Research Proposal Cover Page

Title of research project	Ultrasound-guided peripheral IV vs. standard technique in difficult vascular access patients by ICU nurses.			
Research team	Name	Position	Telephone	E-mail
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Health institution involved	Kingston Health Sciences Centre			
Expected duration	6 months starting from December, 2018 till May ,2019.			
Expected budget	The study will utilize resources condensed within the standard of care.			

Declaration: I agree to submit this final proposal draft for approval and I will have full responsibility to manage the project and to follow up various activities in order to finish it in time. I will ensure that the research will not deviate from the protocol described. If significant protocol amendments are required as the research progresses, I shall submit these to the Research Review Committee for approval. Also I will be responsible to provide progress reports and final report for my program research subcommittee for revision before final dissemination

l-P.I 1: Mohammed Al-Shamsi Date: 01 / 11 / 2018

Ultrasound-guided peripheral IV vs. standard technique in difficult vascular access patients by ICU nurses.

''Research Protocol''

1-Introduction:

Peripheral intravenous access is one of the most common and most important invasive procedure performed by ICU nurses. The importance of being able to insert an IV quickly, successfully and with little discomfort cannot be overestimated. Establishing good peripheral access is essential in ICU because this allows timely administration of fluid and medication and also allow early discontinuation or even avoidance of central line when there are no specific indications for their use.

Failure in establishing good peripheral access is a very frequent problem in ICU because of the high prevalence of chronic illness, peripheral edema, obesity and for many other reasons. Multiple attempts in establishing IV access in difficult IV access (DIVA) patients frequently lead to a high level of patient discomfort and nurse's frustration. Peripheral IV cannulation can be incredibly time intensive for nurses when patients are DIVA. Furthermore, failure of peripheral intravenous cannulation (PIVC) in ICU setting frequently leads to insertion of a central line or PICC which are associated with more risk of catheter-associated infection and other serious complications [1].

Using Ultrasound to guide central line insertion is the standard of care but ultrasound-guided PIVC in difficult patients remained poorly utilized rescue tool despite its potential advantages in the ICU setting. Ultrasonographic guidance may improve the rate of successful PIVC in patients who have been historically difficult to access, leading to less time spent obtaining intravenous access and greater patient satisfaction.

In difficult IV access patients, we hypothesize that ultrasound-guided peripheral intravenous cannulation (USG-PIVC) increases the success rate of peripheral IV access in difficult IV access ICU patients. In addition, we hypothesize the USG-PIVC is a very safe procedure and is associated with very few minor complications.

2- Literature review:

Ultrasound-guided central venous access has been well studied throughout the past few decades, several studies showed an increased success rate and decreased complications compared to the traditional landmark approach [2].

Ultrasound-guided peripheral intravenous cannulation (USG-PIVC) is a technique that can be utilized in patients with difficult peripheral IV cannulation which is a frequent problem encountered in ICU. There are multiple factors associated with failure in establishing peripheral IV access in adults, e.g., obesity, IVDU, DM, nurse's experience and poor peripheral venous visibility and palpability [2,3]. James CR et al. found that clinical gestalt is an excellent predictor in determining the probability of PIVC first-time insertion success or failure. He suggested that clinical gestalt can prospectively stratify patients into groups according to their risk of PIVC placement failure [3].

There are multiple small studies in the emergency literature which found that UG-PIVC by ED physician and nurses in DIVA patients can lead to better success rate, few punctures and greater patient satisfaction compared with traditional landmark technique. In a prospective observational study by Brannam et al., he demonstrated that emergency nurses could be trained to use US-guided PIV access with high success rates and few complications [5]. In another small prospective randomized trial in ED, the superiority of ultrasound-guided peripheral intravenous cannulation was not supported. The investigators found that ultrasound-guided peripheral intravenous cannulation did not decrease the number of attempts or the time to successful catheterization, nor did it improve patient satisfaction compared with the group that did not use ultrasonography [6].

In another small randomized prospective study conducted in an emergency department in 2005, Costantino et al found that ultrasound-guided IV cannulation performed by emergency physicians are more successful than traditional ''blind'' techniques, requires less time, decreases the number of percutaneous punctures, and improves patient satisfaction in patients with difficult I.V access [7]. In a recent single-center randomized prospective study in ED, nurses were found to be more successful in obtaining IV access using US guidance than palpation technique in difficult access patients. Nurses using US-guided technique had a higher success rate of 76% in placing a functional IV compared to 56% using the standard palpation technique [8].

In a single-center retrospective study, a single physician attempt in placing peripheral IVs using ultrasound in difficult cannulation ICU patients found that first attempt success rate was 77% with 99% overall success rate. As a result of placing these PIV catheters, 40 central lines were discontinued, and 34 central lines were avoided. This study has a limitation because it is a retrospective study examining a single physician's experience with the technique [9]. In another

small ICU RCT, the ultrasound-guidance technique was more successful without increasing cannulation time despite the use of additional equipment [10].

In a recent systematic review published in 2016, the authors found that the ultrasound-guided technique improves the success rate of intravenous access significantly (OR = 3.00, $p < .0001$) and decreased the number of attempts in the overall group of difficult intravenous-access patients [11].

Ultrasound-guided peripheral IV cannulation has a steep learning curve. Stolz La found that new learners of the procedure are capable of a greater than 70% success rate after placement of four USG PIVCs. A success rate of greater than 88% is achieved after 15 to 26 attempts [12]

There are multiple factors associated with a high failure rate and shorter catheter survival when USG-PIVC is used. In the study conducted by Michael D et al., he found that veins less than 3 mm in diameter or greater than 1.5 cm in depth were associated with high failure rate [13]. In another study conducted by J. Matthew et al., he found 2 important factors associated with short catheter survival when performed with ultrasound guidance. Deep veins (depth > 1.2 cm) and proximal location were associated with early catheter failure when they are performed with ultrasound-guided technique [14].

Based on many previous studies [6,13,15], complication rate associated with USG-PIVC is the same as traditional blind techniques. Adhockery et al. found that the infection rate of USG-PIVC is the same as a blind technique [14]. Thomas G et al. reported no significant complications in their RCT in USG-PIVC group

3. Methodology

3.1. Study design:

This is a randomized controlled single-site trial with two groups in a parallel design. In this study, we will compare the success rate of ultrasound-guided peripheral intravenous access (experimental group) to a traditional landmark approach (control group) in patients with DIVA. It is a non-blinded study because of the nature of the intervention.

3.2. Setting :

This study will be conducted in the adult intensive care unit of Kingston general hospital which is an urban university teaching hospital with 33 ICU beds and more than 1000 ICU admissions per year.

3.3.Study population:

A convenience sample of ICU patients with difficult cannulation will be selected and enrolled in this study. Difficult cannulation is defined as poorly visible and palpable upper extremities veins due to any cause after two failed attempts using traditional technique. All consecutive patient with difficult cannulation will be assessed for enrolment in this study starting from December 2018 till May 2019. A research assistant will be available for patient enrollment and data collection between 8:00 AM till 5:00 PM during weekdays.

3.4. Inclusion / exclusion criteria

Inclusion Criteria:

- 18 years of age or older
- DIVA patients after two failed attempts

Exclusion Criteria:

- Upper-extremity cellulitis
- Unstable and need urgent intravenous access (central line or IO).

3.5. Study procedure

The study will be conducted in two phases. Phase one will involve education and training of a cohort of nurses to perform US-guided PIVC. Experienced ICU nurses with two years of experience will be recruited to participate in the study. All nurses will have no prior experience in USG-PIVC prior to this study. Education consists of didactic two hours lecture and hands-on practice on synthetic training models (blue phantoms). This will cover basic machine operation, image optimization, sonographic anatomy and ultrasound techniques for guiding PIVC. This will be followed by 2-3 months observation period during which nurses have to perform at least 15 successful ultrasound-guided PIVC on live subjects before actual patients' enrolment. Phase two involved patient enrolment of difficult peripheral access ICU patients meeting specific inclusion and exclusion criteria. Patients will be systematically randomized to the ultrasound-guided or the landmark technique (control) using envelop randomization.

Only upper limb veins will be selected for cannulation. All the cannulation will be done under semi aseptic technique as per standard PIV placement and cleaning procedures. USG-PIVC will be performed using sterile gel for the

procedure, and the ultrasound probe will be covered with sterile adhesive films (e.g., 3M Tegaderm). Two already available departmental ultrasound machines (sonosite edge) will be used for this study. High-frequency probe (5-10 MHz) with single operator out of plane (short access) approach will be used for ultrasound-guided cannulation.

When using USG-PIVC, veins deeper than 1.5 cm from the skin surface and veins with diameter less than 0.3 cm will be avoided because of high failure rate and increased risk of extravasation. Catheter length and size will be selected based on the depth and size of veins to ensure that a sufficient portion of the catheter will remain in the vessel to prevent early failure.

3.6: outcome measures:

Primary outcome measure:

- Successful cannulation by ICU nurses.

Secondary outcome measures:

- Number of punctures attempted.
- 24 hours catheter survival.
- Complications (cellulitis ,phlebitis arterial puncture, nerve injuries, infiltration, hematoma formation).
- Subsequent need for PICC or central line.

3.7. Data collection and processing

Intensive care nurses participating in the study will record all the data related to outcome measures on a preprinted data collection forms in real time. The raw data will be entered by investigators into SPSS software for analysis.

3.8. Data analysis

An intention-to-treat analysis will be performed. Using the power of 80% and alpha of 0.05, the sample size was calculated to be 25 per group. Categorical variables such as success rate, catheter survival rate and complication rate will be presented as a percentage and will be compared using Fisher exact tests. Continuous variables such as insertion time and the number of attempts will be shown as mean, median (with interquartile ranges), and 95% confidence interval (CI) and will be compared using Mann-Whitney U tests. All statistical analysis will be conducted using IBM SPSS Base 25 for Windows.

4. Definitions:

Difficult IV access patient is defined as failure of 2 attempts to cannulate upper limb veins in patients with invisible or non-palpable veins after application of a tight proximal tourniquet. Successful cannulation is defined as the ability to aspirate blood and ability to flush the cannula without resistance to the flow and without evidence immediate extravasation.

Failure PIVC is defined as extravasation with initial infusion or inability to withdraw blood. Failed cannulation is defined as failed three attempts excluding the initial two attempts which are part of the definition of difficult venous cannulation. Time will be recorded in minutes in real time by the ICU nurse with time zero defined as the first skin puncture after patient randomization in the study.

5. Ethical considerations:

The course of research ethics (CORE) will be completed by the researchers, and the study proposal will be submitted for approval to the Queen's university health sciences research ethics board (HSREB). For this research project, we will request to waive the informed consent because the intervention involves no more than minimal risk to patients. Peripheral IV insertion is a minor common procedure, and it is usually conducted by ICU nurses without any form of consenting in intubated ICU patients. It is an essential intervention and part of the standard of care that carries minimal risk. In addition, It is difficult to carry out this research with informed consent because this might affect recruitment and feasibility of this study in the ICU setting. The waiver or alteration will not adversely affect the rights and welfare of patients. Patients' confidentiality will be protected per the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The researchers will follow the code of best practices in research and declare no conflicts of interest that could affect the outcome of the study.

6-Anticipated results/implications:

We expect that USG-PIVC is more successful in establishing PIVC in difficult access ICU patients when performed by highly skilled and experienced ICU nurses. Based on previous researchers, we expect that the complications associated with this technique to be minor and uncommon. If proven useful, this study might popularize the ultrasound-guided technique for insertion of PIVC in DIVA patients and help to advance and improves the quality of patient care.

7-Funding:

For this study, no budget is required. We will use already existing hospital resources. Clinical simulation center at the school of medicine in Queens University will provide the place and equipment for hands-on practice.

8-References

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