I. General Information

Effect of local warming for arterial catheterization in adult cardiac surgery: A randomized controlled trial

II. Background Information

Peripheral arterial catheterization is a crucial clinical technique for real-time blood pressure monitoring and repeated blood draws. However, decreasing first-attempt success rates are observed due to factors such as inexperienced operators and challenging conditions of artery. Multiple attempts can lead to complications, including bleeding, hematoma, vasospasm, dissection, and occlusion. Various arterial catheterization techniques, guided by ultrasonography, have been developed to mitigate these complications. Local warming has been studied for its potential to induce vasodilation and improve success rates.

III. Trial Objectives and Purpose

The main objective of this study was to investigate the influence of local warming at the radial artery (RA) catheterization site on the first-attempt success rate in adult patients undergoing cardiac surgery.

IV. Trial Design

This is a prospective, operator-blinded, randomized controlled trial. The primary outcome was the first-attempt success rate of RA catheterization in the four groups. Secondary outcome included assessing changes in RA size (cross-sectional area and internal diameter) due to local warming, procedure time, number of attempts, and procedure-related complications.

Participants were allocated to four groups: non-warming palpation (NP), non-warming ultrasonography-guided (NU), warming palpation (WP), and warming ultrasonography-guided (WU) groups. Randomization was done using a software tool, and participants' characteristics were summarized. A total of 152 patients were included in the analysis.

During the procedure, standard monitoring including non-invasive blood pressure measurement, electrocardiogram, and pulse oximetry, was performed on the patients in the operating room. The right RA insertion site was preferred unless there were abnormalities such as scars, wounds, or infections, in which case catheterization was done on the left RA. The patient's wrist was extended at a 45° angle over a wrist immobilizer (CAS, SHMEDICAL Co., Ltd., Korea), and a skin-temperature probe was attached.

Local warming was applied to specific groups using a forced-air warmer (WarmTouchTM WT 6000 Warming, Medtronic, USA) set at a temperature of 39°). All participants had skin temperature probes (Philips Intellivue, Philips, Amsterdam, Holland) attached to their wrists. Ultrasonography images of the RA were obtained using a Philips L 12-3 MHz real-time linear-

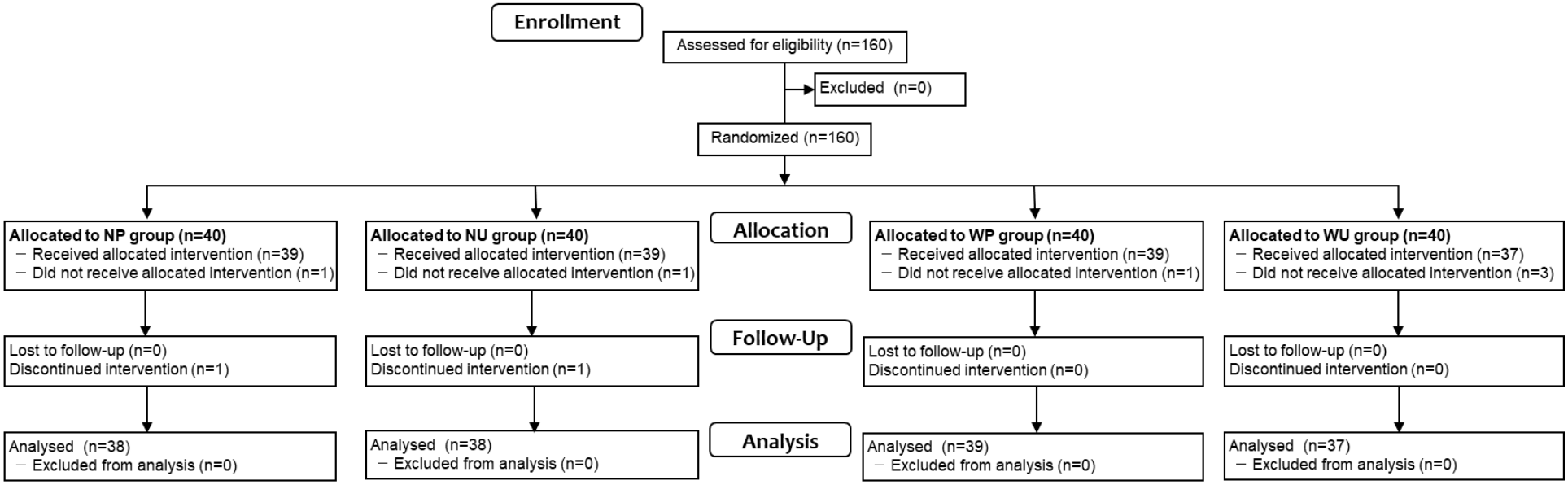
array ultrasound transducer (Philips Medical Systems, Andover, MA, USA). The cross-sectional area (CSA) in square millimeters (mm2), internal diameter (ID) in millimeters (mm), and depth in millimeters (mm) of the RA were measured from stored images taken in the short-axis views.

To account for the potential vasodilatory effects of anesthetics, an initial ultrasonography view of the RA was obtained to establish a baseline after administering anesthetics. Baseline blood pressure and skin temperature at the insertion site were also recorded. Local warming was then applied in the specified warming groups (WP, WU). For the warming groups, after local warming, measurements of the overall warming time, blood pressure, and skin temperature at the insertion site were taken. Short- and long-axis views of the RA were obtained at the same location to reassess the diameter and depth of the RA. In the non-warming groups (NP, NU), blood pressure and skin temperature at the insertion site were noted around 10 minutes later, and short- and long-axis views of the RA were obtained.

Following the collection of baseline and post-procedure ultrasonography views of the RA, skin preparation was carried out using 83% alcohol. Arterial catheterization was performed using either the conventional palpation technique or the ultrasonography-guided out-of-plane technique. The catheter gauge, number of attempts, and procedure time (from skin puncture to confirmation of arterial waveform) were recorded. Complications such as hematoma, and vasospasm were evaluated using ultrasonography.

The assessment of RA size and catheterization procedures were conducted by two experienced anesthesiologists who had performed over 100 arterial catheterizations.

CONSORT 2010 Flow Diagram



V. Selection and Withdrawal of Subjects

Inclusion Criteria:

aged >18 years undergoing cardiac surgery with RA catheterization

Exclusion criteria:

patients with unstable vital signs

pre-existing arterial catheter

preference for other arteries due to surgical technique

patients with inappropriate ultrasonography images, unstable vital signs during anesthesia induction, and high initial body temperature

VI. Treatment of Subjects

Participants in warming groups (WP and WU) underwent local warming using a forced-air warmer. Ultrasonography images of the RA were obtained, and measurements of cross-sectional area, internal diameter, and depth were made. Arterial catheterization was performed using palpation or ultrasonography-guided out-of-plane technique.

VII. Assessment of Efficacy

The primary outcome was the first-attempt success rate of RA catheterization. Secondary outcomes included changes in RA size, procedure time, number of attempts, and procedure-related complications. Statistical analyses were performed using appropriate tests.

VIII. Assessment of Safety

Complications such as hematoma and vasospasm were evaluated using ultrasonography. The occurrence of complications was recorded and analyzed.

IX. Statistics

The sample size was calculated based on previous studies. The first-attempt success rates of palpation- and ultrasonography-guided RA catheterization in adult cardiac surgery were 57.5% and 95%, respectively. We assumed that the first-attempt success rate for RA catheterization was 90% in the WU group and 60% in the NP group. The minimum number of patients for each group needed to provide a study power of 0.8 with a 25% difference and two-sided alpha of 0.05 was calculated as 160 (considering the attrition rate of 10%, 40 cases per group).

Statistical analyses were performed using SPSS. Distribution was tested using the Shapiro–Wilk normality test. The $\chi 2$-test, paired t-test, and Mann–Whitney U test were used to analyze

primary and secondary outcomes.

X. Direct Access to Source

Direct access to the source data and documents used in the study can be obtained by contacting the corresponding author.

XI. Quality Control and Quality Assurance Data/Documents

Prior to the initiation of the study, all members of the research team undergo comprehensive training to ensure accurate and consistent execution of measurement procedures. The trial commences only when minimal inter-observer variability for measurements is achieved, thus ensuring the reliability and uniformity of data collection.

Throughout the course of the trial, internal audits may be periodically conducted to evaluate the coherence and uniformity of the measurements. This practice guarantees the ongoing quality and consistency of the data being gathered.

XII. Ethics

The trial was approved by the institutional review board of Pusan National University Yangsan Hospital (IRB No. 05-2021-117) and conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants.

XIII. Data Handling and Record Keeping

Data collected before and during RA catheterization are recorded in the study protocol and recorded daily in an electronic database by the participating anesthesiologists. All patients included in the study are reported in the study log.

XIV. Financing and Insurance

The authors did not receive external funding, and no information about insurance coverage was mentioned.

XV. Publication Policy

Results of this study will be published in a journal that covers the scope of this work.

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