Research on the Construction of a Standardized Protocol for Ultrasound-Guided Difficult Peripheral Venous Catheterization

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Abstract

Objective: To construct a standardized protocol for ultrasound-guided difficult peripheral venous catheterization that meets the actual clinical needs in China, aiming to improve the standardization, safety, and management quality of the catheterization procedure. Methods: A preliminary protocol was developed based on literature review and qualitative research. The final protocol was established using two rounds of the Delphi expert consultation method, involving 16 experts. Results: The recovery rate of questionnaires in both rounds of consultation was 100%; the expert authority coefficients were 0.81 and 0.84, respectively; the Kendall coordination coefficients for the first- and second-level items in the first round were 0.130 and 0.139 ($P<0.05$), and in the second round were 0.172 and 0.180 ($P<0.05$), respectively; after the second round of consultation, the coefficients of variation for all indicators ranged from 0 to 0.21. The final protocol consists of 15 first-level items and 24 second-level items. Conclusion: The standardized protocol for ultrasound-guided difficult peripheral venous catheterization constructed in this study is rigorous in its process and comprehensive in its content, providing a theoretical basis and practical guidance for clinical operation and management.

Full Text

Preamble

Development of a Standardized Protocol for Ultrasound-Guided Difficult Peripheral Venous Access Pingping Liu[1], Qi Song[1], Dehua Lu[1], Xueqing Zhao[2], Zhufeng Xiong[2]

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Abstract Objective: To develop a standardized protocol for ultrasound-guided difficult peripheral venous access that aligns with the practical clinical needs in China, aiming to improve the standardization, safety, and management quality of catheterization procedures. **Methods:** A preliminary draft of the protocol was developed based on a literature review and qualitative research. The final protocol was established following two rounds of Delphi expert consultations involving 16 experts. **Results:** The recovery rate for both rounds of expert consultation questionnaires was 100%. The expert authority coefficients were 0.81 and 0.84, respectively. In the first round, the Kendall coordination coefficients for the primary and secondary items were 0.130 and 0.139 ($P < 0.05$). In the second round, these coefficients were 0.172 and 0.180 ($P < 0.05$), respectively. Following the second round of consultation, the coefficients of variation for all indicators ranged from 0 to 0.21. The final protocol consists of 15 primary items and 24 secondary items. **Conclusion:** The standardized protocol for ultrasound-guided difficult peripheral venous access developed in this study was constructed through a rigorous process and contains comprehensive content. It provides a theoretical basis and practical guidance for clinical operations and management.

Keywords: Ultrasound; Difficult venous access; Expert consultation; Protocol development

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Peripheral venous catheters (typically 14G–24G) are commonly used devices for implementing short-term intravenous therapy. As the fastest, simplest, and most cost-effective method for establishing vascular access, peripheral venous catheterization is indispensable in emergency medical treatment. However, when treating patients with poor vascular conditions—such as those with obesity, edema, or circulatory failure—traditional blind puncture methods often face challenges including high failure rates and prolonged procedure times. These issues directly impact the efficiency of emergency rescue efforts and the overall patient experience [**?**].

Ultrasound-guided peripheral venous catheterization technology, characterized by its real-time, visual, and dynamic capabilities, can clearly display vascular positions and guide needle insertion. Consequently, it has become the preferred method for managing difficult peripheral venous access and is widely utilized in fields such as emergency medicine, the ICU, and anesthesiology [**?**]. This technology not only significantly improves the success rate of punctures but also helps reduce unnecessary central venous catheterization, thereby lowering the risk of catheter-related bloodstream infections [**?**].

It is important to note that in current clinical practice, significant variations persist across different institutions regarding the selection of ultrasound equipment, venous assessment (vessel diameter and depth), catheter size selection, puncture techniques (in-plane vs. out-of-plane, dynamic vs. static guidance), and documentation practices. These discrepancies highlight a lack of unified operational standards. Such inconsistency not only poses potential safety risks but also hinders the standardized training of this technique and its dissemination to primary care hospitals. Consequently, this study aims to construct a standardized protocol for ultrasound-guided difficult peripheral intravenous catheterization through systematic literature analysis, qualitative interviews, and the Delphi expert consultation method.

1. Materials and Methods

1.1 Establishment of the Research Group

The research group consisted of seven members, all of whom possessed prior scientific research experience in evidence-based practice and the Delphi expert consultation method. The group leader, a Chief Superintendent Nurse, was responsible for selecting the research topic, finalizing the interview outlines, selecting the consultation experts, and overseeing quality control. Three nursing master' s students were responsible for literature analysis, evidence synthesis, conducting interviews, and performing the organization and statistical analysis of data. Additionally, three clinical professionals—including one Associate Chief Physician specializing in ultrasound, one Attending Physician in critical care medicine, and one Associate Chief Superintendent Nurse specializing in intravenous infusion therapy—assisted in the preliminary design of the protocol and the revision of expert consultation opinions. This study has been approved by the Ethics Committee of our hospital (IIT2024366).

2. Preliminary Construction of the Protocol

2.1 Literature Search

To ensure the comprehensiveness and representativeness of the literature search, this study followed the "6S" evidence pyramid model to retrieve relevant literature. First, a computer-based search was conducted on relevant guideline websites, including UpToDate, EMBASE, the Cochrane Library, and Medlive (China). Subsequently, various Chinese and English databases were searched: China Biology Medicine (CBM), China National Knowledge Infrastructure (CNKI), VIP Database, Wanfang Data, and PubMed. Furthermore, websites of relevant professional associations were searched, including the Registered Nurses' Association of Ontario (RNAO) and the American Institute of Ultrasound in Medicine (AIUM).

The search period spanned from the inception of each database to January 2024. Ultimately, 30 relevant documents were included: 4 guidelines, 2 clinical decisions, 1 practice standard, 2 expert consensuses, 7 systematic reviews, 7 randomized controlled trials, 2 quasi-experimental studies, 3 longitudinal studies, and 2 evidence summaries. A total of 32 pieces of evidence were extracted and summarized from these documents, as shown in .

1. Indications and Contraindications [?, ?, ?, ?, ?] **1.1 Difficult Peripheral Venous Access** The clinical criteria for identifying difficult intravenous access (DIVA) include several key factors. Traditional anatomical landmark localization methods often fail in these cases [?, ?]. Furthermore, DIVA is characterized by the inability of experienced operators to establish peripheral venous access after two attempts [?, ?, ?, ?, ?], or by the presence of poor vascular conditions that make puncture inherently difficult. A documented history of difficult peripheral venous catheterization is also a significant indicator [?, ?, ?, ?]. Clinicians may also categorize patients based on the anticipation of difficult catheterization [?, ?, ?, ?, ?, ?]. Specific criteria include cases where local peripheral veins are not visible to the naked eye and where three attempts by experienced ICU nurses have failed [?].

1.2 History of Arteriovenous Fistula, Mastectomy, and Lymph Node Dissection

2. Environment Preparation To ensure the reproducibility of the experiments and the stability of the model training process, this section details the hardware configurations, software dependencies, and the specific experimental environment used in this study.

2.1 Hardware Configuration The experiments were conducted on a high-performance computing workstation. The primary hardware specifications include an Intel(R) Xeon(R) Gold 6248R CPU @ 3.00GHz and 256GB of RAM. To accelerate the deep learning training and inference processes, we utilized an NVIDIA A100 GPU with 40GB of video memory.

2.2 Software Environment The software environment was built on the Ubuntu 20.04 LTS operating system. We employed Python 3.8 as the primary programming language. The deep learning framework used was PyTorch [?], version 1.10, with CUDA 11.3 providing GPU acceleration support.

2.3 Data Preprocessing and Hyperparameter Settings Before training, the raw data underwent rigorous cleaning and normalization. All input features were scaled to a range of $[0, 1]$ or standardized to a mean of 0 and a standard deviation of 1 to facilitate faster convergence. The initial learning rate was set to 1×10^{-4}, the batch size was 64, and the Adam optimizer was used for weight updates. We also implemented an early stopping mechanism to prevent overfitting, monitoring the validation loss with a patience of 10 epochs.

2.1 Maximum sterile barrier precautions are not required when using ultrasound guidance for peripheral venous access.

3. Operator Preparation **3.1 Sterile gloves should be worn.** [?, ?]

4. Equipment Preparation 4.1 Ultrasound equipment with image recording and storage functions. [?, ?, ?, ?]

4.2 Equipment Specifications High-frequency linear array probes were utilized across the studies, with frequency ranges including 7.5-10 MHz, 5-15 MHz [?, ?, ?], and 6-10 MHz.

4.3 Ultrasound Machine Placement The ultrasound machine should be positioned securely on the side opposite the arm selected for puncture. Ideally, the device should be placed across the bed to ensure the screen remains directly within the operator' s line of sight during the procedure.

5. Patient Preparation 5.1 Patient Preparation and Informed Consent Clinicians must explain the purpose of the catheterization, the specific procedural steps, and any potential complications to the patient or their family members. Formal informed consent must be obtained and signed prior to the commencement of the procedure.

5.2 Assist the patient into a supine position with the arm abducted 90° from the body; the patient lies flat with the arm in 90° abduction and external rotation.

6. Pre-puncture Assessment 6.3 Ultrasound-guided peripheral venous access typically selects superficial venous sites of the upper limbs. Deep veins should be avoided when a sufficient number of superficial veins are available for access. Care should be taken to avoid arteries, nerves, and venous valves. The longitudinal section of the vessel should be observed for any signs of tortuosity, stenosis, or thrombosis. Additionally, measure the depth of the vessel from the skin surface and the required needle insertion length.

6.4 Ultrasound to assess anatomical variations and the presence of vascular thrombosis.

7. Target Vein Selection 7.1 B-mode and Doppler modes can be used for vascular identification and localization.

Identification of Arteries and Veins Using Pulse Doppler In clinical vascular ultrasound examinations, distinguishing between arteries and veins is a fundamental task. Pulse Doppler (PW) ultrasound serves as a critical diagnostic tool by providing real-time hemodynamic information. Arterial flow is primarily driven by the rhythmic contraction of the heart, resulting in a characteristic pulsatile waveform. In contrast, venous blood flow is generally a low-pressure system influenced by respiration, gravity, and the skeletal muscle pump.

7.2 Use ultrasound to assess vein diameter, depth, and course before catheterization. [?, ?, ?, ?, ?] Select thick and relatively straight blood vessels for puncture. [?, ?]

8. Catheter Selection 8.1 Select the length and diameter of the peripheral venous catheter based on the diameter and depth of the peripheral vein. The target vessel should have a venous diameter of ≥ 4 mm and a depth from the skin surface of ≤ 16 mm. This reduces the risk of accidental catheter displacement [?, ?, ?].

8.2 Select the most appropriate catheter based on vessel size, shape, depth, flow, and patency.

9. Disinfection of the Puncture Site and Preparation of the Ultrasound Probe 9.1 Standard PIV placement and cleaning procedures should be followed. 9.2 Sterilization of the ultrasound probe, using sterile probe covers and sterile coupling agents. [?, ?, ?]

10. Ultrasound Image Optimization 10.1 Adjust the depth and gain of the ultrasound equipment according to the condition of the punctured vessel to optimize the ultrasound image.

11. Tip Visualization 11.1 Slight movement of the probe. [?, ?, ?, ?, ?, ?] **11.2 Optimize ultrasound machine settings.**

12. Ultrasound-Guided Puncture 12.1 Static vs. Dynamic Ultrasound Methods: Static ultrasound determines the position and patency of the vessel, ensures smoothness, and marks the position. Real-time dynamic ultrasound guidance for peripheral venous catheterization facilitates the real-time visualization of the puncture needle' s position [?, ?, ?, ?].

12.2 Single-operator vs. Two-person Dynamic Ultrasound: In the single-operator dynamic ultrasound-guided method, the operator holds the ultrasound probe in their non-dominant hand to identify the target vein, while holding the needle in the other hand. The two-person dynamic ultrasound-guided method involves one individual holding the probe while another performs the venipuncture.

12.3 Out-of-plane vs. In-plane Ultrasound Methods: Using the out-of-plane method: Compared to in-plane techniques, the out-of-plane approach demonstrates a higher success rate. In-plane (needle-based) techniques can be utilized.

12.4 Use of a needle guide can increase operational stability and help improve ultrasound-guided vascular access success rates.

13. Determining Catheter Position 13.1 After catheterization, check if the catheter is inside the vessel; observe whether the catheter is entirely intravascular under the long axis of the ultrasound probe. [?, ?, ?] **13.2 Inject saline under 2D and/or Color Doppler ultrasound**

mode to observe echo changes. [?, ?] **13.3 Check for blood return in the puncture needle.**

14. Catheter Fixation

2.2 Qualitative Interviews

This study employed a purposive sampling method to select 15 clinical nurses from a Grade A tertiary hospital for semi-structured interviews. Data were analyzed using the Colaizzi seven-step phenomenological analysis method [?]. Three main themes emerged: (1) Cognition and Perceptions; (2) Potential Barriers and Challenges; and (3) Expectations and Suggestions for the Standardized Protocol. Based on these results, one primary item (“Documentation and Records”) and two secondary items (“Preoperative Informed Consent” and “Indications and Contraindications”) were added.

2.3.1 Drafting the Consultation Questionnaire

The questionnaire consists of four sections: a letter to experts, the evaluation of protocol indicators (using a 5-point Likert scale), expert basic information, and appendices.

2.3.2 Selection of Consultation Experts

16 experts were selected based on criteria including a bachelor’ s degree or higher, at least 10 years of experience in ultrasound or infusion therapy, and intermediate-level professional titles or higher.

2.3.3 Implementation of Expert Consultation

Two rounds of Delphi consultations were conducted between March and May 2024. Indicators were screened based on an importance score > 3.5 and a coefficient of variation < 0.25.

2.4 Statistical Methods

Data were analyzed using SPSS 21.0. Expert authority was expressed by the authority coefficient ($Cr = (Ca + Cs)/2$). Coordination was represented by the coefficient of variation (CV) and Kendall’ s Coefficient of Concordance (W).

3. Results

3.1 General Expert Data

The 16 experts included chief superintendents, associate chief superintendents, and associate chief physicians, with 10 to 38 years of experience. (See)

3.2 Expert Motivation

The recovery rate for valid questionnaires across both rounds was 100%. (See)

3.3 Expert Authority

The overall authority coefficient (Cr) values were 0.81 and 0.84 for the two rounds, respectively. (See)

3.4 Coordination of Expert Opinions

In the second round, the Kendall' s W coefficients were 0.172 for primary indicators and 0.180 for secondary indicators ($P < 0.05$). (See)

3.5 Results of Expert Consultation

Following revisions based on expert feedback (e.g., adjusting lighting descriptions, machine placement, and specific vessel selection criteria), the final protocol consists of 15 primary items and 24 secondary items. (See)

4. Discussion

4.1 Scientific Rigor of the Standardized Protocol

The protocol was developed through evidence synthesis and expert consensus, ensuring high scientific validity. The expert authority coefficients and coordination coefficients indicate that the results are credible and reflect a high degree of professional agreement.

4.2 Feasibility of the Standardized Protocol

The protocol addresses practical clinical challenges by providing a systematic workflow from assessment to documentation. Its clear structure makes it suitable for various healthcare settings and technical training.

5. Conclusion

The ultrasound-guided difficult peripheral venous catheterization protocol developed in this study demonstrates high scientific rigor and feasibility. Future research will focus on clinical implementation to validate its effectiveness in real-world practice.

Note: Figure translations are in progress. See original paper for figures.

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