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Research Article

The Use of Indocyanine Green Fluorescence Angiography in Predicting Distal Ischemia Following Arteriovenous Fistula Placement

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Abstract

Objective: Vascular steal syndrome of the distal extremity following Arterio-Venous (AV) fistula placement can occur in up to 2-20% of patients. This occurrence often leads to additional surgery such as the Distal Revascularization with Interval Ligation (DRIL) procedure, or fistula ligation. Although multiple risk factors have been shown to be associated with steal, there currently exists no reliable means by which to predict its development at the time of fistula creation. The purpose of this study was to apply a well-established perfusion measurement examination to the ipsilateral hand at the time of access in order to identify those patients at high risk for steal syndrome.

Methods: Over a three year period (June 2015-June 2018), this study prospectively used indocyanine green fluorescent imaging just prior to and immediately after fistula placement in the OR to test its ability predict steal. This technology is widely used intra-operatively to evaluate perfusion of certain organs (bowel, heart, esophagus, flaps, etc.) to determine perfusion and viability. Multiple points on the ipsilateral hand were imaged just prior to scrubbing the arm and immediately after the dressing was placed. The mean ingress rates of the dye at these points were the primary data points and due to the variability of patients, specifically changes over baseline were specifically studied. The measurements were then correlated clinically with the post-operative outcome. Patients requiring DRIL procedures were separated out at a later date and compared with normal controls.

Results: In 29 consecutive controls with full data, the overall change in the hand perfusion ingress rate after AV fistula placement was 0.17 units/sec or 6%. None of these patients developed vascular steal. Eight patients required a DRIL procedure during the study period. The mean ingress rates pre-operatively between the two groups (5.44 units/sec for controls vs. 5.85 units/sec for those with steal) were not significantly different (Fisher's exact test $p>0.05$). However, the overall mean ingress rate significantly decreased by 2.75 units/sec (46%) in patients with steal ($p<0.05$). In six of the eight patients undergoing a DRIL procedure, the ingress rate returned to near baseline after DRIL procedure and their symptoms resolved. One patient did not improve by imaging or clinically, and one patient showed a decrease in ingress but improved clinically.

Conclusions: Early data shows indocyanine green fluorescence angiography may be useful in predicting the development of vascular steal following AV fistula placement and the success of DRIL procedures.

Keywords: Fluorescent angiography; Hemodialysis access induced hand ischemia; ICG angiography; Steal syndrome

Introduction

Hemodialysis access induced hand ischemia (steal syndrome) is a significant and potentially devastating complication that presents after Arterial Venous Fistula (AVF) placement, effecting 2% to 20% of patients that undergo hemodialysis access placement [1-3]. Symptoms of steal include hand numbness, pain, or weakness to more severe complications including tissue necrosis and gangrene [4,5]. Despite medical advances over the past 20 years, the incidence of steal syndrome remains largely unchanged. Left untreated, patients may suffer long term disabling sequelae including chronic pain, sensory changes secondary to ischemic neuropathy, and tissue loss with or without amputation [1,6]. A variety of factors have been suggested to aid in prediction of patients

that may develop steal syndrome. Multiple patient characteristics such as age, race, comorbidities, and gender have been attempted to be correlated with clinical symptoms, clinical suspicion, and noninvasive testing (digital pressure oxygenation, digital brachial index, Doppler ultrasonography.) [2,3,7-11]. However, the exact applicability of these factors has failed to establish quantitative, reproducible guidelines to identify those patients who will develop steal syndrome [7]. In addition, clinical criteria such as pulse oximetry, Doppler arterial waveform, and digital pressure are limited by other factors including atherosclerosis, peripheral arterial disease, and operator variability making them a difficult diagnostic measure, and reduces their accuracy in predicting true tissue perfusion. Treatment for steal syndrome is focused on improving hand perfusion and may require a variety of procedures ranging from fistula ligation (access sacrificing) to distal revascularization with internal ligation (DRIL, access preserving) [6,12]. Currently, an accepted, reliable, objective analysis of tissue perfusion to predict patients that will develop steal syndrome does not exist.

Near Infrared (NIR) fluoroscopy has been used in conjunction with indocyanine green since its FDA approval in 1958 [13]. Indocyanine green is bound to plasma protein and undergoes biliary excretion, allowing for use in patients with renal disease [14]. Indocyanine green has been used to evaluate tissue perfusion in ophthalmology, plastic and reconstructive surgery (flap placement), cardiovascular surgery, and various abdominal operations in general surgery (laparoscopic cholecystectomy and gastrointestinal anastomosis), as well as in those patients with distal ischemia and vascular trauma [15-28]. The aim of this study was to evaluate the application of fluorescent angiography to the ipsilateral hand at the time of hemodialysis access placement in order to identify those patients at high risk of developing steal syndrome. Subsequent use of fluorescent angiography before and after DRIL procedures was also examined to evaluate its role in objectively identifying successful revascularization. We hypothesized that fluorescent angiography will help to identify patients at a greater risk of developing vascular steal syndrome after AV fistula placement.

Methods

Experimental Design

We identified and studied the use of Indocyanine Green (ICG) fluorescent imaging on a total of 97 nonconsecutive patients undergoing hemodialysis fistula placement at the University of Florida College of Medicine Jacksonville over a three year period from June 2015 to June 2018 to test the ability of fluorescent angiography to predict steal syndrome. From this large group, we used a subset of 29 consecutive patients that did not later develop ischemia to serve as controls. We retrospectively reviewed the medical records of a smaller subset of patients that developed steal syndrome and required Distal Revascularization Internal Ligation (DRIL), and determined the clinical outcomes in correlation with indocyanine green fluorescent imaging at each operative procedure. The study was approved by the Institutional Review Board at the University of Florida College of Medicine, Jacksonville (IRB# 201601003).

Patient Selection

All patients who underwent an elective placement of a primary hemodialysis access (not a revision) with use of indocyanine green fluorescent angiography were selected and medical records were retrospectively reviewed. Patients were excluded if they were pregnant, had an allergy to iodine, had previous history of symptoms of hand ischemia (including paresthesia, pain, weakness, or tissue loss), pathology causing inability to visualize all 12 points of measurement on palm, history of Raynaud's, scleroderma, or CREST syndrome, or if unable to give consent. All patients underwent hemodialysis fistula placement by a group of 3 board certified vascular surgeons at a university medical center. Patient demographics, comorbidities, and medications were also documented and reviewed. Diabetes was defined by any patient on an oral hypoglycemic medication or insulin. Smoking status was defined as current smoker or patients with more than 20 pack year smoking history. Age and race were noted and reviewed. Patients undergoing DRIL procedure were identified and each subsequent operative or re operative intervention was noted as a new encounter.

Spy Angiography

Fluorescent angiography was used just prior to and immediately following completion of operative procedure. Operating room temperatures and patient hemodynamics were maintained throughout the pre-operative and post-operative measurement periods. Briefly, after induction of anesthesia the patient was positioned with his or her operative arm placed in abduction on an arm table with palmar surface facing upwards. The patient's hand was secured and the SPY Elite fluoroscopic device (Novadaq, SPY Elite, Canada**)** was positioned over the ipsilateral hand. The hand was then focused on the SPY Elite screen. Indocyanine green was prepared in 10cc sterile water and 2.5cc of ICG was administered through peripheral intravenous line by anesthesia team. ICG was immediately followed by 10cc flush. Real time recording of the palmar surface of the hand on the side of hemodialysis fistula placement was initiated and continued for 240 seconds with focus on multiple points on the palmary surface of the ipsilateral arm. After conclusion of the imaging the patient underwent planned operative procedure. Postoperatively, sterile drapes were removed and 2.5cc ICG was again administered intravenously in a similar fashion. Spy fluorescent angiography was again initiated for 240 seconds under the same protocol as used preoperatively. Images were reviewed retrospectively

and quantitative values that correlated with pixel strength were obtained. Specific values were recorded for ingress (increase in pixel strength), ingress rate (slope of the graph of pixel strength changing over time), peak perfusion (maximal pixel strength), egress (decrease in pixel strength from point of maximal intensity), and egress rate (slope of decrease of pixel strength.) Ingress correlates with arterial inflow while egress correlates with venous washout. The ingress rates were used as the primary data points due to variability between baseline ingress values (pixel strength). Ingress rates allowed for absolute values that correlate with increase in perfusion compared to each patient's individual baseline. These measurements were compared to clinical outcome as defined by symptoms of hand pain, paresthesia, motor weakness, and/or tissue loss and patients requiring further operative intervention with the DRIL procedure were identified and studied in a similar fashion.

Data Analysis

The statistical plan was executed with the assistance of statisticians listed in the appropriate section as additional co-investigator. Descriptive statistics were computed for all variables. Additional analyses were completed using Fisher exact t-tests for continuous data ($P<0.05$), Wilcoxon Rank Sum test for categorical and demographic variables ($P<0.05$), and chi-square analyses using categorical variables. The independent variables included diabetes mellitus type II, smoking status, gender, and tissue perfusion based on Novadaq SPY fluorescent angiography obtained pre operatively and post operatively. The dependent variables were the occurrence of symptoms of hand ischemia based on the clinical assessments as detailed within the methods section.

Results

During the three year study period, a total of 97 patients met all inclusion criteria, were able to give informed consent, and were attempted to have SPY studies done in the peri-operative time period. Technical failures occurred in five patients, usually due to study timing failure. Fifty-five patients could not be included as controls in the study usually due to lack of at least three month follow-up (23) or access failure (22). Twenty-nine consecutive patients with no post-operative ischemia and with full data sets were then identified and served as controls in order to eliminate any bias. Several types of access procedures were done initially with the majority (17/29 in controls, 5/8 in DRIL) being brachial-cephalic AV fistulas (Table 1). Women were 16 of the 29 controls and 3 of 8 of the DRIL patients, the mean age was 62.9 years, and in controls 18 were African American, 10 Caucasian, and one was Hispanic. In control patients diabetes was present eight patients (27%) and nine (31%) had a history of smoking. In DRIL patients diabetes was present in two patients (25%) and two (25%) had a history of smoking. None of the demographic data showed any significant difference between the control and DRIL groups (Wilcoxon rank sum test p=NS) (Table 2). The mean pre operative ingress rate in control patients did not was not significantly different from the ingress rate after fistula placements (Table 3).

Category	Brachial-Cephalic n (%)	Brachial-Basilic n (%)	Brachial Forearm Graft n (%)
Control	17 (58.6)	8 (27.5)	4 (13.8)
DRIL	5 (62.5)	1 (12.5)	2 (25)

Table 1: Types of Fistulas among Control and DRIL patients.

Patient's Variables	Category	Control (n=29) (%)	DRIL (n=8) (%)	Total, n (%)	P Value
Gender	M	13 (44.8)	5 (62.5)	18 (48.6)	>0.999
	F	15 (55.2)	3 (3.75)	19 (51.4)	
Diabetes Mellitus	No	21 (72.4)	6 (75)	27 (73)	0.45
	Yes	8 (27.6)	2 (25)	10 (27)	
Tobacco Abuse	No	20 (69)	6 (75)	26 (70.3)	>0.999
	Yes	9 (31)	2 (25)	11 (29.7)	

Table 2: Demographic Comparison of Control and DRIL Patients.

Category	Ingress Pre Op Units/ Second		Ingress Post Op Units/ Second		Overall Change Units/ Second		% Change	P value
	Mean	Median	Mean	Median	Mean	Median		
Control	5.44	5.10	5.62	5.40	0.17	0.20	6.16	0.16
Steal Syndrome- Pre DRIL	5.84	5.35	3.09	2.90	-2.75	-2.45	-45.79	<0.01
Steal Syndrome- Post DRIL	4.73	4.75	7.10	6.50	2.38	2.07	82.94	<0.05

Table 3: Comparison of Pre operative and Post operative Ingress Rates in Fistula Patients.

In eight of the patients during the study period, routine follow-up in clinic identified evidence of distal ischemia of the hand. Symptoms included ischemic pain (8), diminished pulse (6), parathesias (4) and tissue loss (2). The time period between access placement and date of DRIL procedure ranged from six weeks to 16 months and averaged 5.8 months. The eight study patients requiring a DRIL procedure during the study period showed a pre-operative mean ingress rate was 5.84 units/sec, which was not significantly different from the control group (Signed rank test p=0.54) (Table 3). Patients that ultimately required a DRIL procedure did have significantly lower post operative ingress rates after their first fistula placement, with a notable change of -45% when compared to pre operative values (Signed rank test p=0.0078). Interestingly, the opposite was observed in these patients after they underwent the DRIL procedure, with an impressive and significant improvement in ingress rate post operatively compared to pre operative values (83%, Signed rank test p=0.04) (Table 3). The overall ingress rate change between control patients (6%) and DRIL patients (-46%) was highly statistically significant (p<0.0002) (Figure 1). In six of the eight patients (75%) undergoing a DRIL procedure, the ingress rate increased and returned to near baseline, with a mean ingress rate increase of +2.38 units/sec with resolution of symptoms (Figure 2A). One patient did not improve by imaging or clinically (0.4 units/sec decrease in ingress rate), and one patient showed a minimal 0.2 units/sec decrease in ingress rate but improved clinically. Overall, it appears that a decrease in ingress rate following access placement as determined by SPY technology of greater than 1.5units/sec is a reasonable threshold for identifying patients with a high risk of distal ischemia. This level was only seen once in 29 controls (3%) but was seen in 7 of 8 patients (88%) in the DRIL group (Table 4). Any improvement in ingress rate following a DRIL procedure is highly predictive of successful revascularization (6/6, 100%) (Figure 2B). Clinical improvement can be seen even without a demonstrable improvement in ingress rate following a DRIL procedure as seen in one of two patients with this result.

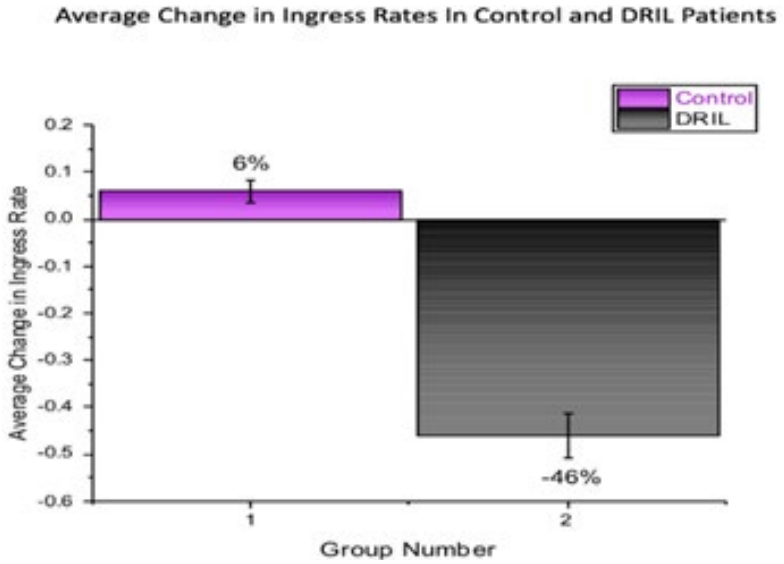

Figure 1: Overall Percent Change in Ingress Rate in Control and DRIL Patients.

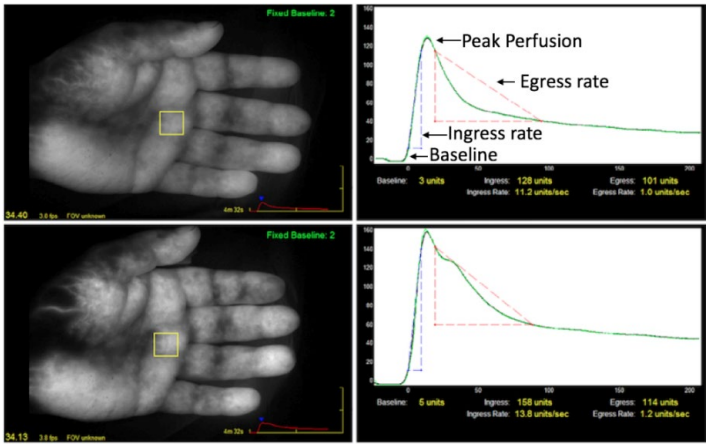

Figure 2: Moderate Improvement in Ingress Rate Following DRIL Procedure.

Discussion

We have successfully demonstrated the use of fluorescent angiography in patients requiring AV fistula placement. Our results suggest that changes in ingress rate measured by fluorescent angiography may predict those patients that are more likely to develop vascular steal syndrome, as well as confirm successful re vascularization after the DRIL procedure. The eight patients that required a DRIL had a significant decrease in ingress rate by at least 1.5 units/second (after initial access placement) which represented a >20% change in ingress rate when compared to their initial AV fistula preoperative values. Only 9 patients (31%) of controls had a decrease in their ingress rate from preoperative to post-operative state and out of these nine patients, decrease in ingress rate was less than 1.5 units/sec (<20% change) and none of these patients developed steal syndrome. This study suggests that a decrease in post-operative ingress rate by greater than 1.5 units/sec may help to identify patients that are more likely to develop steal syndrome.

SPY fluorescent angiography provides both qualitative and quantitative data and does not significantly delay operative time. There was generally a good correlation with clinical results, although some outliers occurred. Several data points indicate there was no significant difference in any specific variable prior to the access procedure. First, the demographic data failed to show any specific factor that predisposed patients to develop ischemia. Second, the initial pre-operative ingress flow was not significantly different between the control group that had no post-operative ischemia and the DRIL group that did. This indicates that some objective measurement is needed to accurately predict those patients likely to develop hand ischemia. We maintained our focus on quantifiable data points representing tissue perfusion with the long term goal of achieving a consistent, easy to perform, universally available and accurate means to predict significant distal ischemia. Other methods have been reported to evaluate tissue perfusion before and after hemodialysis access placement, but none have been universally accepted or routinely performed. In most practices, the diagnosis of hand ischemia continues to be made on a clinical basis identified by the surgeon in routine post-operative visits. Modaghegh et al investigated Digital Blood Pressure (DBP), Digital Brachial Index (DBI), and finger oxygen saturation measurements and found significantly lower values in steal patients vs controls concluding a threshold value of 80mmHg for DBP, 0.7 for DBI, and 94% for O_2 saturation. He described these specified cut off values as a screening tool for asymptomatic patients, as well as a tool to monitor those patients with early symptoms or to guide operative management. Some disadvantages of these tests include dependence on operator ability and variation of individual patient factors (degree of steal syndrome, variability between digits, comorbidities), inability to provide information regarding tissue perfusion of the hand, as well as the possible necessity to include follow up testing and imaging for confirmation [7]. There are a variety of additional studies that have investigated finger pressures and basal digital pressures in hemodialysis access induced ischemia patients. Goff et al recommended a DBI value of 0.6 to identify patients at risk for steal syndrome after performing a retrospective review on postoperative DRIL patients vs controls, as did Papasavas et al with a prospective cohort study measuring DBI [11,29]. Schanzer et al, however, performed a case control study and found a DBI threshold of 0.4 to identify those patients with access induced ischemia suggesting that a specific optimal threshold value has yet to be consistently identified [30].

Doppler ultrasonography has also been used as an adjunctive tool in dialysis access induced ischemia but has been used primarily as a diagnostic tool after patients exhibit symptoms of steal syndrome [31,32]. Angiography has also been used to diagnose and treat steal syndrome secondary to arterial stenosis but this tool has disadvantages that include invasive testing, contrast administration, and radiation exposure [33]. All of these adjunctive methods have notable disadvantages including inability to provide information regarding tissue perfusion throughout the hand and failure to provide an established reproducible guideline to identify patients at risk of developing steal syndrome. This study suggests that ICG fluorescent angiography at the time of AV fistula placement could provide valuable information regarding tissue perfusion, which could be used either alone or in conjunction with established methods noted above.. SPY angiography using indocyanine green has been noted in the literature as an accepted way to aid in the evaluation of tissue perfusion. Unlike CT angiography with contrast administration, ICG maintains a strong safety profile with minimal adverse events reported and is excreted via the biliary circulation allowing for administration in end stage renal disease patients without further renal complications [13]. Near infrared fluoroscopy absorbs light in the range of 805nm-840nm and does

not subject the patient to further radiation, which make this method an appealing approach to evaluate tissue perfusion [14,34,35]. In our evaluation we chose to focus on ingress rate. Ingress value is a measurement of pixel strength which is represented by intensity of the fluorescence and varies with each patient depending on their baseline vascular status. We found that ingress rate (ie looking at the overall change intensity on the palmar surface between baseline and peak intensity over time) could be more accurately and consistently compared between patients. This measurement allows for real time assessment of blood flow which correlates with tissue viability, the outcomes of which could affect wound healing and intraoperative planning.

Fluorescent angiography has now been used in a variety of vascular applications including chronic limb ischemia, vascular trauma, to evaluate wound healing and adequacy of perfusion to bowel anastomoses [36,37]. Riess et al used fluorescent angiography as an additive measure in evaluating perfusion in peripheral arterial d isease. They found significant correlation between fluorescent intensity and ankle brachial index which allowed for visual association of tissue perfusion before and after operative intervention [38]. Braun et al described the use of fluorescent angiography during tibial bypass to evaluate tissue perfusion of the foot in patients with critical limb ischemia and Colvard et al prospectively evaluated the use of ICG angiography as an adjunctive measurement to evaluate distal perfusion after peripheral vascular interventions in patients with claudication or limb ischemia [24,39]. Perry et al described a case report in which fluorescent angiography was used to evaluate post debridement tissue viability during tibial bypass and Unno et al used ICG angiography to confirm patency of a bypass anastomosis noting a case of decreased distal fluorescence which later correlated with bypass graft occlusion [34,40]. Connolly, et al. also utilized fluorescent angiography to guide operative planning after vascular trauma aiding in an outcome that resulted in limb salvage [41]. These studies have demonstrated a wide range of tissue perfusion which may be a source of error as individual variation occurs in normal individuals. This study is the first to evaluate perfusion changes following access procedures and specifically looked at change of perfusion only, thus eliminating any individual baseline variation.

Although not a main goal, this study also looked at the type of fistula performed and if any specific procedure was associated with a higher risk of steal, although other studies have failed to identify any specific type to be high risk. Brachial-cephalic AV fistulas were the predominate access performed in both the control and study groups (60 and 62%). In this study, comparison of the pattern of access procedures was too small to have any meaningful conclusions. It does appear that the types of access procedures done in the both groups follow a similar pattern to our overall practice and percent of total access procedures performed.

There are inherent limitations to our study. We were limited by patient number during this study period. We were also limited by the number of patients that developed steal syndrome. This could be due to the fact that patients may under report their symptoms or may be lost to follow up postoperatively. Furthermore, the operative surgeon is unlikely to re-evaluate the patient for steal syndrome after the fistula is cleared for use and the patient no longer requires operative intervention which may limit our inclusion of those patients that develop steal syndrome >3 months post operatively. We chose to focus on one method of evaluating tissue perfusion and did not correlate ICG angiography values with other techniques such as pulse oximetry or digital pressure measurements. This is be an area of further investigation, because correlating non-invasive testing with ICG angiography may provide an even more accurate measurement of tissue perfusion and may help to identify more robust and reproducible guidelines to diagnose those patients at risk for developing steal syndrome.

Conclusion

Early data suggests that indocyanine green fluorescent angiography may be useful in identifying those patients at greater risk of developing steal syndrome after AV fistula placement. A decrease in the postoperative ingress rate in comparison to preoperative values may provide quantitative data to indicate those patients that are at greater risk of developing hemodialysis access induced ischemia. A 20% decrease in perfusion or a post operative ingress rate that decreases by greater than 1.5 units/second (in comparison to post op ingress rate) appear to be the critical cut-off points at which distal ischemia may occur. Further studies including digital pressure and finger oxygenation in conjunction with fluorescent angiography may provide additional information and threshold values to better predict those patients at risk of developing vascular steal syndrome.

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