (45.4%)</td>
</tr>
<tr>
<td>Female</td>
<td>86 (49.4%)</td>
<td>59 (54.6%)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>21 – 97</td>
<td>17 – 93</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>3 (1.7%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>171 (98.3%)</td>
<td>107 (99.1%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>149 (85.6%)</td>
<td>90 (83.3%)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>21 (12.1%)</td>
<td>15 (13.9%)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (0.6%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Not documented</td>
<td>3 (1.7%)</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td><strong>Type of Stroke</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>160 (92%)</td>
<td>107 (99.1%)</td>
</tr>
<tr>
<td>Transient attack</td>
<td>3 (1.7%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>No stroke diagnosis</td>
<td>11 (6.3%)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Stroke etiology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large artery atherosclerosis</td>
<td>24 (13.8%)</td>
<td>22 (21%)</td>
</tr>
<tr>
<td>Cardioembolic</td>
<td>58 (33.3%)</td>
<td>52 (49.5%)</td>
</tr>
<tr>
<td>Small vessel disease/other</td>
<td>21 (12.1%)</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td>Cryptogenic</td>
<td>47 (27%)</td>
<td>29 (27.6%)</td>
</tr>
<tr>
<td>Missing/undocumented</td>
<td>24 (13.8%)</td>
<td>3 (3.8%)</td>
</tr>
</tbody>
</table>
Table 2

*Comparison of common risk factors (5 comorbidities)*

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>IV Alteplase</th>
<th>IA thrombectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>66.1%</td>
<td>63.0%</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>44.3%</td>
<td>40.7%</td>
</tr>
<tr>
<td>Obesity</td>
<td>28.7%</td>
<td>30.6%</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>20.7%</td>
<td>25.9%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>29.3%</td>
<td>18.5%</td>
</tr>
</tbody>
</table>

**One-way analysis of variance (F-Statistic)**

To compare the 90-day modified Ranking scale (mRS) outcomes of the two groups (IV Alteplase and IA thrombectomy), a one-way analysis of variance (ANOVA) was selected. As noted previously, well-known documented risk factors were considered as covariates, but were not required. The One-way ANOVA showed the following results:

a) IV Alteplase group (170 of 174) had mean = 2.65 (with a range of 0 – 7 range)

b) IA thrombectomy group (78 of 108) had mean = 4.12 (with a range of 0 – 8 range)

The One-way ANOVA result showed that a statistically significant difference was found between the mRS scores at 90 days and the two interventions. Specifically, patients who received the IV Alteplase intervention were found to have better outcomes than those in the IA thrombectomy group \([F(1,246) = 15.62; p = .000]\).

**Discussion of results**

The analysis demonstrated that patients who received IV Alteplase had a better outcome compared to receiving IA thrombectomy. A higher number of patients in the IV Alteplase
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intervention group had an ideal 90-day mRS of 0 (37.6%) compared to those who were in the IA thrombectomy intervention group (12.8%). Additionally, the IV Alteplase intervention group had more patients with better (i.e., lower) mRS at 90 days (0, 1, or 2). However, there are some considerations when looking at the two treatment groups. In many respects, IA thrombectomy may be considered as a more favorable treatment since the treatment window is broader (up to 24 hours from the time the patient was last seen in their baseline of health) compared to that of IV Alteplase (which has a narrower window of 4.5 hours). More also, since the majority of patients miss the opportunity to receive IV Alteplase within that narrower time frame (as the initial total volume of stroke patients was over 2000 patients), IA thrombectomy does provide longer time frame for acute ischemic stroke treatment (given that almost 13% of patients had a complete recovery from their stroke). Although the initial NIHSS scores on presentation were similar in both treatment groups, it is worthy of note that patients with NIHSS scores of less than 6 and no large vessel occlusion were illegible for IA thrombectomy. This means that majority of the patients in the IA thrombectomy group were likely to have a higher pretreatment disability.

In terms of the comorbidities, hypertension, which was the largest comorbidity in both samples was presented at about the same level in both treatment groups. However, dyslipidemia and diabetes were seen more frequently in the IV Alteplase sample than the IA thrombectomy sample. Atrial fibrillation and obesity were much higher in the IA thrombectomy sample than in the IV Alteplase sample. Another interesting revelation was that even though stroke in general is known to be higher in the Black/African American population, the results showed that whites (Caucasians) were almost seven times at a higher risk of suffering a stroke compared to Black/African Americans. Asians had the lowest risk of suffering a stroke according to the results. The results further demonstrated that acute ischemic stroke was more than 90% in both
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treatment groups and in regards to the etiology of strokes, cardioembolic was the highest cause
of stroke followed by cryptogenic and then large artery atherosclerosis with small vessel disease
and other determined etiology being the least in etiology.

**Relationship of the study to the DNP Essentials**

This study fulfills the Doctor of Nursing Practice essentials of clinical scholarship and
analytical methods for evidence-based practice from the American Association of Colleges of
Nursing (AACN, 2006) in that a retrospective review of the treatment options for a leading cause
of death (AIS) was conducted on the outcomes of the two treatments and recommendations were
made based on statistical analysis of the data reviewed. The study also fulfills the DNP program
outcome of critically analyze, synthesize and apply theoretical and empirical knowledge from a
variety of sources to improve nursing practice.

**Limitations**

Even though the sample was taken from the largest comprehensive stroke care center in
the region, the study may not be generalizable given that the sample was from a single hospital.
Also, patients who were not able to seek medical care and treatment may reduce the applicability
of the results to the general population in the region. The data were from a single year and may
not be a true reflection of treatment over time.

**Suggestions for future study/implications**

Future studies should include data from multiple years in order to better assess the
treatment options over time. Also, future studies should include patients who received a
combination of the two treatments to determine the best possible treatment in reducing the
devastating effect of long-term disability from acute ischemic strokes. The study demonstrates an
overall impact of both IV Alteplase and IA thrombectomy in the treatment of AIS and the potential for improving the disability after a stroke.

**Ethical Consideration**

The study received approval from the Institutional Review Board of the University at Buffalo. The information collected excluded all identifiable personal information. Records will be stored on a password encrypted USB flash drive per University at Buffalo School of Nursing guidelines for data storage and management.

**Conclusion**

In conclusion, the results demonstrate that patients treated with IV Alteplase had a better outcome at 90 days than their counterparts in the IA thrombectomy group. However, IA thrombectomy provides an option for patients with presentation of stroke symptoms over five hours. Therefore, given the opportunity to offer either IV Alteplase or IA thrombectomy, the results of this analysis suggest that IV Alteplase should be recommended as first line treatment since it does provide better outcome when it is possible within the constraints of the short time window for administration. When that is not possible, IA thrombectomy does provide an alternative treatment option which can improve outcomes of disability from acute ischemic stroke.
References


Running head: STROKE DISABILITY AT 90 DAYS POST INTERVENTION


Running head: STROKE DISABILITY AT 90 DAYS POST INTERVENTION


APPENDIX A: Literature Review Matrix Table
### Literature review matrix

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Citation (APA 6th)</strong></td>
<td><strong>Design Approach (Qualitative, Quantitative, etc.)</strong></td>
<td><strong>Research purpose or question (specific for this study)</strong></td>
<td><strong>Key Findings</strong></td>
</tr>
<tr>
<td>Badhiwala, J.H., Nassiri, F., Alhazzani, W., Selim, N.H., Farrokhyar, F., Spears, J., ..., Almenawer, S.A. (2015). Endovascular thrombectomy for acute ischemic stroke: A meta-analysis. JAMA. 314(17), 1832-1843.</td>
<td>Systematic review and Meta-analysis of randomized clinical trials of endovascular therapy with mechanical thrombectomy.</td>
<td>The objective was to examine the association of mechanical thrombectomy and clinical outcomes among patients with AIS.</td>
<td>Of 4193 studies initially identified, 2423 patients from 8 trials were included. The mean [SD] age was 67.4 [14.4] years, of whom 1131 (46.7%) were women and the rest males. Rates of angiographic revascularization at 24 hours for endovascular therapy was 75.8% (95% CI, 68.1%-82.2%) vs 34.1% (95% CI, 29.8%-38.7%) for standard therapy (OR, 6.49; 95% CI, 4.79-8.79; P &lt; .001). There was no significant difference in rates of symptomatic intracranial hemorrhage within 90 days between groups: 5.7% (95%, CI; 4.4%-7.3%) for endovascular therapy vs 5.1% (95%, CI; 3.9%-6.6%) for standard therapy (OR, 1.12; 95% CI, 0.77-1.63; P = .56)</td>
</tr>
<tr>
<td>Bendszus, M., Thomalla, G., Knauth, M., Hacke, W., Bonekamp, S., &amp; Fiehler, J. (2015). Thrombectomy in patients ineligible for iv tPA (THRILL). Int. J Stroke., 10(6), 950-955.</td>
<td>Prospective Open-label, blinded endpoint binational two-arm, randomized controlled post-market study.</td>
<td>Comparison of safety and efficacy of stent retrievers with best medical care alone in acute stroke patients not eligible for intravenous r-tPA.</td>
<td>Thrombectomy in patients ineligible for r-tPA was unclear as to whether it improves clinical outcomes. However, thrombectomy does provide evidence of an effective and safe treatment for such patients.</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Design</td>
<td>Methodological Focus</td>
<td>Findings</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Buijs, J.E., Uttenboogaart, M., Brouns, R., de Keyser, J., Kamphuisen, P.W., &amp; Luijckx, G.J. (2016).</td>
<td>Prospective cohort study design</td>
<td>Examined the influence of sex differences about age in the prognosis of stroke after IV tPA treatment</td>
<td>A little over 50% of patients had a good outcome at 90 days after the stroke. Men had an overall better outcome than women (56% versus 45%, P value &lt;.001) in univariate and multivariate logistic analysis showed poor outcome in older age.</td>
</tr>
<tr>
<td>Diard-Detoeuf, C., Debiais, S., Imbert, M., Musikas, A., Guadron, M., Laurent, E., ... Mondon, K. (2015).</td>
<td>Prospective study design of off-label thrombolysis</td>
<td>The study aimed to compare the quality of life of patients greater than or equal to 80 with those less than 80 years at 90 days after thrombolysis</td>
<td>At 90 days (3 months), out of the 88 patients who were treated with thrombolytic therapy (IV tPA), 14 patients died, three patients were lost to follow up four patients could be assessed. Sixty-two patients were assessed at 90 days of which 41 were &lt;80 and 21 were ≥80 years. 94% of those assessed were independent before the stroke. There was no significant difference in the 3-month outcome between the two groups according to the NIHSS and mRS scores, the proportion of patients with favorable outcomes, the proportion of independent patients, and the patients returned home.</td>
</tr>
<tr>
<td>Jiang, S.W., Wang, H.R., Peng, Y., Sun, H., Chen, M., Fei, A.H., &amp; Pan, S.M. (2016).</td>
<td>Prospective cohort study</td>
<td>To examine experience from mechanical thrombectomy using Solitaire stent device in Chinese patients and comparison of results with</td>
<td>There were altogether 83 patients in this study series. The mean patient age was over 60 years (range 21–85), and male patients accounted for 60.2% of the total pool. The results showed that the thrombectomy with Solitaire stent device reached high angiographic recanalization rate and efficiency, while the safety remains the same.</td>
</tr>
<tr>
<td>Study</td>
<td>Other Main Trials in Recent Years</td>
<td>Also Compared with Other Clinical Studies, the Results of This Trials Showed a Relatively Lower Reperfusion Rate Than the Penumbra Pivotal Study, SWIFT Trial, and EXTEND-IA Trail. The Rate of Symptomatic Intracranial Hemorrhage (sICH) and Mortality Rate in This Study Was, However, Higher Than the ESCAPE Trial and the EXTEND-IA Trail</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>---------------------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX B: Modified Rankin Scale tool
Modified Rankin scale tool

<table>
<thead>
<tr>
<th>MODIFIED RANKIN SCALE (MRS)</th>
<th>Patient Name: __________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>Description</td>
</tr>
<tr>
<td>0</td>
<td>No symptoms at all</td>
</tr>
<tr>
<td>1</td>
<td>No significant disability despite symptoms, able to carry out all usual duties and activities</td>
</tr>
<tr>
<td>2</td>
<td>Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance</td>
</tr>
<tr>
<td>3</td>
<td>Moderate disability; requiring some help, but able to walk without assistance</td>
</tr>
<tr>
<td>4</td>
<td>Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance</td>
</tr>
<tr>
<td>5</td>
<td>Severe disability; bedridden, incontinent and requiring constant nursing care and attention</td>
</tr>
<tr>
<td>6</td>
<td>Dead</td>
</tr>
</tbody>
</table>

TOTAL (0–6): ______

References:

Rankin J. “Cerebral vascular accidents in patients over the age of 60.” 

Bonits R, Beaglehole R. “Modification of Rankin Scale: Recovery of motor function after stroke.” 
Stroke 1988 Dec;19(12):1497-1500

Van Swieten JC, Koudstaal PJ, Visser MC, Schouten HJ, van Gijn J. “Interobserver agreement for the assessment of handicap in stroke patients.” 
Stroke 1988;19(5):804-7

Provided by the Internet Stroke Center — www.strokecenter.org
APPENDIX C: Institutional Review Board (IRB) Approval Letter
January 17, 2019

Dear Maxwell Boasiako Antwi:

On 1/17/2019, the IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Type of Review:</th>
<th>Initial Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of Study:</td>
<td>Stroke Related Disability and Treatment Outcome: A retrospective comparison of intravenous tissue plasminogen activator (IV TPA) and Endovascular Intervention (IA thrombectomy) for Acute Ischemic Stroke (AIS).</td>
</tr>
<tr>
<td>Investigator:</td>
<td>Maxwell Boasiako Antwi</td>
</tr>
<tr>
<td>IRB ID:</td>
<td>STUDY00003096</td>
</tr>
<tr>
<td>Documents Reviewed:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>modified rankin tool explanation (2).pdf, Category: Other;</td>
</tr>
<tr>
<td></td>
<td>UPDATED HRP-503 ProtocolTemplate, Category: IRB Protocol;</td>
</tr>
<tr>
<td></td>
<td>Scientific Review 181245439455.pdf, Category: Other;</td>
</tr>
<tr>
<td></td>
<td>Tool for measuring disability, Category: Other;</td>
</tr>
<tr>
<td></td>
<td>UPDATED HRP612 (version2), Category: Other</td>
</tr>
</tbody>
</table>

The IRB approved the study from 1/17/2019 to 1/16/2020 inclusive. The initial study materials for the project referenced above were reviewed and approved by the SUNY University at Buffalo IRB (UBIRB) by Non-Committee Review. The IRB has determined that the study is no greater than minimal risk. Before 1/16/2020 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review application with required explanations. In order to avoid a lapse in IRB approval, it is recommended that you submit your continuing review at least 30 days for an expedited study and at least 45-60 days for a full board study, prior to the approval end date of the study. You can submit a continuing review application by navigating to the active study in Click IRB and selecting ‘Create Modification / CR’. Studies cannot be conducted beyond the expiration date without re-approval by the UBIRB.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Based on the information you have provided in the “University at Buffalo Human Research Protections Program Request for Full Waiver of Individual Authorization for Use of Individually Identifiable Health Information” form (waiver request), the UBIRB has determined a full waiver of the individual authorization required by 45 CFR §164.508.
A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

1) An adequate plan to protect the identifiers from improper use and disclosure;

2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

B) The research could not practicably be conducted without the waiver or alteration; and

C) The research could not practicably be conducted without access to and use of the protected health information.

A brief description of the Protected Health Information for which this alteration or waiver has been granted is provided on the "Request for Waiver of the Authorization for Use of Individually Identifiable Health Information" or "Request for Limited Waiver of the Authorization for Use of Individually Identifiable Health Information for Study Recruitment" which is part of this approval. If HIV information is requested, this waiver is only valid for disclosures consistent with New York Code Public Health Article 27-F.

This full waiver has been reviewed and approved for the above referenced study by the UBIRB to permit you to receive personal health information as specified in section (1) of the waiver request.

UBIRB approval is given with the understanding that the most recently approved procedures will be followed and the most recently approved consent documents will be used. If modifications are needed, those changes may not be initiated until such modifications have been submitted to the UBIRB for review and have been granted approval.

As principal investigator for this study involving human participants, you have responsibilities to the SUNY University at Buffalo IRB (UBIRB) as follows:

1. Ensuring that no subjects are enrolled prior to the IRB approval date.
2. Ensuring that the study is not conducted beyond the expiration date without re-approval by the UBI RB.

3. Ensuring that the UBI RB is notified of:
   - All reportable information in accordance with the New Information SOP (HRP-024).
   - Project closure/completion by submitting a Continuing Review/Modification submission.

4. Ensuring that the protocol is followed as approved by UBI RB unless a protocol amendment is prospectively approved.

5. Ensuring that changes in research procedures, recruitment or consent processes are not initiated without prior UBI RB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

6. Ensuring that the study is conducted in compliance with all UBI RB decisions, conditions, and requirements.

7. Bearing responsibility for all actions of the staff and sub-investigators with regard to the protocol.

8. Bearing responsibility for securing any other required approvals before research begins.

If you have any questions, please contact the UBI RB at 716-888-4888 or ub-irb@buffalo.edu. Please include the project title and number in all correspondence with the UBI RB.
APPENDIX D: Final Power point slides used for oral defense
STUDY TITLE: STROKE RELATED DISABILITY AND TREATMENT
OUTCOME: A RETROSPECTIVE COMPARISON OF IV ALTEPLASE AND ENDOVASCULAR INTERVENTION FOR ACUTE ISCHEMIC STROKE

By
Maxwell Boasiako Antwi, RN, BSN

PURPOSE OF THE STUDY

- The purpose of this study was to compare the disability level at 90 days after treatment with either intravenous (IV) Alteplase or intra-arterial (IA) thrombectomy.

STUDY BACKGROUND

- The leading cause of disability in adult patients (AHA/ASA, 2017; CDC, 2016).
STUDY QUESTION (PICO)

- Population: Patients with suspected acute ischemic stroke who received one of two treatments
- Intervention: Treatment with intravenous Alteplase
- Comparison: Treatment with intra-arterial thrombectomy.
- Outcome: Disability level at 90 days

There was a question the study was trying to answer.

THEORETICAL/CONCEPTUAL FOUNDATION (IHI)

HOW THE STUDY WAS CARRIED OUT

The following were obtained to implement the study:

- IRB approval
- Baseline NIHSS scores
- The type of treatment received
- The treatment outcome (the disability level after treatment)
STUDY METHODOLOGY

Study design and setting
- Study was conducted in an upstate comprehensive stroke care center

Study Sample
- A final sample size of 282 patients was obtained

Pre-treatment and post-treatment measures
- National Institute of Health Stroke Scale (NIHSS) scores
- The modified Rankin Scale scores

VALIDITY/RELIABILITY OF INSTRUMENT

- The mRS tool/instrument (Banks & Moratta, 2007).
- The NIHSS tool (Himble, 2014).

ANALYSIS OF DATA

Data Analysis:
- The data was pulled into SPSS and descriptive statistics and One-way ANOVA were conducted.
RESULTS

Variables for establishing the equivalence of the two treatment groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>IV Alteplase (n=174)</th>
<th>IA Thrombectomy (n=108)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Male</td>
<td>87 (50.0%)</td>
<td>85 (69.6%)</td>
</tr>
<tr>
<td>b) Female</td>
<td>87 (50.0%)</td>
<td>34 (28.4%)</td>
</tr>
<tr>
<td>2) Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>21 - 67</td>
<td>17 - 82</td>
</tr>
<tr>
<td>3) Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Hispanic</td>
<td>3 (1.7%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>b) Non-Hispanic</td>
<td>171 (98.3%)</td>
<td>107 (99.1%)</td>
</tr>
<tr>
<td>4) Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) White</td>
<td>146 (84.9%)</td>
<td>98 (89.3%)</td>
</tr>
<tr>
<td>b) Black/African American</td>
<td>21 (12.1%)</td>
<td>18 (16.5%)</td>
</tr>
<tr>
<td>c) Other</td>
<td>1 (0.6%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>5) Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Type 1</td>
<td>3 (1.7%)</td>
<td>5 (1.9%)</td>
</tr>
</tbody>
</table>

RESULTS CONTINUED

Comparison of IV Alteplase versus IA Thrombectomy using One-way ANOVA

- IV Alteplase group was 174 (61.7%) in comparison to IA thrombectomy which had 108 (38.3%).
- The admission NIHSS
- Averages of outcomes of the two treatment
- The One-way ANOVA result

Comparison of common risk factors (5 comorbidities)

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>IV Alteplase</th>
<th>IA Thrombectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>96.1%</td>
<td>92.0%</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>44.3%</td>
<td>40.7%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28.7%</td>
<td>30.6%</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>20.7%</td>
<td>25.5%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28.3%</td>
<td>10.5%</td>
</tr>
</tbody>
</table>

DISCUSSION OF RESULTS

- Eligibility for either of the two treatment was strongly related to time
- Baseline NIHSS partly determined which treatment
- Outcomes for Alteplase versus thrombectomy discussion
DNP ESSENTIALS AND OUTCOMES

DNP Essentials and DNP Outcome fulfillment
- The study fulfilled a DNP essential and a DNP outcome.

LIMITATIONS

Limitations of the study
The study results have some limitations:
- The study results may not be generalizable since the study sample was from only one hospital.
- Patients who were not able to seek medical care and treatment may reduce the applicability of the results to the general population in the region.
- The data were from a single year and may not be a true reflection of treatment over time.

SUGGESTIONS FOR FUTURE STUDIES/IMPLICATIONS

The following are some suggestions for future studies:
- Future studies should include data from multiple years in order to better assess the treatment options over time. Data should be from multiple hospitals as well.
- Also, future studies should include patients who received a combination of the two treatments.
CONCLUSION

In concluding,
- The study demonstrates an overall impact of both IV Alteplase and IA thrombectomy in the treatment of AIS and the potential for improving the disability after a stroke.
- The study provides promising results of improving treatment outcomes for AIS.
- More attention should be paid to the speed of entry to the hospital and mechanisms.

THANK YOU!

Questions?

REFERENCES


REFERENCES

Institute for Healthcare Improvement (2016). IHI open school for healthcare improvement.

