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The Efficacy of Near-infrared Vein Imaging for the Success of Placing Peripheral Venous Catheters in Adults with Difficult Venous Access

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Background and Study Rationale

IV Access for In-hospital Patients

In-hospital patients are commonly subjected to repeated intravenous infusions and medication administrations. The repeated placement of intravenous catheters is thought to compromise the integrity of superficial veins. Hence, finding a suitable peripheral vein continues to be a recurring challenge for healthcare providers. In addition, complications associated with venous access placement are a common burden, including hematomas, phlebitis, thrombophlebitis, infiltration, and nerve damage. Therefore a tremendous need for easier and more reliable intravenous access is present.

Near-infrared Superficial Vein Imaging

Recently, vein imaging devices became available in the form of portable devices utilizing near-infrared (NIR) light at a wavelength of approximately 850 nm to create a real-time map of superficial veins. With these devices, NIR light is projected onto the surface of the patient's skin where it can penetrate depending on the device's light intensity typically up to 10 mm deep into the tissue [1]. Once NIR propagates through the tissue it encounters some degree of absorption dependent on the characteristics of the tissue molecules. With hemoglobin having a much greater absorption coefficient compared to most other tissue molecules [2], the reflected light signal provides a negative contrast image of blood vessels. While the depth of visualization of blood vessels is dependent on specific tissue conditions, larger vessels underneath the skin typically used for peripheral venous access are expected to be visualized reliably using this technology.

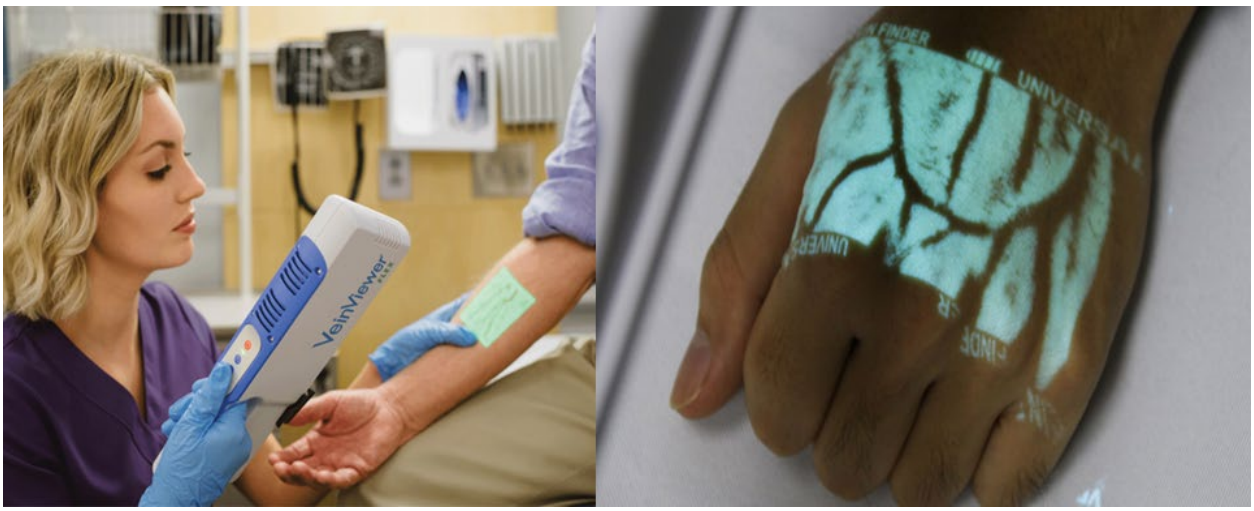

Figure 1: VeinViewer Flex (Christie Medical Holdings, Inc., Memphis, TN)

With the expected improvement of visualizing superficial veins, the manufactures of these devices proposed anticipated clinical benefits to include increased identification of suitable venous access sites, better choice of catheter gauge, and better identification of potential problem locations within veins such as valves and bifurcations. In select circumstances, flushing of the placed IV catheter under NIR visualization may also

provide improved information about the patency of the vein. Overall, improvement in peripheral venous access using this technology may theoretically avoid more invasive venous access catheters, such as peripherally inserted central catheters or central venous catheters.

In the clinical setting, NIR technology has shown to significantly increase the number of identifiable possible cannulation sites compared with normal eyesight [3,4]. However, the improvement in visualization did not automatically translate into improvement in successful cannulation of veins. Specifically, the efficacy of these vein finding devices has shown limited benefit when tested in the pediatric in-hospital population with a nonselective use in all patients. A meta-analysis of 11 RCTs concluded that using NIR light devices did not have an impact on overall failure rate at the first attempt at peripheral intravenous cannulation (PIVC) in pediatric patients [5]. Similarly, in studies evaluating the number of attempts required for successful PIVC found no difference between the NIR light device and traditional methods [6]. Many investigators subjectively felt the NIR device to be helpful; particularly in selected patients [5]. Yet, subgroup analysis did not define the cohort of pediatric patients that would benefit most from this technology. One publication interpreted these outcomes as such that despite improved visualization of superficial veins, successful venous puncture remains heavily dependent on the skills of the operator [7].

The efficacy of NIR vein finders beyond the first line approach, particularly in patients that have failed conventional peripheral venous access methods or in patients that are expected to be a "difficult stick", is not established. Conflicting results have been reported in the pediatric literature regarding the subjective benefit of NIR light devices in patients with perceived difficult peripheral intravenous access [6]. In addition, knowledge about the efficacy of these devices in the adult inpatient setting is mostly unknown. The aim of the present study is to address these knowledge gaps.

Study Objectives

The objective of this project is to define the effectiveness and therefore the role of NIR vein finders in adult patients with difficult peripheral venous access. The specific objective of the proposed randomized controlled trial is to test the clinical success rate of placing peripheral venous catheters in 'difficult' access patients using traditional peripheral venous catheter placement compared to two established methods utilizing NIR vein imaging. We hypothesize that the capability to successfully place lasting peripheral venous catheters is increased with the adjunct of the imaging technology, reducing the number of failed needle sticks, reducing the number of peripheral venous catheters placed throughout a patient's hospital stay, and reducing the need for more invasive catheters such as PICC lines. To test this hypothesis, we utilize a commercially available FDA-approved NIR vein finder which currently is already in clinical use at Lahey Hospital & Medical Center. We are planning to conduct a randomized controlled trial recruiting patients who as part of their routine clinical care will require placement of a peripheral venous catheter and who are considered to have a difficult peripheral venous access. Potential study patients will be randomized into 3 groups:

- Placement of peripheral venous catheter using conventional methods
- Use of a VeinViewer to visualize the most suitable target. Once the target has been identified and marked, the device will be placed aside and the peripheral venous catheter will be placed using conventional methods
- Identification of the most suitable target and placement of a peripheral venous catheter under constant imaging with a VeinViewer

To achieve the goals of this project, we have assembled a highly interdisciplinary team with expertise in clinical peripheral venous catheter placement, biomedical device development, and biostatistics to pursue the following specific aims:

Primary Objective

- to assess the rate of successful initial placement of a peripheral venous catheter dependent on the method used

Secondary Objectives

- to compare variables representing the ease of peripheral venous catheter placement, complication rates, and durability of the catheter within each study treatment arm

Study Design

Study Overview

The proposed project is a randomized controlled trial involving in-hospital patients who receive routine care at Lahey Hospital & Medical Center, Burlington, MA and as part of their planned treatment are scheduled to undergo placement of a peripheral venous catheter in one of the upper extremities. 400 patients (age ≥18), who are scheduled and consented to undergo placement of a peripheral venous catheter in one of the upper extremities as part of routine clinical care and who meet the criteria listed below, will be enrolled. Patient recruitment is expected to take 8 months. Patients will be randomized to 1) placement of a peripheral venous catheter using conventional methods *versus* 2) use of NIR vein imaging to visualize the most suitable target and subsequent placement of a peripheral venous catheter using conventional methods *versus* 3) placement of a peripheral venous catheter under constant imaging with NIR vein imaging. Clinical outcomes obtained will be recorded and analyzed.

Eligibility Criteria

The eligibility criteria were chosen to minimize the risk to the study patient by only including patients who are already planned to undergo placement of a peripheral venous catheter and by excluding any high-risk patients. In order to be considered for the study, patients have to meet the following criteria:

a) Inclusion criteria:

- adult in-hospital patients (≥18 years of age, inpatient and outpatient setting)
- willing to provide research authorization
- scheduled and consented to undergo peripheral venous cannulation of one of the upper extremities to be performed by one of the members of the Vascular Access Team
- determined to be a difficult peripheral venous access defined by one of the following criteria in alignment to the A-DIVA scale to be assessed by one of the members of the Vascular Access Team [8]:
  - failed inspection for more than one visible or palpable suitable vein through conventional methods
  - failed at least one attempt of peripheral venous cannulation through any methods
  - history of difficult peripheral venous access
  - greatest diameter of target vein less than 3mm determined by conventional methods

b) Exclusion criteria:

- clinical contraindication for placement of peripheral venous catheter, including:
  - severe bilateral upper extremity edema
  - severe bilateral upper extremity skin burn
  - severe bilateral upper extremity cellulitis
  - history of bilateral axillary lymphadenectomy

- known severe cardiovascular or pulmonary compromise demanding minimization of procedure time, such as:
  - severe shock with severe cardiovascular instability
  - active CPR
  - major uncontrolled hemorrhage
  - any condition for which the primary healthcare provider is requesting emergent venous access
- scheduled PICC or midline catheter placement
- non-English-speaking patients if an interpreter is not available
- prisoner and any individual involuntarily confined or detained in a penal institution
- impaired capacity to make informed medical decisions

Recruitment

In-hospital patients seen at Lahey Hospital & Medical Center who meet study criteria will be identified by a member of the hospital's Vascular Access Team through direct referral by the patient's clinical care provider. Patients will be approached by the team member at the time of planned placement of a peripheral venous catheter. For patients who are interested in participating in the study and who meet criteria, a verbal informed consent will be obtained in person by the team member. In addition, a written brochure explaining the study will be provided. An application for waiver of written consent will be submitted to the institution's IRB. Recruitment will continue until 400 patients who meet eligibility criteria have been enrolled. It is expected that patient recruitment for the study will be completed within 8 months.

Informed Consent Process

A written informed consent will be obtained in person from eligible patients by a member of the hospital's Vascular Access Team at the time of planned placement of a peripheral venous catheter. The team members have been trained regarding the required elements of information needed to be provided to the patient. In addition, the patient will also receive the information in writing through a brochure provided to the patient at the time of consent. An additional, unsigned copy of the consent form will be given to the patient at the time of consent. The consent form itself will be collected and scanned into the patient's electronic medical records at a later point. A copy of the consent form will be archived in the study folder at a later point.

The person obtaining consent from the study patient will give subjects detailed and comprehensive information about the study, its associated risks, benefits, expected outcomes, and alternative options. For non-English-speaking patients, an interpreter will translate the provided consent information to the potential subject and interpret any questions for the Vascular Access Team member.

Study patients may withdraw at any time by informing the Vascular Access Team member or the principal investigator verbally or in writing. Yet, data already collected and/or generated prior to withdrawal will not be affected.

Study Procedures

Imaging System To Be Utilized

For the study purposes the commercially available FDA-approved VeinViewer Flex (Christie Medical Holdings, Inc., Memphis, Tennessee) will be utilized. The device provides HD imaging and projection of NIR images at a minimum brightness of 5 lumens. The device weighs 0.7 kg and measures 11.6" x 4" x 1.7". It is powered by standard lithium ion batteries or AC outlet. The imaging focal distance is 30 cm. The VeinViewer Flex uses no consumables, requires no patient contact, and does not provide any heat, laser-safety, eye-safety, or radiation concerns. It is considered on FDA class I device and received 510(k) exempt approval for the intended use to indicate the location of blood vessels.

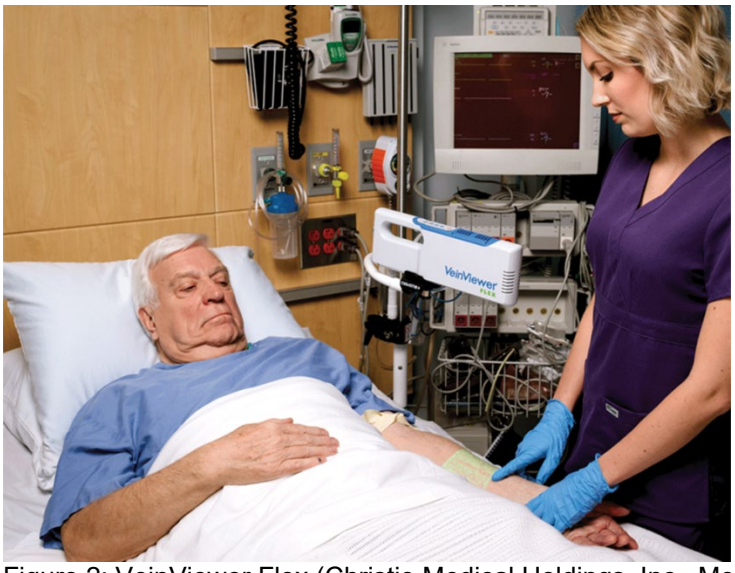

Figure 2: VeinViewer Flex (Christie Medical Holdings, Inc., Memphis, TN)

The device includes distinctive visualization modes through the provided VeinViewer ASSESS Imaging Suite. These include:

- Universal: provides the brightest and most accurate direct-projection, baseline mode
  Purpose: minimizing surface structures such as hair and wrinkles
- Fine Detail: enhances finer structures
  Purpose: identifying small veins in pediatric patients
- Inverse: switches/inverts colors within the image window
  Purpose: customizing the projected image based on factors such as skin tone, density of hair follicles, and room brightness
- Resize: choice of one of three window sizes
  Purpose: for pediatric patients or when focus on only one vessel is needed
- MaxBright: increases image brightness by an additional 40%
  Purpose: for scenarios where greater than standard ambient lighting is present

It is left to the discretion of the Vascular Access Team member to decide which mode is being used during the study procedure. Yet, historically it is expected that most of the time the 'Universal' mode will be utilized.

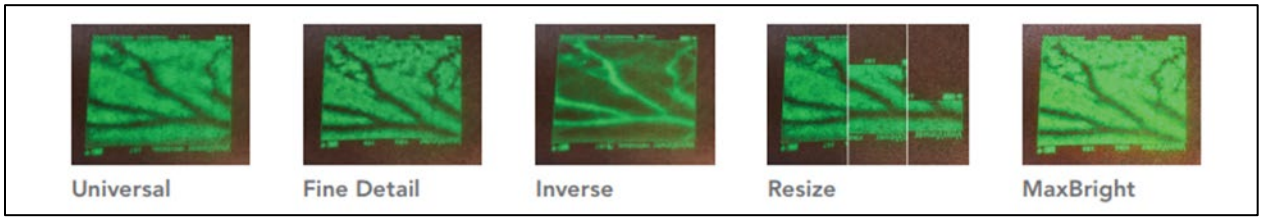

Figure 3: Visualization modes of the VeinViewer ASSESS Imaging Suite

Training of Staff
Each member of the Vascular Access Team involved in a study underwent formal training in the proper use of the VeinViewer device provided by the device manufacture or hospital. In addition, each member had to use the device independently during routine patient care for at least 20 times before being able to participate in the study.
Research training in the form of successful completion of the institutionally required CITI program is mandatory for each participating team member. Additional training on the consent process was provided.

Peripheral Venous Cannulation and Randomization of Study Groups
Patients, who meet eligibility criteria and agree to participate in the study after an informed consent process, will undergo simple randomization. A sealed envelope holding the information of the random assignment will be opened by the Vascular Access Team member. Randomization will assign study patients into 1 of 3 groups/treatment arms with a 1:1:1 ratio:

- Placement of a peripheral venous catheter using conventional methods
- Use of VeinViewer to visualize the most suitable target. Once the target has been identified and marked, the device will be placed aside and the peripheral venous catheter will be placed using conventional methods
- Identification of the most suitable target and placement of a peripheral venous catheter under constant imaging with VeinViewer

When the VeinViewer device will be utilized, multiple areas on the patient's upper extremities will be assessed looking for the most suitable access point according to routine clinical practice. There is no restriction in regards to vein diameter, vein length, or relation of veins to joints. The choice of the location for intravenous cannulation, the use of tourniquets, the use of heating devices, and any techniques to palpate the vein will be left to the discretion of the Vascular Access Team member based on routine clinical practice. This study requires an unobstructed view of the subject's arm under standard hospital lighting conditions.

Investigators have up to 30 minutes or ONE attempt before the study allows for change of technique to the preference of the Vascular Access Team member.

Follow-Up (for in-patients only)

A member of the Vascular Access Team will see the patient in person three days after peripheral venous cannulation and each day thereafter according to routine practice. At the follow-up evaluation patency of the peripheral venous catheter and any complications associated with the peripheral venous catheter will be clinically assessed and documented. Follow-up will be completed once the patient has been discharged from the hospital or once the peripheral venous catheter placed as part of the study has been removed or replaced.

Data Collection

The following variables will be assessed for all study patients at the time of peripheral venous cannulation:

a) primary outcome measures:
- rate of successful initial placement of a peripheral venous catheter (investigators have up to 30 minutes or ONE attempt before the study allows for change of technique to the preference of the Vascular Access Team member)

b) secondary outcome measures:
- number of required needle sticks before successful placement of a peripheral venous catheter
- type of method that resulted in successful placement of a peripheral venous catheter
- number of visible veins suitable for cannulation (each continuous vein will be counted as one cannulation site)
- IV catheter gauge size utilized after completion of IV cannulation
- target vein location (bend of the elbow, forearm, back of hand, other) and side of extremity (right vs. left)
- use of warming of arm
- procedure time
- procedure associated complications
- Vascular Access Team member experience (years in practice)
- Vascular Access Team member survey:
  - subjective difficulty locating a suitable vein
  - subjective difficulty of venous access
  - subjective reasons for the difficulty of identifying veins
  - subjective impression of locating additional veins with VeinViewer device
  - subjective impression of usefulness of the VeinViewer device in successful placement of a peripheral venous catheter
- Patient survey:
  - usual number of IV attempts required
  - patients' satisfaction after completion of IV cannulation

c) clinical patient demographics will be derived from patient history and/or medical records:
- age
- gender
- height

- weight
- dominant hand
- date of procedure

The following variables will be assessed for all in-patient study subjects, if available, at the time of follow-up:

- catheter patency / need for replacement of catheter / type of catheter used for replacement
- presence of complications such as :
  - hematoma
  - phlebitis
  - thrombophlebitis
  - infiltration
  - nerve damage

All abstracted data, including a study number for each patient, will be stored on a password-protected research database on a hospital server at Lahey Hospital & Medical Center. Any identifier, except for date of procedure, will be removed after the follow-up has been completed.

Study Endpoints

Study Endpoints

The primary endpoint of the study will be to assess the rate of successful initial placement of a peripheral venous catheter in patients representing difficult venous access dependent on the method used. Secondary endpoints include various measures of efficacy and quality of peripheral venous catheter placement as a factor of the method used. The results will allow for estimation of the promise of NIR vein imaging for a future clinical use.

Sample Size and Power Determination

The study was designed such that we will need to enroll at least 125 patients per group (375 patients total for all three groups) to have 80% power if the estimated percentage with success in the control group is 50% and 70% in either of the study groups using a two-sided $p<0.0167$ for determining significance (study alpha was divide equally between the three groups).

We have therefore chosen to include 400 patients in the study. We anticipate that this initial data set will provide useful information regarding the effectiveness of the device in difficult access situations. In addition, it will give information about variability of data between patients that will guide the design of any future device and further studies that will answer more specific clinical questions.

Due to the need for appropriately trained staff to be available, the study will only be offered during hours when one of the trained Vascular Access Team members / co-investigators is available. During this time frame, the Vascular Access Team typically encounters approximately 50 patients per week. We anticipate that approximately 40% of these patients will meet study inclusion criteria. We estimate an approximate 60% study recruitment rate. We therefore expect that approximately 12 patients will be recruited into the study per week. The study is therefore estimated to be complete within 8 months.

Data Analysis and Statistical Methods

Direct study group comparison of the primary and secondary outcome variables will be performed using routine statistical tests utilizing a statistician at Tufts CTSI. In addition, the study will collect limited descriptive information pertinent to the effectiveness of visualizing superficial peripheral veins.

Study Monitoring and Safety Plan

Study Monitoring

After the first patient has been enrolled, the principle investigator will review the collected data every four weeks with other members of the study staff. At each research meeting, the principle investigator will evaluate study progress and assess protocol compliance. This will include the informed consent procedure, compliance with eligibility criteria, and identification of protocol violations. The principle investigator will also review all collected data to verify data accuracy, consistency, and integrity. The patients will be physically evaluated 3 days after the procedure by a Vascular Access Team member according to routine practice, unless discharged home or otherwise not available in-hospital, to assess for procedure related adverse events. The principle investigator will review any reports that could be pertinent to a potential adverse event. The principle investigator will be responsible for reviewing data from any adverse event and determining, if applicable, whether the research should be altered or stopped. Any decision to alter or stop enrollment will be reported to the IRB.

Any untoward medical event considered related or possibly related to study participation will be considered an adverse event. Serious adverse events (SAE) will be defined as stated in the IRB SAE reporting policy. Adverse events will be graded for severity according to NCI-CTCAE (version 4.0). For the purpose of safety reporting, the study period will be considered from the day of the procedure to the day of the last follow-up. All adverse events of grade II or greater attributable to study participation will be reported to the IRB. Multiple occurrences of an adverse event that, based on an aggregate analysis, is determined to be an unanticipated problem independent of the severity grade will be reported to the IRB. Any SAEs related to study participation will be reported within 5 business days of the PI learning of the event.

Protection of Human Subjects

Non-invasive vein visualization devices are FDA class 1 devices (CFR title 21 section 880.6970). The VeinViewer Flex device (Christie Medical Holdings, Inc., Memphis, TN) used for this study is registered with the FDA for the intended use to indicate the location of blood vessels (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=241896&lpcd=KZA) . The device will be used in accordance with its labeling (IDE exempt under CFR title 21 section 812.2(c) category 2). Using the VeinViewer in the setting outlined in the inclusion criteria would represent standard of care (i.e. each study arm represents a form of standard of care currently practiced at Lahey Hospital & Medical Center). With the use of NIR light, the patient is not exposed to any significant energy or potential for harm. We therefore conclude that the proposed device is a **non-significant risk device qualifying for an IDE exemption**.

Risks

Complications associated with peripheral venous access placement such as hematomas, phlebitis, thrombophlebitis, infiltration, and nerve damage can occur. However, since only patients will be included who under best medical practice would

undergo placement of a peripheral venous cannula anyhow, the potential added research risk to the study patients is minimal. Specifically, the risk of complications during peripheral venous cannula placement with the use of the VeinViewer is thought to be not greater than with the use of regular eyesight. The risk of the VeinViewer disturbing the flow of patient care is also felt to be insignificant due to the exclusion of patient's demanding minimization of procedure time.

Concerning the clinical patient information collected in the research database, all patient identifying information will be kept to a minimum and will only include medical record number and date of procedure. Furthermore, the data abstracted will be stored in a password-protected hospital server. No patient identifiers will be sent outside of Lahey Hospital, published, or be provided to anyone outside of the research team. Patient identifiers, except for date of the procedure, will be discarded after the last follow-up.

We therefore conclude that the proposed study represents **minimal risk**.

Benefits and Alternatives
At present, insufficient evidence exists to characterize the effectiveness of this imaging technique; particularly in the setting of a difficult peripheral venous access. Therefore, study participation does not provide any proven benefit to the patient.

Apart from not participating in the study and pursuing standard/routine treatment options, there are no alternative options for any potential study patient. The patient's participation in this research study is voluntary. At any time, he or she may choose not to participate in this research study simply by contacting the principal investigator or a study team member. If the patient decides to withdraw consent to participate in the study after placement of the peripheral venous cannula, no new data about the patient will be collected for study purposes unless the data concerns an adverse event related to the study. Yet, all data that has already been collected for study purposes will continue to be used and analyzed.

Importance of the Knowledge To Be Gained
Currently, finding a suitable peripheral vein for access continues to be a frequent challenge for healthcare providers and a significant burden to the patient; issues that are hoped to be addressed by the study device. Due to the sheer volume of peripheral venous catheter placements within the in-hospital setting and the associated detriments to the patient when repeated attempts are needed, any improvement in reducing the number of attempts of peripheral vein cannulations, prolonging the patency of these catheters, and reducing catheter associated complications can have a significant impact on overall patient care throughout the entire in-hospital patient population.

The proposed clinical trial will establish the potential of incorporating a novel NIR vein finder into clinical practice to improve peripheral venous access for in-hospital patients who are considered a 'difficult stick'. Incorporation of such devices, if found to be successful, can fundamentally change patients' experience and reduce complication rates.

Limitations

Overall it is felt that the study has a very robust design. Yet, limitations include bias by any Vascular Access Team member who may favor one method and therefore might create more favorable results with the method of subjective preference (observer-expectancy effect and experimenter bias).

The follow-up was felt to be adequate since most complications are expected to present during the hospital stay. However, long-term complications, such as thrombophlebitis, might be slightly underestimated due to its sometimes later presentation even after removal of the catheter or in patients who have been transferred to a different facility with the catheter still in place. Nevertheless, there is currently no reason to believe that long-term outcomes of a successful peripheral venous catheter are dependent on the method of catheter placement and therefore it is not expected that the study results will significantly be affected.

NIR vein imaging might require a learning curve. To minimize the issue, all Vascular Access Team members have been trained with the device and had to use the device independently during routine patient care for at least 20 cases before being able to participate in the study.

Study Resources and Finances

Institutional Resources

The study utilizes several existing resources available at Lahey Hospital & Medical Center. This does include the completed purchase of two VeinViewer devices which are already in clinical use at the institution.

The Vascular Access Team at Lahey Hospital & Medical Center performs approximately 10 peripheral venous access placements in the inpatient setting per day during regular business hours. The Vascular Access Team leader and members of the Vascular Access Team are investigators or collaborators of the study. The study is supported by the Department of Surgery at Lahey Hospital & Medical Center.

Support for statistical questions will be obtained through an established collaboration with the Clinical and Translational Science Institute at Tufts University.

Financial Resources

The study is supported through the institutional infrastructure. The cost of statistical analysis will be covered through departmental funds.

Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by Lahey Health Corporate Compliance, etc.) cannot participate in this study. All investigators will follow the applicable Lahey Health conflict of interest policies.

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