

Comparison of Different Techniques on First Attempt Success in Difficult Vascular Access

Patients

NCT04821362

July 3, 2018

Study Protocol

This prospective, randomized controlled trial was conducted in a tertiary care emergency department of an academic hospital.

The study included patients describing difficult vascular access history (> 2 attempts on a previous visit), with no visible or palpable veins on the upper extremity, who were assessed to have a difficult procedure by the senior nurse (according to classification; easy–moderate–difficult). Patients who do not provide consent, pregnant, <18 years, and with urgent critical intervention needs were excluded. The randomization scheme was created by the study coordinator with a simple random method. Case report forms were numbered according to the randomization scheme with an equal number for each study groups and distributed equally to the senior nurses by study coordinator. Senior nurses performed the procedure with the corresponding method by randomly and blindly pulling the case report form in a closed envelope when they encountered patients with study inclusion criteria.

The senior nurses of emergency medicine were briefed before the study started. Consent was obtained from senior nurses who wanted to participate in the study. A pretest of 10 questions with theoretical and practical content was applied to measure their basal knowledge level regarding the use of ultrasound and near-infrared light. The principles of determining the venous structures in the upper extremity in the transverse and longitudinal planes, measuring the depth of the vessel, recognizing the arterial structures, performing the procedure on the transverse and longitudinal planes on the dummy were questioned for ultrasound device. For near-infrared light, the principles

of device usage and importance of an appropriate angle were questioned.

A score > 80% in the pretest was accepted as success by the study team. Nurses with a test result $\leq 80\%$ were considered unsuccessful and underwent 4 h of theoretical and 4 h of practical training. During the training, emergency medicine physicians who are experienced in the use of ultrasonography, explained the procedure of vascular access with a single operator method in the transverse and longitudinal planes. In theoretical training, ultrasonography device introduction, principles of use, linear probes and features, horizontal and longitudinal planes concepts, determination principles of venous structures, differentiation of veins from artery and nerve structures, antisepsis techniques, and case report form documentation were explained. For the nearinfrared light device, the introduction of the device, principles of use, distance between the light and area to be treated, and how the device should be positioned were explained. In practical training, ultrasonographic recognition of the normal venous structures of the upper limb on live models, target vein diameter, skin depth measurement, tracing of the target vein, gain settings, and arterial–vein separation were provided. Besides, it was ensured that each nurse performed at least three procedures on horizontal and longitudinal axes ultrasonographically on the forearm mannequin. In the practical training of the near-infrared light device, adjusting the device distance, positioning the device perpendicular to the area to be treated, identifying the vascular structures while the device was operating were shown.

A post-test that includes the same questionnaire in the pretest was applied to all nurses after theoretical and practical training, and nurses who achieved $\geq 80\%$ were included in the study. Based on the literature data, each nurse was allowed to obtain vascular access 10 times under the supervision of the emergency medicine physician before starting the patient recruitment for research.

Sono Site Edge (FUJIFILM Sonosite, Inc.) was used for ultrasonographic procedures, and AccuVein AV 400 (AccuVein Inc.) was used for procedures using near-infrared light.

The first attempt success for peripheral intravenous catheterization is approximately 50%. To increase this success to 70%, the number of patients to be taken for each group with 0.05 type 1 error and 0.80 statistical power was 88. The study population was composed of 90 patients in each group, and 270 patients were planned.

Ethical consent was obtained from the patients before starting the research. To establish a standard approach between the procedures, 18-gauge and 20-gauge catheters were used for the arm and forearm regions, and other regions, respectively. The procedure time was started at the application of the tourniquet by senior nurse. The time was stopped when at least 5 ml of blood was obtained after venipuncture, or at least 5 ml of saline was administered successfully, and the practitioner terminated the procedure. When two attempts were unsuccessful, the third and subsequent attempts were considered as rescue interventions, and these interventions were left to the discretion of the practitioner.

For all approaches, the success of the first attempt, total procedure time, total number of attempts, need for rescue intervention were recorded by study personnels.