Graduate Research Projects                                        School of Nursing

12-2013

# Treatment for Acute Stroke: A Retrospective Study of Erlanger Stroke Patients from 2004-2012

Sarah Henson

Follow this and additional works at: https://knowledge.e.southern.edu/gradnursing

Part of the Nursing Commons

Treatment for acute stroke: A retrospective study of Erlanger stroke patients from 2004-2012

Sarah Henson

12/6/2013

MSN Capstone Paper

A Paper Presented to Meet Partial Requirements

Nursing 594

MSN Capstone

Southern Adventist University

School of Nursing

Treatment for acute stroke: A retrospective study of Erlanger stroke patients from 2004-2012

## Introduction

**Description of the problem**

Stroke is the third leading cause of death in the United States and is the fourth leading cause of disability and cognitive impairment among the aging population (Ovbiagele et al., 2013). Every year 800,000 patients are diagnosed with an ischemic stroke accounting for 1 in 18 deaths in the United States. The majority of these deaths are caused by large vessel occlusions (Lloyd-Jones et al., 2010). It is projected by the year 2030 the direct medical costs among stroke patients will triple to as high as $184.13 billion among people 65-79 years old (Ovbiagele et al., 2013). Current therapy for an acute stroke is the administering of tissue plasminogen activator (rt-TPA) intravenously within 3-4.5 hours of onset of symptom. Unfortunately not all patients fit within the criteria needed to receive this therapy and therefore are unable to receive this treatment (Lloyd-Jones et al., 2010). Other treatment options such as the use of intra-arterial endovascular mechanical clot retrieval devises can be used within eight hours from the onset of stroke, but due to limited data on the long term effectiveness and functional improvement on patients after treatment this option is not adopted as a standard of care for stroke therapy. For this reason only about 5% of all ischemic stroke patients are treated with IV rt-TPA or IA treatments (Lloyd-Jones et al., 2010).

In evaluating the current data, stroke appears to affect more men than women younger than 85 years old, but according to the Framingham study, as women age the risk of stroke increases mostly because they have a longer life expectancy (Ovbiagele et al., 2013). In past years women under the age of fifty were considered to be at a lower risk for stroke than men, but due to the increased awareness of stroke prevention, women ages 45-64 are much more likely to

report a stroke or stroke like symptoms when the onset occurs (Ovbiagele et al., 2013).  When it comes to race and ethnicity Caucasians are still at higher risk of having a stroke, but African American and Hispanics are twice as likely to have multiple strokes or death from a stroke as whites.  It has projected by the year 2050, stoke incidence among the Hispanic population to increase from 16% to 30.2 % whereas the African American community to remain fairly stable (Ovbiagele et al., 2013).  One big factor that has shown to be linked to stroke among minority groups is the lack of low income primary care providers that diagnose and treat risk factors for stroke, such as high blood pressure, obesity, smoking, and diabetes (Ovbiagele et al., 2013). Socioeconomic status makes preventative measures hard to attain and therefore medical care is not sought until a major life illness occurs, such as a stroke.  Other factors related to stroke mortality are varied among regions in the United States.  The Stroke Belt, which is located in southeast United States, has on average a 20% higher mortality rate than the rest of the nation. Among this area North Carolina, South Carolina, and Georgia have the highest mortality rates within the Stroke Belt which has labeled these states "the buckle" of the southeast region (Ovbiagele et al., 2013).  To decrease mortality, stroke symptoms needs to be identified quickly and treatment expedited by using interventional radiological procedures such as the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) device or the Penumbra clot device for the extraction of clots from the brain (Ruff & Froehler, 2013).

**Definitions of terms**

When an acute blockage of blood flow occurs in the brain it causes cell injury and death. This is known as an acute ischemic stroke (AIS).  It is estimated that about 1.9 million neurons die for every minute an AIS goes untreated for this reason a quick diagnosis and treatment plan needs to be in place to prevent severe disability or death (Saver, 2006)  Currently the standard of

care for AIS is intravenous recombinant tissue plasminogen activator (rt-PA), a thrombolytic agent (Meyer et al., 2009).  This treatment can only be administered within three hours of stroke symptoms and if the patient meets certain criteria of inclusion and exclusion parameters.  This current treatment requires rapid assessment, diagnosis and treatment by providers and has thought to be less efficacious for large vessel occlusions (Bhatia et al., 2010).   IV t-PA has also shown to be limited in its ability to restore perfusion when a clot is located within the middle cerebral, anterior cerebral, carotid terminus, and vertebrobasilar arteries where large thrombus occlusion tend to reside (Bhatia et al., 2010).

The need for alternative treatment for acute ischemic stroke has given rise to interventional radiological devices used to extract or dissolve a clot.  The MERCI retriever was developed to be used on patients who were ineligible for the treatment of rt-PA or who fail rt-PA.  This devise is a corkscrew-shaped device that pulls the clot out of the affected artery and into a balloon guided catheter, which temporarily stops blood flow during the clot retrieval.  It later included using intra-arterial tPA in conjunction with this devise and found recanalization rates increased from 43% to 63%.   (Ruff & Froehler, 2013).  The Penumbra system is a different type of neuro-embolectomy devise.  It is designed to remove clot through thrombus aspiration.  In the pivotal trial for FDA clearance 125 patients were studied to assess the safety and effectiveness of the devise to reduce clot in an acute stroke.  The results indicated that the Penumbra system was able to restore blood flow in over 80% of the patient who had suffered a large vessel occlusion, which is higher than other modes of therapy researched (Bose et al., 2008).  By being able to have these tools in place researchers can evaluate patient outcomes and decide on whether current treatment standards need to be replaced or amended.

**Theoretical Framework**

In researching the different treatment options available for stroke therapy the theoretical framework that seems to assess all aspects of the patient is Betty Neuman's Systems Model.  In Neuman's model assessment it states a person as being a layered multidimensional being.  Each layer consists of five person variable or subsystems.  The first refers to the physiological which is the physiochemical structure and function of the body.  The second variable is psychological that deals with the emotions and mental processes.  The third concept refers to the expectations relationships; society and culture can place on the person during a difficult time in their life.  The last two discuss the importance of spiritual and development beliefs over time.

**Purpose Statement/PICO question**

The purpose of this study is to evaluate Erlanger's patients' outcomes from the years 2004-2012 that were diagnosed with an anterior cerebral occlusion; who received IV-tPA and/or interventional radiological interventions using the penumbra or Merci catheter.  Patient outcomes will be measured by assessing the patients modified Rankin scale, NIHSS score, and/or their TICI score pre-procedure, post-procedure and by a 3 month follow-up.

<div align="center"><b>Literature Review</b></div>

Since 1995 intravenous rt-PA has been labeled as the only FDA approved medical therapy for an ischemic stroke.  A randomized, double blind trial conducted by the National Institute of Neurological Disorders and Stroke (NINDS) studied the effectiveness of IV rt-TPA for the treatment of ischemic stroke patients.  Each of the 624 patients was treated within 90 minutes of stroke onset and diagnosis.  This trial carried out two parts this study.  The first arm looked at the patients who were given rt-TPA and whether any early improvements were seen. Early improvements was defined as complete resolution of the neurologic deficit or an

improvement from base line in the score on the National Institutes of Health stroke scale

(NIHSS) by 4 or more points 24 hours after the onset of stroke. Each group was assessed

according to the time from the onset of stroke to the beginning of treatment: 0 to 90 minutes, 91

to 180 minutes, and 0 to 180 minutes after the onset of stroke.  This first arm of the trial found no

significant difference between stroke improvement scores (p=0.56, 0.23,0.21).  In the second arm

of the study it evaluated patients three months after stroke treatment and looked at four primary

outcome measures.  As compared to placebo the second arm of the study showed favorable

improvements evaluated by the global test statistic, the odds ratio for a favorable outcome in the

t-PA group was 1.7 (95 % CI, 1.2 to 2.6; p = 0.008). As compared with the placebo group, there

was a 12 percent absolute (32 percent relative) increase in the number of patients with minimal

or no disability (a score of 95 or 100 on the Barthel index) in the t-PA group. There was also an

11 percent absolute (55 percent relative) increase in the number of patients with an NIHSS score

of 0 or 1 in this group. A similar magnitude of effect was seen with respect to the absolute and

relative improvement in the t-PA group with the use of the modified Rankin scale and the

Glasgow outcome scale.  This study demonstrated that the benefits of IV rt-PA may not be

immediate but clinical outcomes can improve over time.  No significant difference between

mortality rates between the control or treatment groups were discovered upon a 90 day follow-up

(p=0.30) (NINDS Stroke Study Group, 1995).

Bhatia et al. recently studied large proximal vessel occlusions therapies and reported that

patient's with large vessel occlusions, had lower recanalization rates (21%) with rt-PA therapy

alone.  It went on to demonstrate the use of intra-arterial mechanical thrombectomy devices had

an 80% success rate in recanalization of the affected area.  The tool used to evaluate this research

was the Thrombolysis in Cerebral Infarction (TICI) Score.  It found strong relationship between

recanalization and reperfusion, with reperfusion being successful with a 90% or better success rate.  Of those undergoing intra-arterial mechanical thrombectomy 52 of 86 (60.5%) patients who had recanalization had a good outcome compared with 10 of 41 (24.3%) of those without recanalization (relative risk, 2.5; 95% CI, 1.4–4.3).  Patients with recanalization early had a significantly better outcome than those with recanalization later (Bhatia et al., 2010).

Riedel et al. examined the length of the clot in a large vessel such as the middle cerebral artery (MCA) and the use of rt-PA alone.  It showed a significant inverse relationship between the length of the clot before and after treatment with rt-PA therapy.  It concluded the longer the clot the less likely it could be dissolved by using lytic agents (Reidel et al., 2010).

When evaluating medical therapy for acute stroke versus interventional therapies three studies, SYNTHESIS Expansion trial, the IMS-III trial and the MR RESCUE trial all sought to assess medical therapy using rt- PA or endovascular therapy.  All these studies failed to prove one treatment over another.  The SYNTHESIS Expansion trial showed no difference between the patients' modified Rankin scale which was defined as mRS≤1.  It was limited due to lag time to endovascular treatment, and patients were not screened prior to rule out small vessel occlusions before endovascular treatment was performed. The IMS-II trial also evaluated the patients' mRS as a good indicator of functional independence.  This study was halted due to futility when between the 655 subjects enrolled showed no difference in the primary outcome, (38.7% IV tPA vs. 40.8% endovascular therapy.  The limitations of this trial were that CTA or MRA were not required prior to enrollment and so 21% of the enrollees had no large vessel occlusions.  Another downfall was that the Merci device was the only catheter made available even though newer devices were being used, additionally the delay of intervention which on average was found to be 126 minutes between IV tPA and intervention.  The ME RESCUE trial also evaluated medical

therapy versus endovascular techniques but also showed no statistical difference from the

medical therapy group.  Limitations were also due to the use of older devices and longer delays

to intervention, the mean time being six hours after onset (Ruff & Froehler, 2013).

Unfortunately the limitations of these studies have yet to prove which therapy may be

more beneficial to patients who present with an acute stroke.  More studies are needed to

evaluate large vessel occlusion therapy, type of endovascular devices, and functional

independence post stroke and 3 month follow up to be able to clearly understand which treatment

options are best practices for patients who are presenting with stroke symptoms (Hassan et al.,

2013).

## Methods

### Research Design

This is an ongoing retrospective chart review by the Interventional Radiology led by

Blaise Baxter M.D and Jennifer Sparks FNP-BC,  to examine patients with anterior large vessel

ischemic stroke admitted to Erlanger hospital 2004-2012.  This study will evaluate which

endovascular techniques were performed, whether rt-PA was given IV or IA, and then assess

patient outcomes by evaluating the patients TICI score, modified Rankin score, and NIHSS pre,

post and three month follow-up.    This study plans to be the foundation for a prospective,

randomized concurrent controlled study of Erlanger patients presenting with symptoms of acute

ischemic stroke who have evidence of large clot burden in the anterior circulation.  This study

will begin with the evaluation of patient's charts who have suffered an acute embolic stroke.  It

will then be broken down, by identifying, whether the patients received rt-PA (0.9mg/kg to a

maximum of 90 mg), combined IV rt-PA therapy (0.9mg/kg to a maximum of 90mg) and intra-

arterial adjunctive treatment with the Penumbra System or Merci catheter device, or just intra-

arterial treatment with the Penumbra or Merci catheter.  After evaluating which method or methods  were used then variable such age, sex, TICI score, modified Rankin scale, and NIHSS will be combined to evaluate which method seems to have greater success in stroke therapy.

**Population**

Patients ages 18-85 who present with stroke like symptoms at the Erlanger Baroness Campus between the years of 2004-2012 and within eight hours from onset of symptoms were included.   These patients received either IV rt-PA therapy, combined therapy, (intra-arterial rt-PA treatment using the penumbra and/ or the use of the merci catheter) or patients who received treatment using just endovascular devices.  Posterior ischemic stroke patients, pregnant women, and patients who had associated hemorrhage or trauma which coincided with the ischemic stroke were not included in this study.  Other excluding criteria were pre-existing neurological or psychiatric diseases that could confound the study results such as a pre-stroke mRS score $\geq 1$, known severe allergy to contrast media, and/ or history of a stroke within the last three months.

**Variables**

The variables for this research evaluated the following:  age, sex, type of vessel occluded, whether it was an anterior or posterior stroke, timing of the onset of symptoms, arrival time to the emergency room, whether the patient received intravenous rt-PA, time it took once diagnosis was confirmed until when the radiological intervention occurred, what device was used, their pre and post-operative TICI score, NIHSS, and  modified Rankin.  It also compiled whether a cerebral hemorrhage resulted within 24 hours after the procedure or any other complication such as vessel injury.  Other variables assessed were length of stay and need for rehabilitation after. All these variables were compiled to evaluate the success of intervention on acute stroke patients.

**Measurements**

Modified Rankin scale quantifies the degree of disability or dependence in a person's daily activities after they have suffered a stroke, and has become the most widely used clinical outcome measure for stroke clinical trials.

The National Institutes of Health Stroke Scale is a tool used by healthcare providers to objectively quantify the impairment caused by an acute stroke. The NIHSS is comprised of 11 items, each of which scores the patients specific ability between a 0 and 4. For each item, a score of 0 typically indicates normal function in that specific ability, while a higher score is indicative of some level of impairment. The individual scores from each item are summed in order to calculate a patient's total NIHSS score. This score is usually assessed upon admission of an acute stroke and then at discharge and 3 month follow-up.  The maximum possible score is 42, with the minimum score being a 0 (National Stroke Association, 2006).

<div align="center">

**Results and Discussions**

</div>

**How Role Evolved**

I first was made aware about this current research by speaking with Jennifer Sparks FNP who works with the Interventional Radiology Department at Erlanger Hospital.  I discussed with her my desire to get involved with some research project and she told me about some research projects going on within her department.  This evolved as a beginning point to a further prospective study on stroke outcomes.

**Role as Research Assistance**

As a research assistant for this study I performed chart reviews on patients who were admitted with an acute stroke during the year 2010.  I audited over seventy charts and compiled the following outcome variables on an excel spreadsheet.  Other research assistants looked at the other years.  I performed over 60 hours reading, interpreting, synthesizing and logging in data into Excel.  I also assisted the researcher in other ways such as organizing, storing, and filing paperwork for this study.

**Findings**

This study is still in the collection phase of its findings therefore no findings are available to report at this time.  The target completion date is still yet to be determined due to budget cuts and lay off at the facility.

**Evaluation**

Overall I learned a great deal from this experience.   This was my first experience with research and synthesizing information from charts.  I found I gained more knowledge about stroke and stroke therapy.  When I began my chart reviews I found I had to look up a lot of information so I could understand what I was reading from radiological reports and CT scans. Just simple terminology was hard to interpret at first but the more I became familiar with anatomy of the brain and the various tools being used during the procedures I found I was quicker by the end.  When I first began the chart reviews it took me approximately 45 min per chart which was very tiresome and grueling because it was hard to understand the medical jargon, but by the end of this experience it took me probably about 20 minutes per chart review. Overall this was a great experience and it opened my eyes on how hard it is to conduct research, get approval for it and then to follow through with the findings of it.  Hopefully this research will

be finished soon so that they can review what did not work for the majority of patients and

implement a prospective study that will aid in future stroke advancements.

References

Bhatia, R., Hill, M., Shobha, N., Menon, B., Bal, S., Kochar, P., ... Demchuk, A. (2010). Low

    rates of acute recanalization with intravenous recombinant tissue plasminogen activator

    in ischemic stroke. *Stroke*, *41*, 2254-2258.

Bose, A., Henkes, H., Alfke, K., Reith, W., Mayer, T. E., Berlis, A. ... Po Sit, S. (2008, August).

    The penumbra system:  a mechanical devise for the treatment of acute stroke due to

    thromboembolism. *American Journal of Neuroradiology*, *29*, 1409-1413.

    http://dx.doi.org/10.3174/ajnr.A1110

Hassan, A., Aman, M., Chaudhry, S., Grigoryan, M., Tekie, W., Rodriguez, G., & Qureshi, A.

    (2013, February). Value of other endovascular techniques among patients with MERCI

    device failure during the treatment of acute ischemic stroke. *Journal of Vascular and*

    *Interventional Neurology*, *5*(2), 9-13. Retrieved from

    http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3584820/

Healthy People.gov. (2013).

    http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=21

Lloyd-Jones, D., Brown, R., Carnethon, M., Hailpern, S., Ho, P., Howard, V., ... Kittner, S.

    (2010). American heart association statistics committee and stroke statistics

    subcommittee heart disease and stroke statistics 2010 update: A report from the American

    heart association. *Circulation*, *121*, e46-e215.

Meyer, P. M., Schumacher, C., Higashida, R. T., Barnwell, S. L., Creager, M. A., Gupta, R., ...

    Sacks, D. (2009). Indications for the performance of intracranial endovascular

    neurointerventional procedures. *Circulation*, *119*, 2235-2249.

    http://dx.doi.org/10.1161/circulationinterventional procedures

National Stroke Association. (2006). www.stroke.org

Neuman Systems Model. (n.d.). http://www.neumansystemsmodel.org/index.html

Nursing Theories. (2012). www.currentnursing.com

Ovbiagele, B., Goldstein, L. B., Higashida, R. T., Howard, V. J., Johnson, C., Khavjou, O. A., ...
Lichtman, J. (2013, May 22). Forecasting the future of stroke in the United States:  A
policy statement from the American Heart and American Stroke Association. *Stroke*, *44*,
2361-2375. http://dx.doi.org/10.1161/STR.0b013e31829734f2

Reidel, C., Zimmermann, P., Jensen-Kondering, U., Stingele, R., Deuschl, G., & Jansen, O.
(20101). The importance of size.  Successful recanalization by intravenous thrombolysis
in acute anterior stroke depends on thrombus length. *Stroke*, *42*().
http://dx.doi.org/10.1161/STROKEAHA.110.609693

Ruff, Jr., J., & Froehler, M. (2013, June 29). Status of endovascular interventions to treat acute
ischemic stroke. *Current Treatment Options in Neurology*.
http://dx.doi.org/10.1007/s11940-013-0250

Saver, J. L. (2006). Time is brain-quantified. *Stroke*, *37*(1), 263-266.

The European Co-operative Acute Stroke Study-II(ECASS-II). (1999, January 2). ECASS-II:
intravenous alteplase in acute ischemic stroke. *The Lancet*, *353*, 65-66.
http://dx.doi.org/10.1016/S0140-6736(05)74846-7

The National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group. (1995).
Tissue plasminogen activator for the acute ischemic stroke. *The New England Journal of
Medicine*, *333*(24), 1581-1587.