THE UNIVERSITY of TENNESSEE
GRADUATE SCHOOL OF MEDICINE

Title

Improved Outcomes with Pre-Procedure Shockwave IVL of Common Femoral Artery Access Site Prior to Large Bore Access and Pre-Closure.

Investigators

PI: Raj Baljepally, MD
Co-I: Benjamin Fogelson, MD, Muhammad Khan MBBS, Eric Heidel, PhD, Tyler Coombes, MD, James Livesay, DO

Location

University of Tennessee Graduate School of Medicine & University of Tennessee Medical Center

1. INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has been performed with many various access approaches, however superiority to surgical aortic valve replacement was only seen in transfemoral access[1]. Intravascular lithotripsy (IVL) for peripheral arterial disease (PAD) was first investigated in the DISRUPT PAD I and DISRUPT PAD II trials, which demonstrated that IVL resulted in a significant reduction in stenosis severity and minimal vessel injury in patients with severely calcified femoropopliteal disease[2,3] . DISRUPT PAD III showed that peripheral IVL was safe and effective and could enable large-bore sheath advancement through calcified peripheral vessels[4]. Prior to these studies and IVL, heavily calcified iliofemoral arteries remained challenging for transfemoral access for TAVR. A case series previously reported outcomes on "hostile" iliofemoral arteries for TAVR, twelve patients required preparatory PTA prior to advancing the TAVR device, two patients failed the procedure due to common iliac perforation requiring stenting, both of which had severe circumferential calcifications[5]. IVL utilization to facilitate transfemoral access in patients undergoing TAVR with prohibitive iliofemoral vascular disease was shown to be advantageous by disrupting calcification and allowing for safe passage of the large-bore delivery sheaths[6]. This has allowed for the ability to expand the population eligible for TAVR. To our knowledge, there have not been any studies evaluating if Shockwave IVL reduced access site complications as the primary objective. The aim of our study is to evaluate this question.

2. RATIONALE

We believe that utilization Shockwave IVL of calcified femoral access site prior to large bore access will reduce complications and improve outcomes after large bore arterial access.

3. STUDY PLAN

3.1 Study Design

This is a prospective randomized/control trial pilot study to compare clinical outcomes of common femoral artery access in patients undergoing Transcatheter Aortic Valve Replacement (TAVR) at the University of Tennessee Medical. Specifically, we will compare patients utilizing the Shockwave model (M5) Intravascular Lithotripsy (IVL) prior to standard arterial access using the modified Seldinger technique to those utilizing the standard femoral artery access via the modified Seldinger approach without the utilization of intravascular lithotripsy in heavily calcified femoral arteries.

3.2 Objectives

3.2.1 Primary Objective

The primary objective is to observe reduced access site complications in patients with heavily calcified common femoral arteries requiring TARV.

3.2.2 Secondary Objectives

1. Determine the clinical outcomes between groups.
2. Distinguish extravasation post closure at the end of the procedure.
3. Compare the need for open vascular surgery between groups.

4. Examine PTA or Stents to the CFA to help hemostasis or local vascular complications between groups.
5. Number of Perclose devices used between groups.
6. Compare Bleeding/Hematoma between groups.
7. Examine the difference in hospital length of stay between groups.
8. Examine renal function post procedure
9. Difference in pain or numbness in the distal extremity between groups
10. Mortality related to complications from vascular closure site between groups.
11. Conversion to general anesthesia due to additional procedures required to address the CFA access site complications between groups.

3.3 Study Duration

We plan to enroll up to a total of 100 patients, 50 patients in each group. The total study duration will be approximately 12 months post IRB approval and study initiation. We will follow patients for 3 months post procedure for any adverse events; however, we would expect to see them within 3 days if there are events to occur.

3.4 Selection of Study Participants & Informed Consent

Patients at the UT Medical Center who meet the predefined inclusion and exclusion criteria will be enrolled after they provide consent to participate. The nature and purpose of the study will be explained to the patient by one of the investigators and the patient will be given a copy of the informed consent to review. The investigator or study coordinator will answer any questions which the patient may have prior to their signing the consent. The signed informed consent will be kept in the patient's research chart and a copy will be given to the patient. No study related interventions will be performed until after the patient signs the informed consent. The consent process will occur at an earlier date than the actual procedure to give patients plenty of time to review and ask questions.

3.4.1 Inclusion Criteria

1. >18 years of age
2. Patient with a diagnosis of severe aortic stenosis undergoing TAVR
3. Able to read and understand study procedures
4. Willing to participate and sign an ICF
5. Patients with > 90-degree arc of calcium at the large bore access site per CT documentation

3.4.2 Exclusion Criteria

1. Unable to understand study procedures
2. Unwilling to give consent
3. Patients with cognitive impairments that can affect their ability to give consent.
4. Unfavorable calcium distribution of femoral artery

3.5 Discontinuation of Subjects

An individual patient is to be withdrawn from the trial if any of the following criteria apply:

- The patient withdraws consent, without the need to justify the decision
- The patient is no longer able to participate for medical reasons (e.g., surgery, AEs, or other diseases)
- Decision by the PI to discontinue a specific patient for his/her safety (e.g., in case of SAEs)

Data of patients who discontinue or withdraw prior to enrollment will be entered in the study database and will be listed. Data of patients who discontinue or withdraw after enrollment will be documented and the reason for withdrawal will be recorded in the study record. The data will be included in the study database and will be reported.

4. STUDY PROCEDURES

4.1 Screening and Enrollment

Screening assessments will be completed by the study team on a day before the procedure to allow patients time to review and ask questions. Assessments will be initiated after the Informed Consent Form (ICF) Process. A study designee will present the study information to the patient. They will explain the purpose, risk, and benefits to the subject and present them with an IRB approved ICF. The potential participant will be given ample time to read the ICF and all questions and concerns from the subject will be addressed by a study team member. No procedures will be initiated prior to the subject signing and dating the ICF. After the subject signs the ICF, a copy will be given to them for their records. Participants will be informed that they can decline participation in the study without any effect on their health care. They can also withdraw their consent, including the consent to do various screening tests, at any time.

4.2 Datapoints/procedures to be collected/obtained:

- Informed Consent
- Medical History Review for Inclusion/Exclusion Criteria
- Concurrent Medication Review
- Pre-TAVR CT scan review
- Review of pre procedure laboratory results
- Demographics
- Pre-procedure consultation/progress notes
- Post procedure notes (consult, progress, discharge summary)
- Post procedure laboratory results and imaging
- Post discharge follow up office notes and vital signs

  If subjects meet all I/E criteria, they will be Enrolled, and the following will be recorded
- Flow rates prior to and post procedures
- Documentation of extravasation post closure at the end of the procedure.
- If open vascular surgery occurred
- Number of perclose devices used

- Bleeding/Hematoma outcomes
- Hospital length of stay
- Renal function lab results post procedure
- Pain or numbness in the distal extremity post procedure
- Whether conversion to General Anesthesia was needed during procedure
- Review of post-procedure laboratory results
- Surgical/procedure reports
- Mortality
- Discharge summary
- Adverse event monitoring

4.3 Study Assessment Methods

4.3.1 *Informed Consent Process*

Patients at the UT Medical Center who meet the predefined inclusion and exclusion criteria will be enrolled after they provide consent to participate. The nature and purpose of the study will be explained to the patient by one of the investigators and the patient will be given a copy of the informed consent to review. The investigator or study coordinator will answer any questions which the patient may have prior to their signing the consent. The signed informed consent will be kept in the patient's research chart and a copy will be given to the patient. No study related interventions will be performed until after the patient signs the informed consent. The consent process will occur before the actual procedure day to assure the patient has plenty of time to review and ask questions.

4.3.2 *Withdrawal of Consent*

Patients may withdraw from the study at any time. Patients should make every attempt to complete the study as specified. Investigators should encourage patient treatment compliance and adherence. All deviations from the planned treatment schedule will be documented.

4.3.3 *Study Intervention Administration*

The patient will be randomized using a randomized generator to either Group 1 (intervention) or Group 2 (control).

Study approach will be administered by Dr. Raj Baljepally.

1. We will first obtain access on the Common Femoral Artery (CFA) contralateral to the planned large bore access.
2. We will use a 6 F sheath and an Omniflush or similar catheter over an 0.035 Benson, Wholey or Advantage- glide wire.
3. We will then advance a 0.014 wire distal into the external iliac and remove the Omniflush catheter.
4. Over the 0.014 wire, we will advance Shockwave 60 mm balloon sized to the distal CFA balloon and perform IVL of the contralateral CFA.
5. After completing shockwave IVL we will then access the CFA with Fluoroscopy/US guidance and preclose followed by placement of a large bore sheath.

5. RISK

5.1 Physical Risks

Although the procedure approach being used in this protocol has been well tested for efficacy and safety, there may be potential risks associated with participation. Any medical treatment can have temporary and permanent side effects and can cause unforeseen adverse reactions, intolerance, or worsening of co– morbidities, which could lead to acute adverse event such as worsening kidney disease, allergic/immunologic reaction, infections, vascular complications, stroke, or death. All of which are risks associated with the TAVR procedure itself and are of low probability and discussed in detail prior to the TAVR procedure. With any invasive procedure, there may be unforseeable risks associated with the procedure resulting in complications or physical harm. Any subject with known medical conditions, or on a concurrent medication in which the study intervention is not recommended, will be excluded from participation.

The intervention used in this study are currently in common use and will be administered in accordance with current standards (ultrasound and fluoroscopy-guided vascular access, modified Sledinger technique) which are put forth in attempts to mitigate any potential risks. Patients will be carefully screened for contraindications to participation prior to study enrollment. We will monitor for adverse events in enrolled patients.

5.2 Intervention Risk

There is the potential risk of an interventional failure for study participants. The study results may not support the primary hypothesis that in patients with severely calcified femoral arteries, a pre-treatment with Shockwave intravascular lithotripsy intervention will not result in a decrease in femoral artery access site complications. It is possible that the intervention will prove to be less effective than the current standard method in which Shockwave intravascular lithotripsy is not used prior to access and placement of the TAVR delivery system.

Indications for Use—The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications—Do not use if unable to pass 0.014” (M5, M5+, S4) or 0.018” (L6) guidewire across the lesion-Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.

Adverse effects–Possible adverse effects consistent with standard angioplasty include:

- Access site complications
- Allergy to contrast or blood thinner
- Arterial bypass surgery

- Bleeding complications
- Death
- Fracture of guidewire or device
- Hypertension/Hypotension
- Infection/sepsis
- Placement of a stent
- renal failure
- Shock/pulmonary edema
- target vessel stenosis or occlusion
- Vascular complications
- Risks unique to the device: device malfunction or failure
- Excess heat at target site.
- Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention
- Atrial or ventricular extrasystole-Atrial or ventricular capture

5.3 Psychological Risks:

A potential psychological risk could occur if patients feel a sense of coercion to participate in the trial. The likelihood is small because patients will be assured in the informed consent document and face-to-face discussion that participation is purely voluntary and they can withdraw their participation at any time. Other potential psychological or emotional risks of fear, anxiety, guilt, confusion, depression, or social stigmata could occur, however this likelihood is small as we will provide as much information as possible during the consent and debriefing process.

5.4 Research Risk

Identifiable patient information will be securely stored by the study team. For this specific project, all information related to patients will be identified only by patient initials and study number. However, for research purposes, it may be required to collect PHI such as age, DOB, Medical Record Number and dates of diagnoses. Only the study team will have access to this data and it will not be shared with anyone outside of the study team. The greatest research risk, although rare, is the loss of confidentiality caused by unauthorized release or misuse of information from research records.

6. BENEFITS

Although there may be immediate clinical benefits for some patients in this trial who are assigned to the study intervention, the anticipated primary benefit is the future potential to decrease any vascular access complications that would lead to additional procedures or interventions, improve the safety of inserting the TAVR device delivery system.

Information obtained from this research may help patients in future achieve better health outcomes and provide clinicians with pertinent information about treating severely calcified femoral arteries prior to placement of the TAVR delivery system in attempts to make the

procedure safer for these particular patients. The treatment may be more effective than the treatments that are currently available.

7. ENDPOINTS/OUTCOMES

7.1 Efficacy

1. *Evaluate for contrast extravasation post closure of femoral artery at the end of the procedure*
2. *Determine need for Vascular surgery consultation*
3. *If vascular complication, was PTA, stenting, or open surgery used*
4. *Number of perclose devices used to close the femoral artery access site*
5. *Determine presence of other vascular complications I.e. bleeding, hematoma, emboli etc.*
6. *Review lab values and vital signs to determine if there is any clinical deterioration (drop in hemoglobin, worsening of creatinine, development of hypotension/shock, infections/sepsis)*
7. *Determine if there is a difference between hospital length of stay*
8. *Assess for difference in pain/numbness in distal extremities post-procedure*
9. *Assess for differences in mortality related to complications between the groups*
10. *Failure of treatment*

7.2 Safety

1. Number of related AE(s)
2. Number of related SAE(S)
3. Side effects reported by subjects or observed by study team

8. ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

AEs that are considered possibly, probably or definitely related to the study procedure will be recorded in the CRFs. AEs will be assessed starting with onset, and evaluation will continue until resolution is noted, or until the investigator determines that the patient's condition is stable.

All AEs will be characterized by the following:

- AE name
- Start and Stop dates
- Relationship to study procedure
- Severity
- Action taken
- Outcome

Relationship

The investigators will assess the AEs and using their clinical judgment will assign an attribution to the AE using the following categories:

- **Unrelated** – The AE *is clearly NOT related* to the study procedure
- **Unlikely** – The AE *is doubtfully related* to the intervention

- **Possibly** – The AE *may be related* to the study procedure
- **Probably** – The AE *is likely related* to the study procedure
- **Definitely** – The AE *is clearly related* to the study procedure

Severity

The severity of the AEs should be graded by the investigator as follows:

- **Mild** – Transient discomfort; no prescribed medical intervention/therapy required and does not interfere with daily activities.
- **Moderate** – Low level of discomfort or concern with mild to moderate limitation in dailyactivities; some assistance may be needed; medical intervention/therapy required.
- **Severe** – Discomfort and limitation in daily activities, assistance required; medical intervention/therapy required.

Action Taken

The action taken in response to the AE should be reported using the following categories:

- None
- Procedure or physical therapy
- Withdrawn from study due to AE
- Hospitalization
- Prescription drug therapy
- Non-prescription drug therapy
- Other (specify)

Outcome

The clinical outcome of an AE should be characterized as follows:

- Resolved without sequelae
- Resolved with sequelae (specify)
- Ongoing (i.e. continuing at time of study discontinuation)
- Death
- Unknown/lost to follow-up
- Other

SAE Reporting

All SAEs will be documented in the CRFs. SAEs will be reported to the local IRB per the following guidelines:

Adverse event reports will only be submitted to the local IRB if they are determined by the principal investigator to be: unanticipated, serious, and possibly, probably or definitely related to a research study procedure.

An SAE determined to be due to worsening of a pre-existing co-morbidity unrelated to the procedure will not be documented as an SAE. Such as a repeat hospitalization due to worsening COPD, diabetes, etc. As these can be expected and unrelated to the study in patients with these pre-existing conditions.

SAEs meeting these criteria (except for deaths) must be reported to the IRB *within 5 working days* of the study team's notification of occurrence. Deaths that are unanticipated and are possibly, probably or definitely related to a research study procedure must be reported to the IRB *within 24 hours* of notification of occurrence. Any relevant follow-up information regarding the SAE should be submitted to the IRB as soon as it becomes available and/or upon request. SAE reports to the IRB must include the following: subject identifier, adverse event or problem description, the event relationship to the test article or underlying condition, seriousness assessment, whether the event was anticipated or unanticipated, type of report (initial or follow-up), date of injury, whether the intervention was stopped, and, if so, whether it was re-started, and whether the event provides new risk information that alters the risk-benefit assessment and/or should be added to the informed consent disclosure.

9. STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

9.1 Sample Size Determination

The researchers could not find an evidence-based measure of effect size from the existing literature. Therefore, this project will be considered a pilot study. The researchers believe there will at least be 10-20% reduction in complications associated with the treatment based on clinical experience. An a priori sample size calculation was performed using a 20% reduction, and with a two-tailed hypothesis, a power of 80%, and an equal allocation ratio to treatment arms, a total of n = 100 participants was generated. Therefore, the researchers plan on enrolling n = 50 participants in each treatment arm, totaling n = 100 participants. The effect size yielded from the final analysis will be used to power a future, larger trial between the two treatment arms.

9.2 Statistical Methods

Descriptive and frequency statistics will be used to describe the demographic, clinical, and prognostic characteristics of the randomized sample. All inferential analyses will be performed in an "intention-to-treat" fashion. A "per-protocol" analysis will also be performed. For the primary outcome, access site complications, both bivariate (chi-square or Fisher's Exact test) and multivariate (logistic regression) analyses will be performed to compare the two groups. Unadjusted odds ratios (OR) with 95% confidence intervals (95% CI) will be generated for the chi-square analyses and adjusted odds ratios (AOR) with 95% CI will be calculated for the logistic regression analyses. Baseline demographic, clinical, and prognostic characteristics will be compared between the treatment arms using between-subjects inferential analyses after randomization to test for any significant differences. Any significant

differences at baseline will be accounted for in the primary analysis using logistic regression. Chi-square or Fisher's Exact test will be performed to compare the treatment arms on distinguishing extravasation post-closure at the end of the procedure (yes/no), comparing the need for open vascular surgery (yes/no), utilizing a PTA/stent to help with hemostasis or local vascular complications (yes/no), bleeding/hematomas (yes/no), pain or numbness in the distal extremity (yes/no), mortality related to complications associated with the vascular closure site (yes/no), and conversion to general anesthesia due to additional procedures required to address CFA access site complications (yes/no). Cross-tabulation tables with frequencies, percentages, and associated OR with 95% CI will be reported and interpreted for all bivariate analyses of categorical, secondary outcomes. For count variables and non-normal continuous parameters (number of perclose devices, LOS, and serum creatinine), Mann-Whitney U tests will be performed to compare the two treatment arms. Medians and interquartile ranges will be reported and interpreted for the non-parametric analyses of the count and continuous parameters. Survival analysis will be performed using Kaplan-Meier in order to compare the two treatment arms on "time-to-event" outcomes. Mean and median times to events will be presented. Log-rank, Breslow, and Tarone-Ware tests will be used to compare the respective groups. Survival plots will also be graphed. All analyses will be performed using SPSS Version 29 (Armonk, NY: IBM Corp.) and statistical significance will be assumed at an alpha value of 0.05.

10. STUDY MANAGEMENT

The PI and study team have the site resources, time availability, and the patient population needed to complete this protocol under GCP guidelines. The PI is ultimately responsible for the conduct of the trial; however, he will delegate authority to appropriate members of the research team. The PI will ensure the following:

- Study team complies with be GCP and other regulatory requirements.
- The study team allows monitoring and auditing of regulating institutions.
- Ensures person delegated trial responsibilities are qualified and trained appropriately.
- Ensure that study team members have sufficient time to properly conduct and complete the trial.
- Ensure that all persons assisting with the trial are adequately informed about the protocol, the treatments being administered, and their study-related duties and functions.
- Ensures compliance with GCP guidelines regulatory requirements.
- Will maintain a list of research team members and delegated duties.
- Assures protocol compliance.
- Reports protocol non-compliance appropriately.
- Obtains IRB approval.
- Following regulations and guidelines to protect subject rights, safety, and welfare.
- Assures compliance by all research team members of GCP regulations

11. DATA MANAGEMENT

Data will be collected and managed by trained study team members. Data will be stored in the Office of Research Support (ORS) by the study team, which has limited access. Data collected

during the study will be retained in patients' research records for at least 6 years after the study is completed. At that time, the research information not already in the patients' medical records will be destroyed, per institutional guidelines.

11.1 Data Protection

Throughout the study, measures to ensure the privacy of information on study subjects will be maintained. All project investigators and staff have been trained in the use of human subjects in research and have received training in the new HIPAA regulations. Subjects and staff will be informed of the confidentiality of information and assured that data will be used only for statistical purposes in which the individual cannot be identified. Conversely, no identifiable information on any individual will be released to anyone other than project personnel without a signed medical release from the subject, or where appropriate, the next of kin or a physician in case of a life-threatening emergency to the subject. All project personnel will be instructed not to discuss any cases with persons other than project personnel.

For this specific project, it may be required to collect PHI such as age, DOB, Medical Record Number and dates of diagnoses. Only the study team will have access to this data, and it will not be shared with anyone outside of the study team. Data will be collected on paper source documents and transcribed into the GSM REDCap system. Only study team members will have access to the database. The database will utilize the study number assigned and will not include the subject's name or MRN. All subjects will have an assigned number. All completed paper forms will be kept in locked files in locked rooms to which only project personnel have access.

11.2 Data and Safety Monitoring

Monitoring will be completed by the GSM Office of Research Support and/or The Office of Clinical Trials and include a review of original case records. It will include monitoring to assess patient safety, the consent process, record-keeping, protocol adherence, and data collection. The Investigator will record all protocol deviations. Unexpected clinically significant adverse events will be reported to the IRB. In general, the investigators will monitor any adverse reaction to study procedures conducted during the study. Any missing data will be omitted from the final statistical analysis.

11.3 Protocol Deviations

A protocol deviation is failure to follow procedures specified in the approved research protocol, which include (but are not limited to), deviations from study inclusion/exclusion criteria, or failure to follow criteria for subject follow-up, withdrawal, or timely monitoring procedures. Protocol deviations will be reported per the UTGSM IRB SOPs.

11.4 Records

11.4.1 Source Documents

Source documents provide evidence for the existence of the patient and substantiate the integrity

of the data collected. Source documents will be stored and maintained by the study team in a secure location. Data entered in the database that are transcribed from source documents must be consistent with the source documents or the discrepancies must be explained. All electronic data must be derived from source documents.

11.4.2 Direct Access to Source Data and Documents

The PI will permit trial-related monitoring, audits, and regulatory inspection, providing direct access to source data/documents.

11.4.3 Storage of Records

The PI will retain the source documents and essential documents for a period of at least 6 years after the research is completed and the study is closed with the IRB. Records will be kept longer if other requirements apply.

12. COMPLETION OF STUDY

When the trial is completed, the PI will inform the IRB and sponsor of the completion in writing.

13. REFERENCES

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