STUDY DESIGN: PREDICTION OF VASCULAR ACCESS STEAL SYNDROME, IN HEMODIALYSIS PATIENTS, USING DIGITAL PRESSURE MEASUREMENTS

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Abstract

Research Question:

In hemodialysis patients with arteriovenous fistula, can a digital pressure measurement done prior to fistula placement positively predict the development of vascular access steal syndrome after fistula placement?

Background, Significance, and Rationale for the Question:

In 2017, End Stage Renal Disease (ESRD) affected 746,557 people in the United States, with 86.9% beginning renal replacement therapy through hemodialysis (HD). This requires an access for dialysis, through arteriovenous (AV) fistula. There are numerous complications associated with hemodialysis access. The most extreme is ischemic loss to limbs. Currently, there is no literature on a measurement that could be used to predict the occurrence of ischemia, as vascular access steal syndrome, prior to placement of an AV fistula. Digital pressure, a measurement of blood flow, was identified by Schanzer as a tool to diagnosis ischemia in AV fistula patients. This retrospective study aims to use digital pressure data measurement to identify a threshold value of digital pressure prior to fistula placement that will predict ischemia after hemodialysis access placement and use.

Materials and Methods:

A retrospective study will be performed. Patients seen at DFW Vascular Group and University Vascular Associates will be identified for the study. Patients will be identified as having had an AV fistula placement between the years of 2010 and 2020. Data collection from medical records will include digital pressure measurement before AV fistula placement and at all subsequent visits throughout hemodialysis treatment. Additional variables, such as sex, age, and the presence of pertinent comorbidities, will also be collected as secondary factors to identify possible confounding variables and for use in future research. In addition, the development of limb ischemia/vascular access steal syndrome will also be identified. Statistical analysis will be performed using a logistic regression to identify the probability of vascular access steal syndrome development for a given digital pressure value.

Anticipated Results, Conclusions, and Impact:

We anticipate that individuals with a lower digital pressure prior to AV Fistula placement are more likely to development vascular access steal syndrome. We expect to find a threshold value that will give practitioners a digital pressure measurement that can be used as an alert. After identification of these high-risk patients, clinicians can manage care more appropriately, using pharmacological treatments or closer monitoring, to prevent or prolong the onset of ischemia. This may be helpful in preventing life-altering amputations or decreases in hand/arm function. It may also reduce healthcare costs for the patient and system.

Research Question

In hemodialysis patients with arteriovenous fistula, can a digital pressure measurement done prior to fistula placement positively predict the development of vascular access steal syndrome after fistula placement? We hypothesize that hemodialysis patients with AV fistula with low digital pressure measurement before access placement will demonstrate a higher likelihood of developing vascular access steal syndrome. In addition, if a positive association is found, we suggest researching whether age, sex, and comorbidities are associated with predictive values.

Introduction, Significance, and Rationale

Introduction

Existing literature demonstrates significant research of the risk factors for the development of vascular access steal syndrome, and diagnostic criteria. Risk factors include; age over 60 years, female sex, tobacco use, diabetes, peripheral vascular disease, coronary artery disease, and hypertension[1]. Diagnosis of distal limb ischemia is done using physical exam and tests like the digital pressure and digital-brachial index (DBI). On physical exam, the typical presentation of a patient with vascular access steal syndrome will include ipsilateral hand pallor, weak radial pulse, pain, and possible skin necrosis or ulcers. A 2004 meta-analysis performed found that ischemia can be diagnosed with a digital pressure of < 50 mmHg and DBI of < 0.6 [2]. A 2006 study found that a basal digital pressure of < 60 mmHg or a DBI of <0.4 were highly associated with hand ischemia [3]. The accuracy of the use of digital pressure measurement in the diagnosis of hand ischemia is encouraging to the possibility of this measurement in the prediction of vascular access steal syndrome.

Significance

The incidence of End Stage Renal Disease (ESRD) is expected to reach 1,259,000 by 2030 [4]. This increased incidence will lead to an increased number of patients being treated with hemodialysis.

The primary method of dialysis access is arteriovenous fistula (AVF). In this procedure, an anastomosis is created between an artery and vein in the forearm of the dialysis patient. The nondominant arm is typically used, between the cephalic vein and radial artery. Physiologically, a vein has significantly lower pressure than an artery. In an AV fistula, the high arterial pressure is transmitted to the vein. Over the course of time, typically in three months for the fistula to fully mature, the vein dilates leading to venous thickening to support the increased pressure [5]. From this venous thickening, a physiologic steal syndrome can occur, causing blood to flow through the access and away from the distal part of the forearm and hand [1,5,6].

Vascular access steal syndrome can lead to hand ischemia, which is diagnosed using doppler examination, digital photoplethysmography, or pulse oximetry [7]. This ischemia can progress to severe complications such as intermittent claudication, severe pain at rest, gangrene, and amputation [7]. These complications lead to an obvious decline in quality of life for the patient, as evidence by increased number of clinic visits, deficit or disability in activities of daily living, and financial burden of increased access to healthcare services. Identifying an easy, non-invasive method to identify those patients at higher risk for developing vascular access steal syndrome will have an important impact on patients undergoing AV fistula operation.

Rationale

Digital pressure is a cost-effective, non-invasive, and time efficient measure to track the progression of ischemia in the distal upper extremity preoperatively and postoperatively. Several studies have shown the positive diagnostic value in using digital pressure for the diagnosis of steal syndrome[3,7], but only one study has identified the possibility of using digital pressure in predicting the development of steal syndrome prior to AV fistula placement. Valentine et. al found that preoperative finger pressure are lower in patients who develop steal syndrome after hemodialysis access [8]. Valentine's small sample, of sixty patients, was unable to positively predict a preoperative digital pressure threshold value in which steal syndrome is inevitable[8].

This study intends to add to the existing literature on digital pressure measurement in AV fistula patients with steal syndrome. Specifically, this is the first retrospective study focused on finding a threshold value of digital pressure preoperatively to predict the development of steal syndrome postoperatively.

Additionally, we feel that the secondary aims of this study will serve two purposes. First, adding to current literature on risk factors for the development of steal syndrome in AV fistula patients. Second, the possibility of identifying a multi-factorial model for predicting steal syndrome in AV fistula patients.

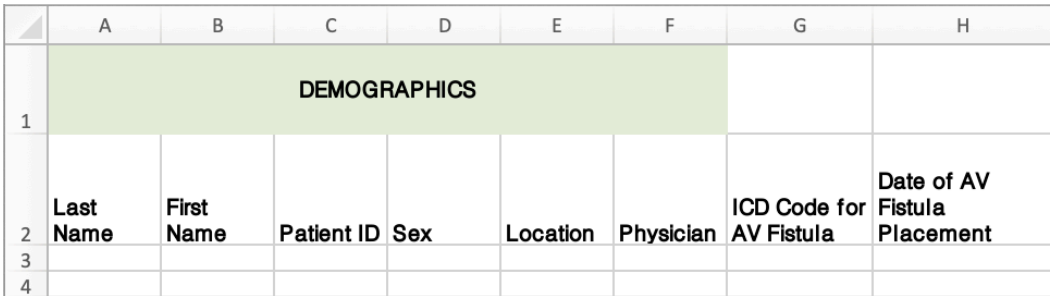
Materials and Methods

General Study Details and Resources

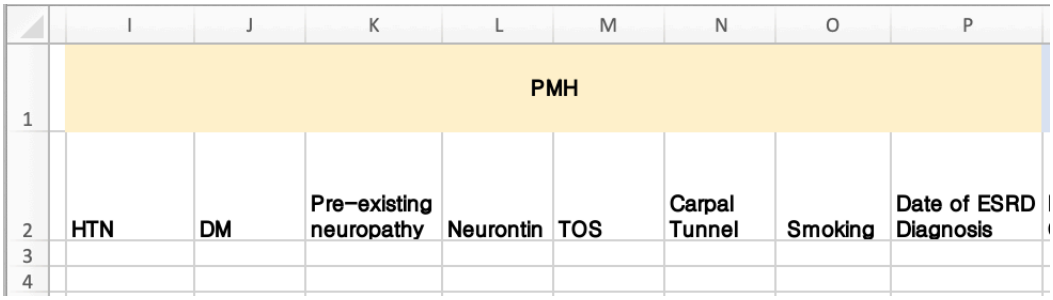
Subjects will be selected who have arteriovenous fistula placement for the use of hemodialysis treatment for ESRD, of all ages, and were followed by vascular surgeons at DFW Vascular Group in Dallas, TX and University Vascular Associates in Los Angeles, CA. DFW Vascular Group works in multiple locations, with six vascular surgeons, and utilizes Core Lab and GE Centricity for medical records. The University Vascular Associates group has nine vascular surgeons and uses Core Lab and E-Clinical for medical records.

Electronic medical records, including Core Lab, GE Centricity, and E-Clinical, will be accessed using a remote server that is password protected. All patient data will be stored in files on the remote desktop that can only be accessed by research group members. All data will be deidentified.

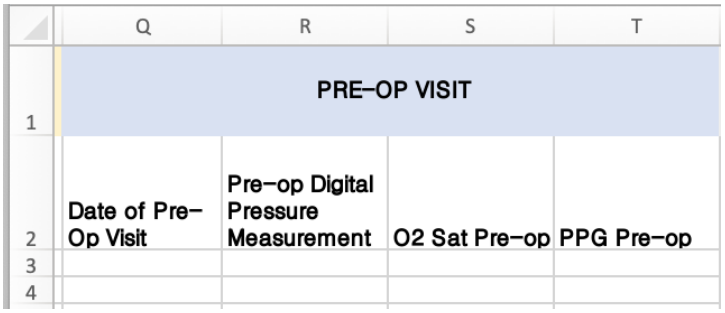
Following acquisition of patient data from the databases mentioned above, data should be recorded on an excel spreadsheet, as organized below.



	A	B	C	D	E	F	G	H
1	DEMOGRAPHICS							
2	Last Name	First Name	Patient ID	Sex	Location	Physician	ICD Code for AV Fistula	Date of AV Fistula Placement
3								
4								



	I	J	K	L	M	N	O	P
1	PMH							
2	HTN	DM	Pre-existing neuropathy	Neurontin	TOS	Carpal Tunnel	Smoking	Date of ESRD Diagnosis
3								
4								



	Q	R	S	T
1	PRE-OP VISIT			
2	Date of Pre-Op Visit	Pre-op Digital Pressure Measurement	O2 Sat Pre-op	PPG Pre-op
3				
4				

	U	V	W	X
1	POST-OP VISIT			
2	Date of Post-Op Visit	Post-op Digital Pressure Measurement	O2 Sat Post-op	PPG Post-op
3				
4				

	Y	Z	AA	AB	AC	AD	AE	AF
1	POST-PROCEDURE							
2	Amputation	Gangrene	Sensory Deficit	Ulcer	Volkman Contracture	Pain	Diagnosis of Steal Syndrome? (Y/N)	Date of Diagnosis of Steal Syndrome
3								
4								

Subject Identification

Study participants will be identified within the electronic medical records using ICD 10 codes for AV fistula creation. After patient identification, digital pressures, age, sex, and pertinent comorbidities (DM and HTN) will be collected and organized using an Excel document. The number of patients identified is not yet known but we will be identified patients from 2010 to 2020. Patients will be excluded if they do not have complete records.

Subjects will then be separated into two groups, development of vascular access steal syndrome and absence of vascular access steal syndrome. The digital pressure readings for each patient will be examined.

Retrospective Primary Endpoint Data Collection and Basic Recording

Patients meeting study inclusion criteria will be included in this portion of the study. Upon identification, each subject will be evaluated retrospectively, looking throughout their course of treatment to obtain the following data marker: digital pressure measurement.

I. Digital Pressure Measurement Before AV Fistula
II. Digital Pressure Measurements After AV Fistula
III. Diagnosis of Vascular Access Steal Syndrome

Secondary Endpoint Data Collection and Basic Recording

Following completion of the primary analysis, the secondary factors collected may be analyzed to see if they are associated with vascular access steal syndrome. The secondary factors include; age, sex, and positive diagnosis of comorbidities.

Recruitment

There will be no recruitment as this is purely a retrospective study.

Statistical Analysis

Statistical analysis will be performed using a logistic regression to identify the probability of vascular access steal syndrome development for a given digital pressure value.

Results

As this thesis project describes study design and implementation, there are no results.

Discussion and Innovation

If the hypothesis of this study is supported by the statistical analysis, it would suggest that there is a digital pressure threshold value preoperatively, that can predict steal syndrome after AV fistula creation in hemodialysis patients. This threshold value can then be used to identify patients before AV fistula placement. This identification will be important in possibly decreasing the severe complications that can occur in vascular access steal syndrome, such as limb amputation.

In addition, the identification of high-risk patients can be used during patient education prior to AV fistula placement. Patients will be educated in the initial signs and symptoms of limb ischemia, like pallor and pain, which will encourage them to seek medical care prior to tissue death or irreversible damage. This will increase patient literacy and give patients more autonomy in their care. It is suspected that this will further facilitate a positive physician-patient relationship, leading to better patient outcomes. In addition, preventing these morbidities will improve the quality of life for the patients as well as save future healthcare expenditures.

Conclusions

In the completion of this project, we anticipate difficulty in the following aspects of study design; obtaining outcomes of follow-up data, obtaining an accurate list of deceased participants, and incomplete medical records from primary data visits.

In regard to obtaining follow-up data, we anticipate a significant number of patients lost to follow-up. We suggest that the study team attempt to contact study participants using the last contact information the clinics have on file. This would improve the quality of the data and study outcomes but would require IRB approval and consenting any study participants, which would increase the time and resources required for study completion. The goal for these follow-up calls would to have accurate data points for significant morbidity or mortality, such as amputation or death.

In regard to obtaining an accurate list of deceased participants, we suggest submission of all study participants to the national death registry. This represents another challenging aspect as this would require a signed consent from the next-of-kin.

In regard to incomplete records, this is a common study limitation that will need to be addressed in the study conclusion.

In conclusion, we recommend a study team of at least four people and a timeframe of at least 2 years in order to obtain the data and complete the IRB process with patient contact.

Compliance

This is a retrospective study and all CITI training required for the access of data should be completed prior to beginning investigation. The Research Coordinator of the California Vascular Research Foundation, Min Kyu Lee, will be responsible for tracking and maintaining the compliance of all study members. Additionally, all study members must ensure that access to the remote server that holds the electronic medical records is completed at a secure location in which other people outside of the research group will be unable to view data.

References

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