Use of SU-VEID™ As An Adjunct to Vein Visualization Technology to Improve Peripheral Venous Access Success in Children

NCT05204082

September 15, 2021

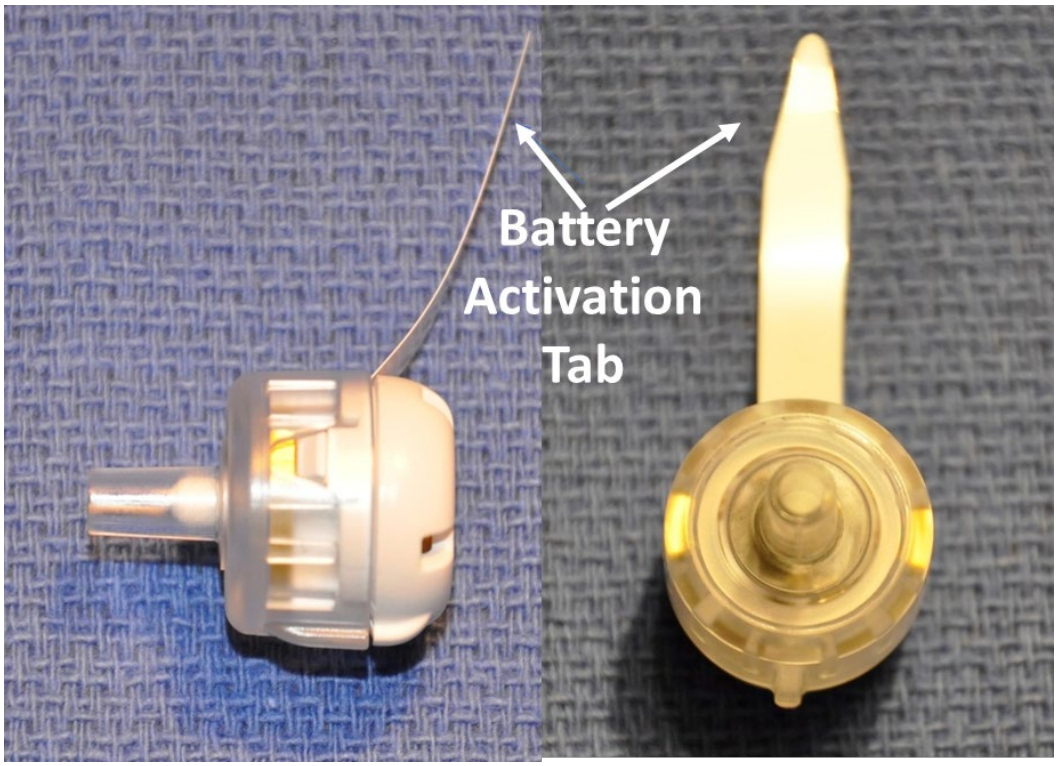
Use of SU-VEID as an adjunct to vein visualization technology to improve peripheral venous access success in difficult venous access patients

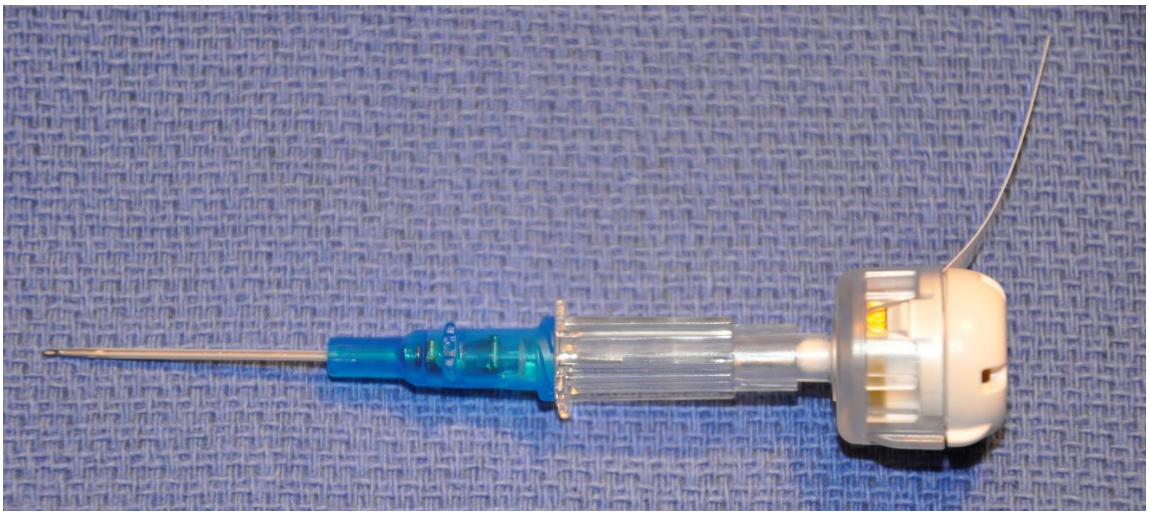
Title	Use of SU-VEID as an adjunct to vein visualization technology to improve peripheral venous access success in children
Study Number	1.0
Study Objectives	Intravenous access is often technically difficult in children because of the small diameter, inability to feel or see the veins. We propose to determine if use of the SU-VEID™ in children facilitates an increase success rate of peripheral intravenous starts, in comparison to conventional vein entry techniques.
Study Device	SU-VEID **S**ingle **U**se **V**ein **E**ntry **I**ndicator **D**evice. Electronic pressure sensing device, integrated to a conventional needle catheter, and which indicates continuously during intravenous cannulation: whether the tip of the needle is inside or outside of a vein, to assist a clinician in intravenous cannulation.
Indication for Use	The SU-VEID is used to indicate the location of the vein (in relation to a tip of a needle): including indication of vein entry, vein double puncture (infiltration), vein re-entry and vein exit of an intravenous catheter system's needle.
Study Design	1- General a. SRNAs, CRNAs, and Physicians in the anesthesiology department who normally performs IV Starts as part of patient care may participate. b. Study type: Prospective, Randomized Controlled Trial 2- Clinician Training Each participating clinician will watch a training video and practice on a phantom to gain proficiency with the SU-VEID device prior to study participation. 3- The trial - The potential intravenous catheter inserter will assess the difficulty of the IV start preoperatively - Pre-surgical subjects requiring an IV without adequate visually visible veins on the arms will be considered difficult venous access and approached for consent. - Subjects who are consented/ assent will be assigned a study number and randomized to either standard IV insertion or with SU-VEID by the research assistant - The clinician will perform procedures with or without SU-VEID, according to the randomization scheme. To allow analysis across all clinicians, an individual clinician's participation will be limited to no more than 50% above/below the number of subjects that would occur if the subjects were distributed equally 4- A minimum of 200 subjects per control group and 200 subjects for the Study group. - Subjects will be stratified to 200 (100 control, 100 SU-VEID) total using near infra-red vein (NIR) visualization and 200 (100 control, 100 SU-VEID) total using ultrasound (US) vein visualization. Targeting type I/II error rates of 0.05 and 0.2, respectively, this sample size would detect improvement of first pass success from 50% to 66%.
Study Groups	Pediatric patients in surgical pre-op (0-18 years old), requiring an I.V. catheter for surgery who are difficult venous access.

Study Population	Inclusion -Patient age ≤ 18 requiring an IV for surgery who is difficult venous access -Written informed consent/ assent from the patient or legal guardian. Exclusion -Patient age > 18 -placement of the IV will be done according to standard operating room procedures, which typically is after induction of general anesthesia by mask
Number of Subjects	A total of 400 difficult venous access patients will be stratified between using either 200 NIR or 200 US vein visualization technology to achieve venous access. Within each vein visualization device group, the patients will be randomized to either standard or using SU-VEID as an adjunct for IV catheter insertion. Please see above for sample size calculation.
Study Duration	6 months
# of Clinical Sites	1
Primary End Points	IV Start first-attempt success rate increases when using the SU-VEID Device in comparison to the conventional procedure.
Secondary End Point	1- Success rate of IV access within two sticks when using NIR technology. 2- Success rate of IV access within two sticks when using US technology. 3- Total procedural time required to achieve successful cannulation in comparison to conventional IV Start procedure.
Statistical Analysis	Paired T-test (Each clinician conducts procedures with and without the device), Chi-Squared (Measuring differences in vein difficulty pre-assessment versus control and study group success rate),
Study Sponsor	Angie Technologies Ltd.

Device Description

SU-VEID is a vein entry indicator device. The device is an electronic and algorithm-controlled pressure sensitive device, tiny, and integrated to flash chamber of an IV catheter. The device signals by beeps and lights instantly when entering the vein lumen and continues signaling as long as the tip of the needle is within the vein. After exiting the vein (either backwards or forward), once the tip of the needle re-enters the vein, the device signals again. Hence the device is an aid for venous lumen entry and alerts the clinician if the needle strays outside the lumen during the insertion process. The auditory feedback is overt, faster and more sensitive than the venous pressure/ capillary action required to see blood in the flash chamber. Moreover, the device allows the clinician to focus their vision on the insertion technology (ultrasound screen or NIR field), rather than divide it between that and the flash chamber. Therefore, it is believed that it will improve stick success.





SU-VEID attached but not activated

BACKGROUND

Problem worth solving
Every year in US, hundreds of millions of IV placements are conducted. Nurses and Physicians experience the difficulties and the stresses which are involved with vascular access. Improving first attempt success is an important goal which will reduce vessel injury, pain of multiple insertions, reduces the risk of catheter related blood infections, risk of staff needle stick injuries, cost and increases patient satisfaction.

Clinical Benchmark
IV Start average number of attempts is >2 in general population, and ≥ 3 attempts in difficult venous access patients.
IV placements failures are up to 50% of the time before the IVs reach the end of their intended use.

Clinical Background
Venipuncture may be utilized for intravenous therapy or for sampling of venous blood. In human medicine, this procedure may be performed by a medical practitioner, for example a physician, a nurse, medical technician, a paramedic, or a phlebotomist,. Venipuncture is one of the most routinely performed invasive procedures and may be performed in order to obtain blood for diagnostic purposes, to monitor levels of blood components, to administer therapeutic treatments including medications, nutrition, or chemotherapy, and/or to collect blood for later uses, e.g., for blood donation, and more.
Venipuncture is performed by inserting a needle, such as an intravenous catheter into a blood vessel of the patient. For efficient performance of the procedure, the practitioner must have an indication when the needle enters and/or exits the vein. The most common indication is obtained by visual observation of the blood flowing from the vein though the needle to a flashback chamber or an associated reservoir (e.g., a syringe).

Intravascular catheter systems, such as peripheral intravenous catheters, are essential in modern medical practice.
The conventional method of placing an IV catheter into a vein is using a catheter over-the-needle technique. Puncturing the skin with a needle catheter, moving the needle in surrounding tissues towards a targeted blood vessel, and puncturing the wall of the target vein provides a visual indication of blood within the flash chamber. Depending on the venous pressure and volume status, this indication of the needle being within the lumen of the vein can be variable, delayed or even falsely positive if the needle strikes the wall of the vessel again and goes outside of the lumen. All these scenarios contribute to missed IV placements and reduced first stick success.

Complications of incorrectly placed IV catheters include infiltration by medication administered in a high concentration to the local tissues around the vein instead of distributing in the blood system, causing hematoma, tissue damage, phlebitis, extravascular drug administration, thrombosis, delay of treatment, catheter related blood stream infection and loss of vein ultimately contributing to the patient being difficult vascular access.

Strategies to improve PIVC success with difficult venous access patients include devices such as ultrasound and other vein visualization technology. These devices have a significant learning curve and may produce poor results due to variability of skill level and the complexity of placement of IV catheters in patients with limited venous targets.

Description of the SU-VEID

The SU-VEID is a sterile disposable device for indicating a position of the needle tip relative to a blood vessel of a patient, detecting and indicating entry of an intravascular catheter into a blood vessel. The device is configured to be attached to a proximal end of the catheter so that a lumen of the catheter is in continuity with the device, and the pressure of the blood or surrounding tissues is continuously measured using a pressure sensor of the device.

The device comprises: a pressure sensor configured to produce pressure values correlative to the surrounding pressure; a signal processor; an emitter configured to produce sound and an emitter configured to produce light. The pressure sensor responds to the changes in the pressure within the needle and activates a signal by an algorithm. The signal is indicated through simultaneous activation of the sound and light emitter. Accordingly, the device enables an instant identification of penetration by an intravascular catheter of both walls of a blood vessel by means of analysis of pressures history and changes in the pressure levels. The indications are instant, enabling the clinician to react instantly to the emitters signal, thereby avoiding double puncturing (infiltration). Furthermore, the indications are correlated to the state of the tip of the needle, i.e., a different indication signal is received while the tip of the needle is within the vein than when the tip of the needle is outside the vein.

The instant response also solves the problem of double penetration, i.e., crossing the distal wall of the vein, as in the case of double penetration the signal indication will cease. The cannula then needs to be slightly pulled back in position, until the signal is obtained once again without the cannula being removed from the patient's body. This increases the probability of completing and finalizing the procedure while the cannula is properly situated inside the vein.

Risk

The SU-VEID is a low-risk device. The structure and principle of operation are such that the occurrence of adverse reactions is highly unlikely and hazard due to malfunction of the device is negligible.

The device interfaces with the existing procedure of catheterization of a blood vessel.

Worst Case Scenario, such as device failure, would not be predicted to impact PIVC as one would utilize the standard indication of the blood coming back into the needle.

Any adverse reactions reported by subjects or noted by study personnel will be recorded and reported.

A risk management and estimations were performed according to ISO 14971 (2007)

Further, SU-VEID does not interfere with the normal blood return into the flash chamber of the catheter so its use does not obstruct a clinician's normal cues of entry into the vein. What it does is identify the precise time of entry into the lumen even if the patient's volume status is low and blood refill into the catheter is slow. This should allow the clinician to reduce "back wall" injury of the vessel and hence increase success.

Benefit

Subjects may benefit by having the IV catheterization procedure performed with less attempts, easier and quicker with the SU-VEID device, therefore less exposure to risks.

Further, SU-VEID does not interfere with the normal blood return into the flash chamber of the catheter so its use does not obstruct a clinician's normal cues of entry into the vein. What it does is identify the precise time of entry into the lumen even if the patient's volume status is low and blood refill into the catheter is slow. This should allow the clinician to reduce "back wall" injury of the vessel and hence increase success.

Terms:

SU-VEID	Disposable sterile vein entry indicator device, FDA approved.
Success	The cannula is placed inside a vein and secured.
Fail	The procedure stopped due to a failure or the cannula found to be placed outside a vein right after completing the procedure, or a short time later.
IN-State	The needle's tip or the cannula's tip are inside a vein.
Sound of success	Fast beeps (8 per second) indicating in-vein Success state.
Sound of operation	Slow beeps (1 per second) indicating out of vein state
Half Detach	A temporary state while pulling the needle from a cannula or sliding forward the cannula on the needle for about an inch, the clinician normally ceases the detachment for a moment and hold (to see the blood upward in cannula) while the needle is still partially inside the cannula.
Full Detach	A state, where the needle is fully pulled out from the cannula.
AT	Angie Technologies Ltd.
SPIV	Short Peripheral Intravenous
DVA/DIVA	Difficult Intravenous Access