

## DOES USE OF PORTABLE ULTRASOUND ASSIST IN STARTING ARTERIAL CATHETERS?

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Arterial blood gas values are needed to properly treat critically ill patients. When arterial blood samples are needed repetitively, an indwelling catheter can be placed in the radial, brachial, or femoral artery. This arterial catheter, also called an "arterial line," "art line," or "a-line," allows blood specimens to be obtained without a new puncture of the artery.

The standard technique for insertion of an "a-line" begins with obtaining informed consent from the patient or the designated family member. The patient can give informed consent for the procedure if awake and aware of the explanation of the benefits and risks. For example, if a patient is sedated and judged by the medical team to be unable to understand both the need for the procedure and its risks, then that patient cannot give informed consent. The family member or designate of the patient can provide informed

consent and sign the hospital permission form when the patient cannot participate. This form would be filed with-in the patient chart.

Informed consent for standard hospital procedures is separate from informed consent for research participation. The family member or designate giving informed consent for a hospital procedure is not automatically the same person giving informed consent for participation in a research project. Also, the person requesting informed consent might be different since consent for research can only be obtained by trained research personnel.

Our project was to investigate the procedure of "a line" insertion with the use of two different portable ultrasound devices designed to assist the operator in locating the artery. The standard portable ultrasound system used by our nursing staff was the Parks Medical Electronics, Inc. Ultrasound Doppler Flow Detector, Model 811-B (Aloha, OR 97007). This device, with a detection head size of 6 mm, is not well suited to help with insertion of arterial lines. The Escalon Vascular Access Ultrasound Doppler Guided Needle Assembly (Wayne, PA 19807) is a newer device. Its ultrasound probe is within the lumen of the "a-line" itself, and is withdrawn after insertion. This project used equipment from both Parks Medical Electronics, Inc. and Escalon Vascular Access.

The design for this research project was prospective, unblinded, uncontrolled, using patients clinically needing an "a-line" and providing informed consent for research. Prospective means looking ahead and collecting data into the future, starting from the IRB approval date of the project. Unblinded refers to the investigators knowing which device they were using. There could not be a blinded design since the two ultrasound devices could be identified during use. There would be no control group, i.e., a group having a different intervention for comparison. However, there would need to be a random order to select which of the two ultrasound devices is used first. At the end of the research project, the number of subjects enrolled with the Parks Medical Electronics, Inc. device used first should equal the number of subjects enrolled with the Escalon Vascular Access device used first. The most common way to establish this random order is through a random number generator to provide a list of random numbers. The order of the numbers will correspond with the order of the subjects enrolled. If the number is odd, then the Parks Medical Electronics, Inc. device is applied first. If the number is even, then the

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Escalon Vascular Access device is applied first. The use of random numbers instead of sequential numbers scrambles the order of the two devices while equalizing the use of each device.

As we have noted for other research projects funded by an outside agency, the first step between the principal investigator of the research project and the sponsor is to arrange a Confidentiality Agreement, also known as a Non-Disclosure Agreement (NDA). This NDA assures the sponsor that the principal investigator and other members of the investigative team will not disclose any research project related information into the public domain unless first approved by the sponsor. The public domain includes speaking to colleagues, publication of journal articles and book chapters, and presenting poster or slides at local, national, or international conferences. A standard NDA is usually provided by the sponsoring company.

The second step for research projects funded by an outside agency is submission of papers to the Institutional Review Board (IRB) by the principal investigator describing details of the proposed research project. These IRB papers describe the project design and include a consent form, as required, for each subject to sign before enrolling and participating in the research project. IRB approval is necessary before initiating the research project through gathering data or enrolling subjects in the project.

The third step for research projects funded by an outside agency is creating a funding account for handling salaries and supplies. A budget is needed for the total project, either tallied per subjects enrolled or by calendar year. This budget is also reviewed and approved by the outside agency and the financial officer at the site of the research project.

Now let's review the research project: The Background or Introduction of the research project explains interest in the topic and why the topic is significant. "A-line" insertion is often difficult, requiring multiple attempts even for experienced operators. Portable ultrasound devices are an advanced way to locate the artery through audio feedback from signals from the artery itself. The audio signal is pulsatile and loudest when the ultrasound probe is aimed closest to the artery.

The Question proposed is: Does the type of portable ultrasound device assist in starting arterial catheters? (Note: The Question asked in every research project always has the possible answers: "yes" and "no.") The preconceived answer by researchers to the Question is called the Hypothesis. For this project, the Hypothesis was: Yes, the type of portable ultrasound device will assist in starting arterial catheters.

For the Methods, the Respiratory Care staff identified patients needing an arterial catheter. The goal for the project was 100

total subjects, 50 subjects having the operator use the Parks Medical Electronics, Inc. device first and 50 subjects having the operator use the Escalon Vascular Access device first when attempting to start the "a-line." Each of the patients had to sign an informed consent form per the IRB. A surrogate could sign if the patient was not awake and aware. After the informed consent was signed, a sealed envelope designated for that subject was opened with the preprinted random number. If this number was odd, then the Parks Medical Electronics, Inc. device was used first, followed by the Escalon Vascular Access device if the "a-line" was not successfully started using the Parks Medical Electronics, Inc. device. If this number was even, then the Escalon Vascular Access device was used first, followed by the Parks Medical Electronics, Inc. device if the "a-line" was not successfully started using the Escalon Vascular Access device. The duration of the project was one year or until the required enrollment was achieved. The difference between success with the Parks Medical Electronics, Inc. device versus the Escalon Vascular Access device would be compared using the rank sum test with  $p < 0.05$  defined as significant.

To formulate the Results, the database was 100 subjects. The use of the Parks Medical Electronics, Inc. device resulted in successful "a-line" insertion in 11/50 subjects = 22%. The use of the Escalon Vascular Access device resulted in successful "a-line" insertion in 45/50 patients = 90%. The difference between success with the Parks Medical Electronics, Inc. device versus the Escalon Vascular Access device was significant using the rank sum test.

The Conclusion was use of the Escalon Vascular Access device was superior to the Parks Medical Electronics, Inc. device when starting arterial catheters. Therefore, in this project, the Hypothesis was supported, corresponding to a "yes" answer to the Question. (Note: When writing the Conclusion, the Hypothesis must be addressed whether it was supported or not.)

The Reflections offers an opportunity to critique the research project, suggesting possible modifications that would improve the quality of the research. For example, a control group could be incorporated using no ultrasound device when the operator starts an "a-line." Additionally, patients needed a comparison by their age and blood pressure in the limb having the "a-line." These measures may reflect on atherosclerosis affecting the arterial system.

Future Research is important because research should lead to more research. For example, this research project could lead to a larger, multi-site project based on the same experimental design.

References from similar research and the reference for non-parametric statistics are included in the Bibliography section.

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Conflicts of Interest are listed for all Respiratory Care Practitioners and others participating in authorship of the project. Conflicts include ownership of stock or receipt of services or gifts from both Parks Medical Electronics, Inc. and Escalon Vascular Access.

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