

Guideline Development – The 2023 Korean Society for Phlebology Clinical Practice Guidelines for the Ultrasonographic Evaluation of Varicose Veins of the Lower Extremities

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Varicose vein is a disease with a high prevalence that is commonly seen in everyday life. Accurate diagnosis using ultrasound is essential for venous diseases, but due to the nature of the disease and ultrasonographic techniques, there are a lot of intervention in subjective judgment. Therefore, it is necessary to establish clear standards for the diagnosis methods and standardize procedures of varicose veins. Recently, the diagnosis and treatment of venous diseases has increased rapidly, and the resulting social costs have become a problem. In celebration of its 20th anniversary, the Korean Society for Phlebology published this guideline, 'The 2023 Korean Society for Phlebology clinical practice guidelines for the ultrasonographic evaluation of varicose veins of the lower extremities' because it was determined that the establishment of accurate diagnostic standards using ultrasonography was urgently needed. (Ann Phlebology 2023;21:53-59)

Key Words: Guideline, Diagnostic imaging, Diagnosis, Varicose veins, Ultrasonography

Introduction

For the past 20 years, the Korean Society for Phlebology has strived to provide clear treatment guidelines and clinically evidence-based treatments for patients with venous diseases.

Therefore, under the basic premise that accurate diagnosis using ultrasonography is essential, this guideline, 'The 2023 Korean Society for Phlebology clinical practice guidelines for the ultrasonographic evaluation of varicose veins of the lower extremities' was developed.

This guideline was drafted by the Academic Committee of the Korean Society for Phlebology, and revised and supplemented by the Medical Guidelines Committee. In the actual guideline development process, the highest quality surgical specialists in Korea, led by key executives of the Korean Society for Phlebology, participated.

To ensure the medical objectivity of this guideline, we mainly referred to the latest varicose vein treatment guidelines from related societies in the United States and Europe, which have long proposed standards for ultrasound examination of superficial veins of the lower extremities.

Academically, chronic venous diseases, chronic venous insufficiency, and varicose veins have some differences in definition or disease category. However, in this guideline, to avoid confusion and ensure consistency of expression, the most commonly used term, 'varicose veins,' is expressed collectively.

The Korean Society for Phlebology hopes that this guideline will be used appropriately by all patients, doctors,

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and policy experts involved in the diagnosis and treatment of varicose veins, and that it will not be used for commercial purposes or insurance screening.

Process of guideline development

1) Organization of the committee

(1) Committee composition

The committee was composed of eleven experts of the Guidelines Steering Committee, five experts of the Guidelines Development Committee, one methodology expert, and eight experts of the Guidelines Advisory Committee.

(2) Roles and areas of expertise of each committee

The Guidelines Steering Committee managed the overall operation, including clinical practice guideline development planning, process management, publication, and dissemination, and was composed of eleven experts, including current and former executives of the Korean Society for Phlebology. The Guidelines Development Committee was responsible for the actual clinical practice guideline recommendation development process, including evidence search and selection, evidence summary, recommendation writing, consensus, and external review, and was composed of the Korean Society for Phlebology, Medical Guidelines Committee. Methodology expert provided advice and education on the methodological aspects of the guideline development process. The Guidelines Advisory Committee reviewed and advised on the draft recommendation to review the content and methodological validity of the guideline.

2) Purpose and scope of the guideline development

(1) Purpose of the guideline development

Recently, the diagnosis and treatment of chronic venous diseases, chronic venous insufficiency, and varicose veins have been increasing in Korea. Accordingly, by presenting objective and standardized diagnostic criteria for ultrasound examination, which is the most important in diagnosis of varicose veins, the goal is to prevent problems such as overtreatment and misdiagnosis, protect the public's right to health, and prevent damage to medical professionals due to unnecessary disputes (1-4).

(2) Intended users of the guideline

The guideline is applied to all patients who have chronic

venous diseases, chronic venous insufficiency, or varicose veins. Doctors from primary, secondary, and tertiary medical institutions that treat varicose veins and policy experts related to varicose veins use the guideline.

(3) Target population of the guideline

The guideline is applied to all patients suspected of having varicose veins among those with symptoms related to varicose veins.

(4) Scope of the guideline

This guideline is intended for patients with symptoms related to varicose veins. However, since the guideline targets blood vessels that require 'surgical treatment' for varicose veins, the blood vessels subject to evaluate are limited to superficial veins, deep veins, and perforating veins of the lower extremities.

3) Method of the guideline development

This guideline was developed using an adaptation method and referred to the GRADE-ADOLOPMENT framework presented by the GRADE group (5).

(1) Selection of key questions

In July 2022, the 'Standard Imaging Recommendation for Pulsed-wave Doppler Ultrasound Testing for Venous Insufficiency' was presented for the first time at the Korean Society of Phlebology conference, and after that, questions asked at various conferences or received by the Korean Society of Phlebology were collected. Among them, the Guidelines Steering Committee selected questions that were deemed repetitive and medically important and derived key questions. The final decided key questions are shown in Table 1.

(2) Search of guidelines

Primary search terms were selected through discussions between the Guidelines Development Committee and methodology expert, and a search formula was established through PubMed. The database used is MEDLINE, and the search was performed on July 27, 2023. The final search sources were added to the Appendix 1. Among the fourteen searched medical guidelines, two guidelines from other fields and four guidelines written in languages other than English were excluded from the subsequent process. Most of the finally selected prior guidelines were expert-consensus guidelines, so they were not suitable for quality

Table 1. Summary of key questions

| |
|---|
| Key Question 1. |
| What tests should be performed on patients suspected of having varicose veins? |
| Key Question 2. |
| What are the appropriate probes and settings when examining varicose veins with ultrasound? |
| Key Question 3. |
| What is the preferred patient's position and method when performing ultrasound examination of varicose veins? |
| Key Question 4. |
| What is the standard ultrasound imaging method for evaluating reflux of varicose veins? |
| Key Question 5. |
| What are the criteria for positive reflux in each target vessels in varicose veins? |
| Key Question 6. |
| What are the standard recommendations for ultrasound documentation of varicose veins? |

Table 2. Definitions of strength of recommendation

| Strength of recommendation | Definitions |
|----------------------------|--|
| Strong | It is strongly recommended that clinicians provide the service (examination or treatment) to eligible patients. |
| Conditional | It is recommended that clinicians provide the service (examination or treatment) to eligible patients in optional or specific circumstances. |
| Insufficient | Benefits and harms cannot be confirmed due to insufficient evidence. |

assessment of guidelines using AGREE2.

(3) Selection of guidelines

Among the eight guidelines selected after the above search, documents deemed appropriate for each key question were primarily selected, and other appropriate protocols and manuals were also selected. Among the previously searched literature results, the latest literature was confirmed, and since the development of this guideline is based on applicability in Korea, domestic studies were additionally searched and selected.

(4) Selection of references, recommendation and strength of recommendation

Referring to the literature selected above, the Guideline Development Committee selected the most appropriate references for each recommendation, wrote recommendations, and decided on strength of recommendation. For each key question and recommendations, the member in charge analyzed the evidence, wrote a summary of rationality, risk, applicability, etc., and determined the strength of recommendation based on these. The summary of evidence and strength of recommendation for each recommendation were finally reviewed and confirmed by the Guideline Development Committee. The strength of

recommendation was defined as three levels (Table 2).

(5) Expert review and consensus of the guideline

The RAM (RAND-UCLA Appropriateness Method) method proposed by the U.S. RAND group was accepted (6). A total of eleven experts to participate in the survey were selected through recommendation by the Korean Society of Phlebology. They were specialists in related fields with experience in research or treatment of varicose veins at primary, secondary, and tertiary medical institutions.

The coefficient variation (CV; standard deviation divided by the arithmetic mean) was calculated to determine whether to conduct additional surveys. If it is less than 0.5, no additional survey is needed. If it is 0.5 to 0.8, it is stable, but we will flexibly discuss additional surveys. If it is over 0.8, we will conduct an additional survey.

As a result of the first survey, the coefficient variations were all below 0.5, indicating a high level of agreement. If the level of agreement was low, below an average of six points, or if there were many opinions on changing the strength of recommendation or revisions, it was decided to conduct a secondary survey.

Table 3. Key questions and recommendations

| | |
|--|----------------------------|
| Key Question 1 | |
| What tests should be performed on patients suspected of having varicose veins? | |
| Recommendation | Strength of recommendation |
| 1. To diagnose varicose veins, duplex ultrasonography should be performed. | Strong |
| Key Question 2 | |
| What are the appropriate probes and settings when examining varicose veins with ultrasound? | |
| Recommendation | Strength of recommendation |
| 2-1. It is recommended to use a vascular linear probe to obtain accurate standard images. | Strong |
| 2-2. Ultrasonography is performed under settings that minimize spectral broadening, blooming artifacts, mirror images, noise spikes, false positives, and false negatives. | Strong |
| Key Question 3 | |
| What is the preferred patient's position and method when performing ultrasound examination of varicose veins? | |
| Recommendation | Strength of recommendation |
| 3. Ultrasonography should be performed with the patient in a standing position. However, if standing position is not possible, ultrasonography can be performed in reverse Trendelenburg position. | Strong |
| Key Question 4 | |
| What is the standard ultrasound imaging method for evaluating reflux of varicose veins? | |
| Recommendation | Strength of recommendation |
| 4-1. The method involves applying pressure with the hand or a compression band (distal augmentation) or using the Valsalva maneuver to induce reverse flow in the upper limb veins, and then assessing the presence and degree of venous reflux. | Strong |
| 4-2. During reflux testing, measurements should be taken in a longitudinal view of the blood vessels. | Strong |
| 4-3. Color Doppler ultrasound examination alone is not sufficient as a diagnostic criterion for reflux. To objectively demonstrate the presence of reflux findings, pulsed-wave Doppler ultrasound examination should be performed. | Strong |
| 4-4. In the case of perforating veins, measuring in a transverse view may be more practical as obtaining measurements in a longitudinal view can be physically challenging. | Conditional |
| Key Question 5 | |
| What are the criteria for positive reflux in each target vessels in varicose veins? | |
| Recommendation | Strength of recommendation |
| 5-1. At least 0.5 second of reflux is considered a positive result for the great saphenous vein (GSV), anterior/posterior accessory saphenous veins (AASV/PASV), small saphenous vein (SSV), perforating vein, tibial vein, and deep femoral vein. | Strong |
| 5-2. At least 1.0 s of reflux is considered a positive result for the common femoral vein, femoral vein, and popliteal vein. | Strong |
| 5-3. Reticular veins, spider veins, and telangiectasias are commonly observed even in the absence of reflux in the saphenous veins, and their clinical significance in the measurement of reflux under ultrasound has not yet been demonstrated. As such, ultrasound diagnostic criteria for these conditions are not presented. | Insufficient |
| Key Question 6 | |
| What are the standard recommendations for ultrasound documentation of varicose veins? | |
| Recommendation | Strength of recommendation |
| 6-1. It is recommended to specify in letters the name and location of the blood vessel to be measured. | Strong |
| 6-2. In the case of perforating veins, it is recommended to accurately record the size and location. | Strong |
| 6-3. The change in blood flow direction, which is a characteristic of venous insufficiency, is characterized by the fact that the augmentation waveform caused by calf compression and the reflux waveform caused by retrograde flow are located in opposite directions relative to the baseline (horizontal axis), so the direction of blood flow is well established. We recommend that you measure it so that it appears. | Strong |
| 6-4. It is recommended to mark the reflux section on the ultrasound image and then indicate the reflux time in seconds or milliseconds. | Strong |

4) Revision of the guideline

(1) Revision cycle of the guideline

This is planned to be reviewed for revision within five years, and if the evidence for the relevant disease or evaluation changes significantly, early revision is possible.

(2) Revision process of the guideline

The revision process of this guideline is based on the principle of adaptation, and is developed by applying the same development process of this guideline. However, if deemed necessary as a result of searching for newly added evidence, de novo process may be used in combination.

5) Funding and conflict of interest

(1) Funding

The Korean Society for Phlebology supported the development of this guideline including literature searching, conferences, and other statistical activities. However, this organization did not influence the content of the guideline.

(2) Conflicts of interest

All of the members who involved in the development of this guideline disclosed their real and explicit interests related to the development activities of the guideline. None of the members had experience in the development or approval process of guideline under review before the development of the present guideline, nor had they had any relationship with companies related to medicines, commodities, and services related to the guideline within the two years before developing the guideline.

6) Distribution of the guideline

This guideline will be published on the website of The Korean Society for Phlebology for related clinicians. Additionally, this guideline will be freely downloaded, and released in prints (Table 3).

Conclusion

Accurate diagnosis using ultrasound is essential for venous diseases. We hope that this guideline will be helpful and serve as an indicator for standardized and accurate diagnosis. This guideline, which consists of six key questions and fifteen recommendations, was written based on clinical evidence and expert consensus. In the future, we will strive to develop 'treatment guidelines of varicose

veins' that cover not only ultrasound-based diagnosis but also various treatments and patient management.

Conflict of interest

The authors declare no potential conflict of interest.

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APPENDIX 1. Guideline search sources

[Medline]

2023/07/27

1. varicose veins [MeSH Terms] 19,454
2. “Varicose vein” [Title/Abstract] OR “Varicose” [Title/Abstract] OR “Varicoses” [Title/Abstract] OR “Varix” [Title/Abstract] OR “Varices” [Title/Abstract] OR “reticular vein” [Title/Abstract] OR “telangiecatasia” [Title/Abstract] 29,342
3. 1 OR 2 37,784
4. Ultrasonography [MeSH Terms] 487,266
5. “Ultrasound” [Title/Abstract] OR “Ultrasounds” [Title/Abstract] OR “Diagnostic Ultrasound” [Title/Abstract] OR “Diagnostic Ultrasounds” [Title/Abstract] OR “Ultrasound Imaging” [Title/Abstract] OR “Ultrasound Imagings” [Title/Abstract] OR “Ultrasonic Imaging” [Title/Abstract] OR “Ultrasonic Imagings” [Title/Abstract] OR “Ultrasonographic Imaging” [Title/Abstract] OR “Ultrasonographic Imagings” [Title/Abstract] OR “Medical Sonography” [Title/Abstract] OR “Doppler” [Title/Abstract] OR “Duplex” [Title/Abstract] OR “Pulsed Doppler” [Title/Abstract] OR “Pulsed wave Doppler” [Title/Abstract] 431,390
6. 4 OR 5 709,445
7. 3 AND 6 5,112
8. 7/Guideline 14