Title: Safety and Feasibility of the Infinity Guide Catheter for Neurointerventional Procedures Using Transradial Access

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RESEARCH PROTOCOL

STUDY INFORMATION

- **Title of Project:**
  Safety and Feasibility of the Infinity Guide Catheter for Neurointerventional Procedures Using Transradial Access

- **Principal Investigator Name:**
  Priyank Khandelwal

- **Principal Investigator Div. & Dept.:**
  Department of Neurological Surgery

- **Principal Investigator Contact Info:**
  Pk544@njms.rutgers.edu
  DOC 8th floor, University Hospital, Newark, NJ
  973-972-2323

- **Protocol Version and Date:**
  V3.0 09.8.2020

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1.0 Research Design

1.1 Purpose/Specific Aims

1) Assess the safety and feasibility of the Stryker AXS Infinity LS large bore catheters for neurointerventional procedures using the transradial approach
2) Assess rate of conversion from transradial to the transfemoral approach when these catheters are used
3) Secondary aim: Assess radial artery occlusion rates post procedure

A. Objectives

The main objective of this single arm study is to evaluate the safety and feasibility of the AXS Infinity LS (Stryker, Freemont, CA, USA) and AXS Infinity LS Plus (Stryker, Freemont, CA, USA) catheters during the transradial approach through a secondary use of the data collected during neurointerventional procedures. This includes evaluating the conversion rates to a transfemoral approach. A secondary aim of the study is to assess the radial artery occlusion rates post procedure.

B. Hypotheses / Research Question(s)

We hypothesize that the large bore Infinity LS and Infinity LS plus catheters are safe and feasible for neurointerventional procedures with transradial access. We further hypothesize that radial artery occlusion rates will remain within the range reported in the literature (1-10%).

1.2 Research Significance

Most cerebrovascular pathologies, including ischemic stroke, aneurysms, carotid stenosis, arteriovenous malformations, and brain tumors, are treated through a minimally invasive endovascular approach. Historically, the right common femoral artery has been the preferred access site for these procedures. Over the last 2 decades, radial access for coronary angiography has been widely accepted by interventional cardiologists as the literature has consistently demonstrated its safety and feasibility.[1-4] Given the positive results demonstrated for cardiac interventions, the transradial approach (TRA) has emerged as a feasible alternative for neurointerventional procedures as it was demonstrated to be safer, improve patient comfort, and decrease costs and procedural time when compared to the traditional transfemoral approach (TFA).[5] While there is ample evidence in the cardiac literature demonstrating the TRA to be superior to the TFA, publications regarding the TRA in neurointerventional literature are only just emerging.

Due to its recent adoption, most neurointerventionalists are only slowly converting to the TRA. Other than the initial learning curve associated with adoption of the TRA, neurointerventionalists also cite the inability to use large bore catheters to provide adequate support during interventional cases. Most large bore catheters are designed for the TFA. These catheters are generally 6 Fr (2mm outer diameter) or larger. When performing interventions, access into the distal cerebrovasculature requires the use of larger bore support catheters to allow for adequate manipulation of smaller catheters which are passed through them. The smaller size of the radial artery, when compared to the femoral artery, at times can prevent the use of guide catheters larger than 6 Fr (>2mm). Even when the artery in larger than 2mm, the artery can go into significant vasospasm and clamp down after initial access. This results in the inability to advance or retract the catheter, and in certain cases can result in a retained catheter. We routinely administer antispasmolytic agents after arterial access in order to prevent vasospasm. Due to the risk of vasospasm, radial artery catheters must also be coated with a hydrophilic coating, which allows for adequate lubricity when then catheter is travelling against the walls of the radial artery. Adequate lubriciousness of the catheter also prevents significant vasospasm due to the decreased friction at the catheter-vessel wall interface.

In cases where the radial artery enters vasospasm limiting the use of the TRA, or when the interventionalist has trouble catheterizing the target vessel, the procedure is converted to the TFA. We

routinely prep both the radial and femoral access sites prior to the procedure in case conversion is required.

Following a neurointerventional case performed through the TRA, hemostasis within the vessel is achieved using a band which applies pressure. The band is inflated with air, and over time, air is slowly released. This allows for “patent hemostasis,” enough pressure to prevent bleeding from the artery, but not enough to occlude it.

On post-operative day (POD) 1, we perform a reverse Barbeau test at the patient’s bedside to assess the patency of the radial artery. This requires the placement of a pulse oximeter on the hand and manual compression of the ulnar artery. If the patient’s pulse oximeter waveform flattens after manual compression of the ulnar artery, this would signify that the radial artery might be occluded. In this case, we would obtain a radial artery ultrasound. If the pulse oximeter waveform remains at baseline, no further testing would be required. We routinely check the radial artery for possible occlusion on POD 1 as well as at the 1 month follow-up. If the artery appears to be occluded on examination at 1 month, an ultrasound is obtained. Radial artery occlusion is generally asymptomatic and the rate has varied in the literature.

The preliminary experience from our own institute as well other neurosurgical practices has anecdotally demonstrated that the AXS Infinity LS and Infinity LS plus catheters can be used without any issue for TRA neurointerventional cases. While both these catheters are FDA approved for neurovascular access and are used routinely during the TRA, there has not been a formal study evaluating the safety and feasibility of this catheter when used with the TRA. Our goal is to analyze this prospectively collected clinical data to evaluate the safety and feasibility of these two catheters via the TRA. We will also formally analyze the rates of radial artery occlusion as well as conversion to the femoral approaches when these catheters are used.

1.3 Research Design and Methods

A. Research Procedures

Patients who are undergoing endovascular intervention will be enrolled into the study and the research team will prospectively abstract information from their medical chart. As the metrics analyzed in this study are already normally collected, our study can be considered as a secondary use of the data. The procedure will be done using standard criteria as per operator preference. All interventional cases at our institution undergo a “radial first” approach, meaning that the access site of choice is the radial artery. We measure the radial artery size to ensure that the artery is greater than 2.4 mm in order to use the Infinity catheter (8Fr). If the artery does not meet the size criteria, we can only use a 6Fr sheath, and the data recorded during the procedure will not be utilized for analysis in this study. The procedures will be performed in the Neuroangiography suite at University Hospital. The study will not impact or change the procedure in any way. The preoperative and postoperative care will be the same for all the patients. No tests will be done outside of standard of care.

B. Data Points

All data points which will be analyzed in this study are already routinely collected intra and post procedure. The values recorded for procedural times including the time of accessing the artery, time to place the guide catheter into the desired intracranial vessel, time to complete the procedure, conversion to the femoral approach, spasm noted in the artery and radial occlusion rate at x 24 hours and one month will be analyzed.

Outcomes and complications data recorded at 3 different time points- Day 1 after the procedure, at the time of discharge, and at 1 month follow-up will be analyzed. The patient is seen in clinic at 1 month for follow up, which is standard of care for patients undergoing interventions.

C. Study Duration

We intend to include approximately 100 patients from our center. When including follow-up of at least 1 month, the duration of the study would be about two years. Data collection will be from 10/1/2020-9/30/2022.

D. Endpoints

The endpoints would be complete data collection as needed in this study.

1.4 Preliminary Data

Preliminary data is not available from this study. The data related to this study is only available from the literature.

1.5 Sample Size Justification

Total of 100 patients will be included in this study. All the patients needing an intervention will be evaluated for eligibility for the study.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The patients who are eligible for intervention will be included. We will review there collected clinical data: age and sex as well as past medical history (Hypertension, hyperlipidemia, diabetes, atrial fibrillation, tobacco use). The radial artery size measured will be reviewed. We will also record whether the case was converted to the TFA. The peri-operative and post-operative care will be the same for all the patients in both groups.

Both the intervention approaches are standard of care at the current time. Catheter is FDA approved and is already used in most interventional procedures.

No tests will be done outside of standard of care.

The preoperative and post-operative outcomes will be reviewed in terms of placement of catheter into the desired vessels, spasm and occlusion of the RA and complications such as hematoma, dissection of the RA.

B. Dependent Variables or Outcome Measures

The procedural times including the time of accessing the artery (groin puncture, time to place the catheter into the desired vessels, and complications such as dissection of the RA, hematoma at the access site, spasm of the RA, catheter retention, radial artery occlusion and time to complete the procedure will be noted.

1.7 Specimen Collection
N/a

1.8 Data Collection

A. <u>Primary</u> Data Collection

- Location: The data collection will be obtained from the Neuro Angiography Suite. The data will also be collected from electronic health records. The data will be stored in the hospital computer in DOC building on the 8th floor and will be password protected. Only the study investigators and designated study staff will have access to the data.

- Process of Data Collection: The neurosurgery attendings or the neurosurgery fellow and resident involved in the study will collect the data.

- Timing and Frequency: The data will be collected in a prospective manner as the interventions are performed.

- Procedures for Audio/Visual Recording: Not applicable

- Study Instruments: Not applicable

- Ethnographic Studies, Interviews, Or Observation: Not applicable

- Subject Identifiers: MRN will be used to initially identify patients. Once data is collected, MRN will be removed and a unique subject number will be applied

B. Secondary Data Collection

- Type of Records: Medical charts/EMRs/and the PACS (imaging records)

- Location: Medical Records—Epic, and PACS. IRB permission, no other permission is required. DOC office and Neuroangio IR suite.

- Inclusion/Exclusion:

- **Inclusion Criteria**
  - Age group 18 years and above.
  - Patients undergoing neuro-embolization using large bore catheters

- **Exclusion Criteria**
  - Patients with Radial artery diameter less than 2.4 mm measured with Ultrasound
  - Age<18
  - Patients who have previous surgeries at either approach site which precludes the use of one of the approach sites.
    - Patients who has poor collateral circulation, Raynaud's phenomenon, radial loop, brachial or subclavian stenosis, aberrant origin of the subclavian artery.
    - Pregnant patients

- Data Abstraction Form(s): uploaded

N/a

2.0 Project Management

2.1 Research Staff and Qualifications

The study data collection, procedures performed during the study will be performed by the endovascular physicians or fellows. They have been doing these procedures routinely. They have been made familiar with the study protocol. Study staff trained to perform the procedure are: Neil Majmundar, MD; Amit Singla, MD; Ivo Bach, MD; Taha Nisar, MD; and Pratit Patel, MD. In addition, the study coordinator, Roxanne Nagurka will assist with data collection.

2.2 Research Staff Training

All endovascular attendings and fellows involved in the study are trained to do stroke interventions and trained in stroke management. They have been actively involved in stroke publications and understand the concept of this current study as well. All study personnel have also undergone HIPAA and CITI training.

2.3 Resources Available

Not applicable

2.4 Research Sites

University Hospital, Doctors Office Center (DOC)

3.0 Multi Center Research

N/a

4.0 Research Data Source/s

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

This is a study performed through the secondary use prospectively collected data from patients undergoing neurointerventional procedures via the TRA. Therefore, any patient who will require endovascular procedure and fits the inclusion criteria will be identified for potential inclusion in the study.

B. Recruitment Details

No additional recruitment is required for this study. The patients who are brought to the hospital requiring possible endovascular intervention will have their clinical data recorded as usual. The patients will be screened for inclusion if they are a candidate for the study.

C. Subject Screening

Subjects will be screened by the PI on the following criteria:

- **Inclusion Criteria**
  - Age group 18 years and above
  - Patients undergoing neuro-embolization using large bore catheters
- **Exclusion Criteria**
  - Patients with Radial artery diameter less than 2.4 mm while measures through US or angiographically
  - Pediatric patients
  - Patients who have previous surgeries at either approach site which precludes the use of one of the approach sites
  - Patients who have poor collateral circulation, Raynaud's phenomenon, radial loop, brachial or subclavian stenosis, aberrant origin of the subclavian artery

4.2 Secondary Subjects

Not applicable

4.3 Number of Subjects

A. Total Number of Subjects

The total number of subjects will be 100 patients

B. Total Number of Subjects If Multicenter Study

Not applicable

C. Feasibility

We accomplish 15-20/month interventions at University Hospital. Excluding some patients for different reasons such as patient's non-willingness to participate in the study, unable to perform intervention through TRA for some reason. With these numbers it should take us about 5-6 months to enroll the desired number of patients in the study.

4.4 Consent Procedures

A. Consent Process

N/A

B. Waiver or Alteration of Consent Process

- Waiver or Alteration Details

  We will not be informing patients that we will be collecting information from their electronic medical record to enter into our excel spreadsheet to determine the safety and feasibility of the TRA. Therefore, we are seeking a waiver of consent.

- Destruction of Identifiers

  Identifiers will be deleted from the database after the extraction of 1month follow up data.

- Use of Deception/Concealment

  N/A

a. Minimal Risk Justification

This study does not pose any additional risk to the subjects to be included. They will receive the same standard of care as it is done now. The only risk could be the unintended exposure of their PHI. Every effort will be made to protect their PHI such as the access will be provided to the personnel included in the study.

b. Alternatives

None

c. Subject Debriefing

N/A

C. Documentation of Consent

- Documenting Consent

  N/A

- Waiver of Documentation Of Consent (i.e., will not obtain subject's signature)

  We will not be asking participants to sign a consent form as this will be the only link to identifying the patient once their MRN is deleted from the database.

4.5 Special Consent/Populations

A. Minors-Subjects Who Are Not Yet Adults

Minors will not be included as subjects.

B. Wards of the State

N/A

C. Non-English-Speaking Subjects
N/A

D. Adults Unable to Consent / Decisionally Impaired Adults

- NJ Law-Assessment of Regaining the Capacity to Consent

  N/a

- Capacity to Consent

  N/a

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
None

B. Compensation/Incentives
None

C. Compensation Documentation
N/A

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects
- Reasonably Foreseeable Risks of Harm
  - Minimal risk category.
  - This study does not pose any additional risk to the subjects to be included. They will receive the same standard of care as it is done now.
  - The only risk could be the unintended exposure of their PHI. Every effort will be made to protect their PHI such as the access will be provided to the personnel included in the study.

Risk of Harm from an Intervention on a Subject with an Existing Condition
N/A
- Other Foreseeable Risks of Harm
  N/A
- Observation and Sensitive Information

N/A

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks of Harm to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
N/A

E. Minimizing Risks of Harm
NA

- Certificate of Confidentiality
  NA
- Provisions to Protect the Privacy Interests of Subjects
  NA

F. Potential Benefits to Subjects

This study may not offer any direct benefit to the subjects to be involved in this study. However, it may be helpful to our practice in future and may help the future patients.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

We will be using the Medical record number while we are collecting the data for the study. Once the data has been collected, the patient identifier will be erased from the study database.

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. Special Populations
N/A

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

n/a

6.0 Data Management Plan

6.1 Data Analysis

- The feasibility of Infinity LS and Infinity Plus catheter for neurointervention using TRA.
- Interim analysis after 50 cases.
- Data will be analyzed with the help of a statistician.

6.2 Data Security

- The data will be stored in the hospital computer and will be password protected. Only the study investigators and designated study staff will have access to the data. Once the 1 month follow-up visit is completed and data has been abstracted from the EMR, the subject's MRN will be deleted from the excel sheet and the subject will be assigned a unique identifier. The unique number will have no link to the MRN identifying the subject.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

We will perform interim analysis of the data after enrolling 50 subjects. Data will be reviewed for successful completion of the procedure, rate of radial to femoral conversion, hand ischemia, RAO.

B. Data/Safety Monitoring Board Details

Three Members will be part of the Data / Safety Monitoring Board who will independently monitor the data for the study. Interim analysis will be done mid-way through the study.

6.4 Reporting Results

A. Individual Subjects' Results
N/A

B. Aggregate Results
N/A

C. Professional Reporting
The study results will be presented at a national and International level meeting and also the manuscript will be written which will be submitted to the peer- reviewed journal for consideration of publication.

D. Clinical Trials Registration, Results Reporting and Consent Posting
N/A

6.5 Secondary Use of the Data
N/A

7.0 Research Repositories – Specimens and/or Data

N/a

8.0 Approvals/Authorizations

Agreement from UH uploaded

9.0 Bibliography

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