Protocol

1. **Title:**

Investigating the Influence of Catheter Advancement Techniques on Needle Tip Movement During Intravenous Insertion

2. **Investigators**

PI: Nikolaus Gravenstein
Co-PI: S. Hamad Sagheer

Co-Investigators:
Mayank Kotadia

3. **Background and Significance:**

Previous studies have explored various aspects of intravenous (IV) insertion techniques, focusing on factors such as needle size, angle of insertion, and patient comfort. However, there is limited research on the influence of different catheter advancement techniques on needle tip movement in the process of advancing the catheter off the needle. The proposed study aims to fill this gap by investigating whether needle tip movement during catheter advancement is affected by whether the individual performing the insertion pushes the catheter off the needle themselves (either one handed or two handed) or if the catheter is advanced off the needle by another person.

4. **Specific Aims:**

Aim 1: To assess the impact of three different catheter advancement techniques on needle tip movement during intravenous insertion.
Hypothesis 1: The needle tip will exhibit less movement during catheter advancement when performed by another individual compared to advancement by the inserter.

5. **Research Plan:**

Study Design: This study will employ a within-subject, crossover design where each participant serves as their own control. Each participant will do intravenous catheter insertions using an instrumented IV catheter and peripheral vascular access simulator using three different catheter advancement techniques: self-advancement (one-handed), self-advancement (two-handed), and catheter advancement by another individual. The order of techniques will be randomized.
Setting: The study will take place in the simulation laboratory or a clinician break area in the hospital.
Study Subjects: Participants will include adult volunteers who in the course of their work or training place peripheral IV catheters. The sample size will be determined based on power analysis to detect significant differences in needle tip movement.
Main Outcome Measures: The main outcome measure will be needle tip movement during catheter advancement, measured to within 0.2mm accuracy using a UF built IV simulator equipped with tracking technology.
Analyses: Statistical analyses, such as paired t-tests or non-parametric equivalents, will be conducted to compare needle tip movement between different catheter advancement techniques. Additionally, potential confounding variables, such as participant demographics or experience level, will be accounted for in the analyses.

PARTICIPANT SELECTION CRITERIA:

IRB Project #: 202400590
IRB Version: 07/12/2023
PI Version: 10/18/2021

We propose including 50 subjects, 18 years of age and older. Potential subjects will be approached via email listservs to inquire about potential interest in participating in the study. If they express interest, their information will be passed along to members of the study team. Consent will be obtained from the subject after the study has been explained and all questions have been answered. 50 subjects are anticipated to be enrolled.

Inclusion criteria shall be as follows:

1) 18 years of age or older
2) Willing to consent to the study
3) has some experience placing IV catheters

Exclusion criteria shall be as follows:

1) Subject refuses to consent
2) Younger than 18 years of age
3) **No experience inserting IV catheters**

After consent, the following information will be gathered from the participant:

- Demographic information (age, sex)
- Educational Status
- IV catheter experience placement

The targeted study population will include adult volunteers 18 years or older who in the course of their work or training place peripheral IV catheters. The setting in which the research will take place is the Harrell Medical Education Building (HMEB) Simulation Laboratory or in a clinical break area.

UF/Shands students and staff are included within the targeted study population as they are primarily involved in the procedure- intravenous catheter insertion- under examination. Pregnant women will be considered for this project as part of the general population and not as a targeted study population. Safeguards to minimize any coercion or undue influence include potential subjects being informed of the study via an email listserv and having them voluntarily approaching the research team indicating interest in inclusion in the research. Safeguards against coercion of students include: Investigator is not their instructor or advisor, the research is not part of a course curriculum, and there is no course credit for research participation.

Potential subjects will be approached via email listserv advertising to inquire about potential interest in participating in the study. If they express interest, their information will be passed along to members of the study team.

Protected health information will not be accessed for this project. Measures taken to protect the confidentiality of subjects include: Computer-based files will only be made available to personnel involved in the study through the use of access privileges, passwords, and encryption; Whenever feasible, identifiers will be removed from study-related information.

Consent will be obtained by the research team including, Nikolaus Gravenstein (PI), S. Hamad Sagheer (Co-PI Investigator), Hyunyoung Lim (Co-Investigator), and Mayank Kotadia (Co-Investigator). Subjects will be asked to consent following recruitment and prior to commencing the study and collecting data. The Informed Consent form will be used as the summary of consent discussion. Subjects will be given the opportunity to take the consent home to discuss with family members, friends, and/or someone knowledgeable about the protocol. Coercion or unduly influencing subjects during the consent process will be minimized by emphasizing the voluntary nature of this study with additional reassurance that participants can withdraw from the study at any time without penalty. Additionally, there will be an ample opportunity for questions and no incentives will be provided through the entirety of the study.

DESIGN

STUDY PROCEDURES:

After a particular individual is identified, the research team will directly contact the subject to explain the nature of the research and the reason for contacting.

Then, an informed consent form will be provided to include details of the investigation and intended procedures. After clarifying potential questions, the treating team will be notified about the inclusion. Those that consent to participate will undergo the following procedures:

Study course:

1. Participant Recruitment and Consent:
    i. Identify potential adult volunteers aged 18 or older involved in peripheral IV catheter insertion.
    ii. Approach potential subjects via email listservs, inviting them to participate.
    iii. Explain the study details and obtain informed consent from interested participants.
    iv. Emphasize voluntary participation, the ability to withdraw without penalty, and address any questions or concerns.
2. Study Setup and Preparation:
    i. Set up the study simulator equipment in the Harrell Medical Education Building Simulation Laboratory or in a clinical break area.
    ii. Ensure all necessary equipment, including the instrumented IV catheter and peripheral vascular access simulator, are prepared and functional.
3. Participant Orientation:
    i. Orient participants to the study procedures, including the use of the IV simulator and catheter advancement techniques.
    ii. Provide instructions on the three different catheter advancement techniques: self-advancement (one-handed), self-advancement (two-handed), and catheter advancement by another individual.
4. Data Collection:
    i. Each participant will perform up to 3 IV catheter insertions using each of the specified techniques.
    ii. Participants will use the instrumented IV catheter to insert into the peripheral vascular access simulator.
    iii. Needle tip movement from intent of catheter advancement to 5mm of advancement off the needle will be measured with 0.2mm accuracy using the electromagnetic tracking technology of the simulator.

iv. Data collected will include needle movement after simulated vein punction and during catheter advancement off the needle (in mm) which will be recorded within the simulation program and output as a de-identified Excel file.
v. The order of catheter advancement techniques will be randomized to minimize bias.

5. Interim Analysis/Results and Conclusion (if applicable):
   i. Evaluate the study progress and any emerging trends or patterns in the data.
   ii. Consider any necessary adjustments to study procedures or sample size based on interim findings.
   iii. Draw conclusions based on the statistical analysis and address the study hypothesis. Discuss implications for clinical practice and potential areas for further research.

Study Visit Schedule (total time 15 minutes):
Participant arrives at the simulation setting.
Participant undergoes orientation and consent. This includes orientation to study procedure and equipment, explanation of catheter advancement techniques, and informed consent process. Following consent, patient demographic information and educational status will be obtained. Total time required: Approximately 10 minutes.

Participant performs IV catheter insertion using 3 techniques: 1 (Self-advancement single hand), technique 2 (Self-advancement both hands), and technique 3 (second person assisted) in randomized order. Total time required: Approximately 5 minutes. Participant's participation is concluded.
In this study, the observation to be carried out is the total distance of needle tip movement while performing intravenous catheter insertions using three different catheter advancement techniques including: Self-advancement with one hand; Self-advancement with two hands; Catheter advancement by another individual.

There is no placebo or other treatment involved in this study. The experimental control is the comparison between the three different catheter advancement techniques. Each participant serves as their own control in a within-subject, crossover design. The order in which participants perform IV catheter insertions using the different techniques is randomized, minimizing potential biases. This randomization helps ensure that the results are not influenced by the order in which the techniques are tested.

Following the consent process, the information about subjects that will be obtained from subjects is demographic data limited to age and sex as well as education status and clinical experience as well as their preferred catheter advancement technique for routine catheter placement. In addition, participants will be asked if they are familiar with the three different techniques, and what their preferred method is for difficult catheter placement. This information will be obtained by the research team prior to the start of the study at the HMEB Simulation Laboratory.

ADMINISTRATIVE RESPONSIBILITIES:
There is no Data Safety Monitoring Board (DSMB) or an oversight committee for this research project. Given the very low risk to the participants, no formal plan to monitor subject safety will be employed.

STATISTICAL METHODS, DATA ANALYSIS, AND INTERPRETATION:

In our theoretical pilot study, the mean of the needle tip movement for each group was made 3, 2, and 1 mm, respectively. We calculated the sample size to detect a mean paired difference of 0.3 (10% of group 1) with an estimated standard deviation of differences of 0.5 between the group 1 and group 3. Given a significance level of 0.05 with a power of 90%, and dropout of 10%, we finally targeted the enrollment of 30 participants.

The Kolmogorov–Smirnov test will be performed for the normality test. For continuous variables, we will use RMANOVA if they follow a normal distribution, otherwise we will compare means with the Friedman test. Categorical data will be compared with Chi-square test. For the primary outcome, the mean lengths of the needle tip movement will be compared using the repeated-measures ANOVA or non-parametric equivalent. And then we will perform the Bonferroni correction for post hoc test. A p-value less than 0.05 was considered significant. Statistical analyses were conducted using SPSS.

The analyses will involve comparing needle tip movement measurements obtained from each participant across the three different catheter advancement techniques. Statistical software such as SPSS will be used to perform the analyses and generate descriptive statistics and inferential results. Data analyses will be conducted primarily by the research team, including Hyunyoung Lim, Hamad Sagheer, and Mayank Kotadia.

Interim analyses may be conducted to assess the progress of the study and evaluate any emerging trends or safety concerns. However, given the nature of the study and the minimal to no risk involved, formal stopping rules are not anticipated.

DATA STORAGE AND DE-IDENTIFICATION PLANS:

All data will be stored on departmental password protected encrypted share drives or in UF approved cloud environments (i.e. LabArchives) that only the study staff will have access to. At the conclusion of the data collection and analysis, all data will be permanently de-identified.

6. Possible Discomforts and Risks:

There are minimal (clean needle stick) risks to the participants as a result of the study. No identifiable information is being collected ameliorating any additional risk due to disclosure of identifiable information.

7. Potential Benefits:

There is no potential for direct benefits to participants beyond potentially objectively identifying a best technique for them.

The research study will benefit future populations by informing them of a technique which may indirectly improve quality of patient care and reduce IV catheter insertion failure.

8. Conflict of Interest:

No investigators have a conflict of interest beyond authorship in any resulting publication(s).

9. References:

1. Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang E. Accepted but unacceptable: peripheral IV catheter failure. J Infus Nurs. 2015 May-Jun;38(3):189-203. doi: 10.1097/NAN.0000000000000100. PMID: 25871866.

2. Dychter SS, Gold DA, Carson D, Haller M. Intravenous therapy: a review of complications and economic considerations of peripheral access. J Infus Nurs. 2012 Mar-Apr;35(2):84-91. doi: 10.1097/NAN.0b013e31824237ce. PMID: 22382792.
3. Elia F, Ferrari G, Molino P, Converso M, De Filippi G, Milan A, Aprà F. Standard-length catheters vs long catheters in ultrasound-guided peripheral vein cannulation. Am J Emerg Med. 2012 Jun;30(5):712-6. doi: 10.1016/j.ajem.2011.04.019. Epub 2011 Jun 23. PMID: 21703801.
4. Millington SJ, Hendin A, Shiloh AL, Koenig S. Better With Ultrasound: Peripheral Intravenous Catheter Insertion. Chest. 2020 Feb;157(2):369-375. doi: 10.1016/j.chest.2019.04.139. Epub 2019 Oct 22. PMID: 31654617.
5. Stone R, Walker RM, Marsh N, Ullman AJ. Educational programs for implementing ultrasound guided peripheral intravenous catheter insertion in emergency departments: A systematic integrative literature review. Australas Emerg Care. 2023 Dec;26(4):352-359. doi: 10.1016/j.auec.2023.06.001. Epub 2023 Jul 7. PMID: 37423812.