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Application of Acoustic Radiation Force Pulse Imaging Technology in the Evaluation of the Efficacy of Calf Intermuscular Vein Thrombosis

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Background: The continuous advancement in ultrasound technology has given rise to Acoustic Radiation Force Impulse (ARFI) elastography, which boasts non-invasiveness, ease of operation, rapid inspection, and high accuracy. It has been successfully employed in detecting tissue hardness across various diseases. This study aims to investigate the application of acoustic radiation force pulse imaging technology in evaluating the efficacy of calf intermuscular vein thrombosis.

Methods: This study is retrospective in nature, involving a total of 120 patients diagnosed with calf intermuscular venous thrombosis (MCVT) who were admitted to our hospital. These patients were selected retrospectively as the subjects for our research. They were subsequently divided into two groups: the control group and the observation group. The control group received standard nursing care and simple pressure therapy, while the observation group underwent anticoagulant drug treatment. The shear wave elastic hardness of both groups was measured, with the recording of ultrasonic elasticity scores and the average elastic modulus value (E-mean, in kPa). Furthermore, a comparison was made between the two groups regarding thrombus disappearance time, blood flow patency, and the clinical treatment effect.

Results: At the 1, 3, and 6-month marks of the treatment period, the ultrasonic elasticity scores in the observation group were consistently higher compared to those in the control group. Additionally, the shear wave elastic hardness in the observation group was consistently lower than that in the control group, and these differences were found to be statistically significant ($p < 0.05$). The total effective rates for the control and observation groups were 83.33% and 95.00%, respectively. Notably, the clinical total effective rate in the observation group was significantly higher than that in the control group, and this difference was statistically significant ($p < 0.05$). The thrombus disappearance time in the observation group was significantly shorter than that in the control group, and the blood flow rate was significantly higher than in the control group, with both differences being statistically significant ($p < 0.05$).

Conclusion: ARFI plays a crucial role in assessing the efficacy of MCVT by effectively revealing the hardness and location of the patient's thrombus tissue. This technology aids doctors in gaining a more precise understanding of the deep vein thrombosis condition. Notably, ARFI is characterized by high safety levels and exhibits positive effects due to its painless and non-invasive nature.

Keywords: acoustic radiation force pulse imaging technique; ultrasound elastography; calf intermuscular venous thrombosis; curative effect evaluation

Introduction

Deep vein thrombosis (DVT) of the lower extremities is a prevalent peripheral vascular condition encountered in clinical practice. This condition involves abnormal blood coagulation within the deep veins, leading to luminal blockage, impaired blood flow, and elevated pressure in the distal veins. Consequently, individuals may experience symptoms like body swelling and pain [1,2].

Calf intermuscular venous thrombosis (MCVT) stands out as the most common subtype and has the highest incidence rate, constituting approximately 50% of all cases [3]. MCVT specifically refers to thrombosis occurring in the venous plexus of the gastrocnemius and soleus muscles [4]. Despite its high incidence, clinical symptoms such as lower limb swelling and pain are often subtle due to the slender nature of calf intermuscular vein branches, leading to frequent oversight by patients [5,6]. However, the critical nature of MCVT becomes apparent as, without timely intervention, it may progress to involve proximal veins. In severe instances, this progression can culminate in pulmonary embolism, underscoring the importance of prompt diagnosis and treatment [7].

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Currently, there is ongoing debate both domestically and internationally regarding the necessity of anticoagulant therapy for MCVT. Some studies argue that employing simple physical pressure therapy for MCVT can alleviate clinical symptoms without an increased risk of recurrence [8,9]. Conversely, other research suggests that timely anticoagulant therapy can impede the progression of MCVT to more proximal lower extremity deep vein thrombosis, effectively reducing the incidence of pulmonary embolism [10,11]. While lower extremity venography remains the gold standard for diagnosing lower extremity venous thrombosis, its use is limited by the need for highly skilled operators, invasiveness, and the inability to be repeated. Additionally, it is not suitable for individuals with allergies, pregnant women, and others with special conditions [12,13]. Consequently, there is a pressing need for safe and effective diagnostic methods to enhance the quality of patient care.

Amidst the ongoing progress in ultrasound technology, Acoustic Radiation Force Impulse (ARFI) elastography emerges as a promising option. ARFI offers non-invasiveness, ease of use, rapid examination, and high accuracy. It has demonstrated utility in detecting tissue hardness across various diseases [14]. Building on previous research, this study analyzed the application of ARFI in evaluating the effectiveness of different treatment modalities for lower limb intermuscular vein thrombosis in 120 patients. The findings aim to provide valuable reference data for the clinical management of lower limb intermuscular vein thrombosis.

Materials and Methods

Research Subjects

A total of 120 patients diagnosed with MCVT and admitted to our hospital between January 2022 and June 2023 were retrospectively chosen as the subjects for this research. Based on the clinical judgment regarding anticoagulant therapy, the patients were categorized into two groups: the control group and the observation group, each consisting of 60 patients. In the control group, there were 34 males and 26 females, with ages ranging from 26 to 69 years and an average age of (49.93 $\pm$ 5.54) years. The observation group comprised 33 males and 27 females, with ages ranging from 25 to 70 years and an average age of (50.26 $\pm$ 4.68) years. No statistically significant differences were found in the comparison of general data between the two groups, indicating their comparability.

Approval for this study was obtained from the medical ethics committee of the hospital (2021-K-282-01), and informed consent was obtained from the patient or their family member throughout the entire experimental process. All procedures in this study adhered strictly to the ethical guidelines outlined in the Declaration of Helsinki.

The inclusion criteria for this study encompassed: (1) The patients are diagnosed with acute lower extremity MCVT, and the onset time is less than 14 days. (2) Routine ultrasonography confirmed the presence of isolated calf intermuscular venous thrombosis without involving deep veins. (3) Those who have no contraindications to anticoagulant therapy and can receive anticoagulant therapy. Exclusion criteria involved: (1) Patients who needed catheter thrombolysis or surgical thrombectomy due to their illness. (2) Those who have experienced active bleeding within the past 1–2 weeks, or suffer from hemorrhagic diseases such as cerebral hemorrhage, gastric ulcer, malignant hypertension, and who cannot receive thrombolysis and anticoagulant therapy. (3) Patients with severe lower limb swelling and poor image quality. (4) Patients with abnormal blood coagulation function or complicated blood system diseases. (5) Individuals with abnormal function of major organs (liver, kidney).

Diagnostic Criteria for Intermuscular Venous Thrombosis

Ultrasonic images of acute-phase MCVT reveal distinct characteristics. The intermuscular vein's lumen in the calf appears visibly dilated and tortuous, with a smooth intima. Within the lumen, there is a presence of flocculent solid hypoechoic filling, some of which are close to anechoic, occasionally accompanied by floating fine light spots. Cross-sectional imaging displays multiple circular or elliptical flocculent echoes or low echoes between muscles. Notably, the probe's pressure cannot compress the affected lumen, and there is an absence of blood flow signal within the lesion. When the lumen is partially blocked, a clear and tidy boundary between the thrombus formation and surrounding muscles is observed. Scattered dots or strips of blood flow are detectable around the thrombus, with no regurgitation signal at the valve. The normal spectrum in the vein at the embolism site disappears or exhibits no blood flow spectrum, and low-level wavelets appear at the distal end of the embolism. In contrast, there is no phase change in the spectrum during respiration, and the blood flow spectrum remains unchanged when the distal extremity is squeezed. Old thrombus is characterized by isoechoic or moderately strong echo attached to the vessel wall, with a rough, uneven, localized, or diffusely thickened vessel wall. The lumen is typically close to or smaller than normal, displaying uneven thickness.

Under pressure from the probe, the lumen undergoes compression, resulting in a thinning of the blood flow signal. Notably, there is no change in the lumen during the Valsalva maneuver. Within the lumen, irregularly and notably strong echoes are observed. Complete blockage of the vessel results in the absence of detectable blood flow signals. In cases of partial blockage, orbital blood flow signals are visible around the lumen. Proximal to the blockage, blood flow velocity is accelerated, while distally, a significant decrease is observed. Some patients may exhibit superficial vein tortuous dilation as an additional characteristic.

Treatment Method

Patients in the control group received standard nursing care and pressure treatment. Self-adhesive elastic bandages were applied, wrapping the toes from the dorsum of the foot to 15 cm from the upper edge of the patella. The upper bandage covered approximately 1/3 of the lower bandage, with the bandage pressure gradually decreasing from bottom to top. The foot's back bandage could be inserted into one finger, while the thigh bandage could be inserted into two fingers. During treatment, the elastic bandage was replaced every 3 days. Post-discharge, patients continued compression therapy using medical-grade sequential decompression elastic stockings with an ankle pressure of 15 mmHg (1 mmHg = 0.133 kPa).

In the observation group, patients received a subcutaneous injection of enoxaparin (4000 IU, Alfa Wassman Pharmaceutical Company, Italy, approval number: H20140481) every 12 hours, and concurrent oral warfarin for anticoagulant therapy. The initial warfarin dose was 2.5 mg/day. Prothrombin time was checked within 3 to 5 days, and drug dosage was adjusted based on individual patient circumstances. Once the International Normalized Ratio (INR) reached 2–3, enoxaparin was discontinued, and INR was maintained between 2–3 in subsequent treatment.

Detection Method

Ultrasonic elasticity score: The Siemens Acuson OXANA2 color Doppler ultrasonic diagnostic instrument, equipped with a 12 MHz frequency linear array probe (9L4), and the virtual touch quantification (VTQ) quantitative analysis system were utilized in this study. A consistent physician conducted routine two-dimensional ultrasound examinations on all subjects, and the obtained image data were stored in a computer workstation for standardized analysis. Patients were instructed to lie supine and maintain relaxed lower limbs during the examination. The initial routine ultrasound examination ensured that the included angle between the sound beam and the direction of blood flow was less than 60°. The gastrocnemius intermuscular vein on the affected side of the lower extremity underwent continuous scanning to generate two-dimensional images along the horizontal and vertical axes. Echogenicity, homogeneity of the thrombus, and the observation of internal blood flow filling in the lumen were recorded. The thrombus echo intensity was assessed relative to the muscle fascicle echo around the blood vessel adjacent to the lesion. Echo intensity categories included hyperechoic, isoechoic, and hypoechoic, recorded as higher than, equal to, and lower than the muscle fascicle echo, respectively. In cases where a thrombus displayed a mixture of multiple echoes, the overall echo intensity, representing the largest proportion, determined the final result. A two-dimensional ultrasound score was assigned: 1 point for hypoechoic, 2 points for isoechoic, and 3 points for hyperechoic. An additional point was added for inhomogeneous thrombus echo, while no points were added for homogeneous echo.

Shear wave elastic hardness comparison: The hand-held probe is delicately positioned on the body surface over the thrombus vein, adopting the long-axis section. The shear-wave elastography (SWE) Dual mode is employed to simultaneously display two-dimensional and elastic images (range 0–180 kPa). The region of interest is meticulously adjusted to encompass the vascular structure of the lesion and its surrounding tissue. The software automatically measures the value once the image stabilizes, recording the average elastic modulus value (E-mean, kPa) for both groups of patients. In cases of complete occlusion, the Q-Box is adjusted to 50% of the inner diameter of the blood vessel lumen and placed at the center for elastic measurement and recording. For incomplete occlusion, the Q-Box is adjusted to 50% of the inner diameter of the thrombus, and elastic measurements are recorded at the center of the thrombus. Multiple measurements ($\geq$3 times for each segment) are performed at the upper, middle, and lower segments of the venous thrombus, and the average value is considered the final result. To ensure data authenticity and reliability, the same doctor, utilizing the same method, examines all patients after 1, 3, and 6 months of treatment for both groups. Measurement results are consistently recorded, maintaining the consistency and accuracy of the collected data.

Evaluation of Clinical Efficacy

Patients in both the pressure therapy group and the anticoagulant therapy group underwent ultrasound examinations at 1, 3, and 6 months. The evaluation of the clinical treatment effects for both groups was based on ultrasound results and the improvement of clinical symptoms. The total effective rate (%) was calculated as (cured + effective) cases/total cases $\times$ 100%, with cured defined as a smooth vessel wall, anechoic lumen, clear sound transmission, absence of obvious thrombus in sonographic images, smooth venous blood flow in color Doppler ultrasonography, and disappearance of clinical symptoms such as limb swelling and pain. Effective cases displayed a non-smooth vessel wall, some undissolved thrombus, partial recanalization, and relief in limb pain and reduced swelling. Ineffective cases exhibited poorly transparent lumen, heterogeneous echoes, no deformation under probe pressure, absence of obvious blood flow signals in color Doppler ultrasonography, and no improvement in limb pain and swelling.

The thrombus disappearance time and blood flow were recorded and compared between the two groups. The blood flow rate (%) was calculated as the number of blood flow cases/total number of cases $\times$ 100%.

Statistical Analysis

Statistical analysis of the data was conducted using SPSS 25.0 (IBM, Armonk, NY, USA) statistical software. Descriptive analysis included a normality test for continuous variables. For data conforming to the normal distri-

Table 1. Comparison of ultrasound elasticity scores between the two groups at 1, 3, and 6 months of treatment ($\bar{x} \pm$ s).

Groups	Patients	1 month after treatment	3 months after treatment	6 months after treatment
Control group	60	1.34 ± 0.13	$2.47 \pm 0.33^{\triangle}$	$3.59 \pm 0.37^{\triangle\blacktriangle}$
Observation group	60	2.48 ± 0.22	$3.52 \pm 0.40^{\triangle}$	$4.67 \pm 0.48^{\triangle\blacktriangle}$
t-value		34.556	15.684	13.803
Comparison between groups p-value		<0.001	<0.001	<0.001

Note: Compared with the same group after 1 month of treatment, $^{\triangle}p < 0.05$. Compared with the same group after 3 months of treatment, $^{\blacktriangle}p < 0.05$.

Table 2. Comparison of shear wave elastic hardness between the two groups of patients at 1, 3, and 6 months of treatment ($\bar{x} \pm$ s).

Groups	Patients	1 month after treatment	3 months after treatment	6 months after treatment
Control group	60	10.84 ± 0.86	$8.57 \pm 0.73^{\triangle}$	$7.62 \pm 0.67^{\triangle\blacktriangle}$
Observation group	60	9.78 ± 0.79	$7.36 \pm 0.65^{\triangle}$	$6.51 \pm 0.46^{\triangle\blacktriangle}$
Comparison between groups p-value		<0.001		

Note: Compared with the same group after 1 month of treatment, $^{\triangle}p < 0.05$. Compared with the same group after 3 months of treatment, $^{\blacktriangle}p < 0.05$.

bution, results were presented as mean $\pm$ standard deviation ($\bar{x} \pm$ s). Repeated measures analysis was employed for comparisons between groups at multiple time points. Categorical variables were expressed as frequencies and rates (n %), with analysis conducted using the chi-square test. A significance level of $p < 0.05$ was considered indicative of statistical significance.

Results

Comparison of Ultrasound Elasticity Scores between the Two Groups of Patients

The results of the two-dimensional ultrasound examinations for both groups revealed that the ultrasound elasticity scores in the observation group were significantly higher than those in the control group at 1, 3, and 6 months of treatment ($p < 0.05$), as illustrated in Table 1.

Comparison of Shear Wave Elastic Hardness between Two Groups of Patients

The outcomes of two-dimensional ultrasonography indicated that the shear wave elastic hardness in the observation group was significantly lower than that in the control group at 1, 3, and 6 months of treatment ($p < 0.05$), as detailed in Table 2.

Comparison of Clinical Curative Effect between Two Groups of Patients

Following treatment, the total effective rates for the control group and the observation group were 83.33% and 95.00%, respectively. Notably, the clinical total effective rate in the observation group was significantly higher than that in the control group, and this difference was found to be statistically significant ($p < 0.05$), as presented in Table 3.

Comparison of Thrombus Disappearance Time and Blood Flow Rate between the Two Groups

Subsequent to treatment, the thrombus disappearance time in the observation group was notably lower than that in the control group, and this disparity was statistically significant ($p < 0.05$). Furthermore, the blood flow rate in the observation group exhibited a significant increase compared to the control group, with the difference proving statistically significant ($p < 0.05$), as shown in Table 4.

Discussion

ARFI (Acoustic Radiation Force Impulse) technology is an ultrasonic elasticity technology that leverages shear wave velocity values to assess the elastic properties of targeted tissues [15]. This study reveals its application potential in predicting the degree of vascular sclerosis by utilizing shear wave velocity values obtained through ARFI elasticity technology. While there have been limited studies applying this technology to evaluate the efficacy of MCVT, the findings of this study suggest that ARFI proves effective in clinically assessing MCVT. ARFI technology demonstrates its capability to effectively reflect the hardness and location of thrombus tissue in MCVT patients. It stands out for its painless, non-invasive nature, ensuring high safety levels for patients. The positive role played by ARFI technology in determining efficacy in the context of MCVT underscores its potential as a valuable tool in clinical assessment.

Studies have indicated that thrombosis is primarily influenced by three main factors: venous intima injury, slow blood flow resulting in venous blood stasis, and blood hypercoagulability [16]. Among these factors, vascular intima damage serves as the prerequisite for deep venous thrombosis formation. The shedding of vascular endothelium and the exposure of collagen beneath the intima trigger the re-

Table 3. Comparison of clinical efficacy between the two groups [cases (%)].

Groups	Patients	Cure	Effective	Invalid	Total effective rate
Control group	60	31 (51.67)	19 (31.67)	10 (16.67)	50 (83.33)
Observation group	60	41 (68.33)	16 (26.67)	3 (5.00)	57 (95.00)
χ^2-value					4.227
p-value					0.041

Table 4. Comparison of thrombus disappearance time and blood flow rate between the two groups ($\bar{x} \pm$ s).

Groups	Patients	Thrombus disappearance time (weeks)	Blood flow rate [cases (%)]
Control group	60	13.42 $\pm$ 2.31	41 (68.33)
Observation group	60	9.57 $\pm$ 1.82	53 (88.33)
t/χ^2-value		10.141	7.070
p-value		$<$0.001	0.008

lease of various biologically active substances, initiating the endogenous coagulation system. Simultaneously, due to changes in charge, platelets aggregate and adhere, leading to thrombosis [17].

Underlying conditions such as malignant tumors, varicose veins, renal failure, and heart failure, along with high-risk factors like anticancer radiotherapy, chemotherapy, oral contraceptives, hormone replacement therapy, obesity, and smoking, can elevate the prevalence of MCVT [18,19]. MCVT often goes unnoticed due to mild and non-acute symptoms. However, once a thrombus detaches and enters the lungs through blood circulation, it can cause pulmonary embolism [20]. Therefore, it is crucial in clinical practice to disseminate knowledge about MCVT-related detection and raise awareness among patients and healthcare professionals. Close observation of diagnosed MCVT patients is essential to prevent life-threatening pulmonary embolism.

Research has emphasized that accurately assessing thrombus hardness is pivotal in determining MCVT staging and treatment [21,22]. A study by Huang *et al.* [23] utilized ultrasound elastography to evaluate isolated thrombus, revealing that as the days of thrombus formation increased, elasticity decreased, and hardness increased. This study, validated by histopathology, demonstrated the accuracy of ultrasound elastography in evaluating thrombus hardness. Additionally, Rayes A *et al.* [24] employed elastography to assess thrombus hardness at different stages, noting significant variations. ARFI, a non-invasive imaging method, plays a role in the auxiliary evaluation of MCVT diseases. Based on ultrasound elastography, ARFI employs mechanically induced shear wave formation to detect Shear Wave Velocity (SWV) and assess thrombus hardness [25].

This study focused on 120 MCVT patients in our hospital, exploring the application of ARFI in evaluating the efficacy of MCVT under two treatment methods: simple pressure therapy and anticoagulant therapy. The results indicated higher ultrasonic elasticity scores in the observation group compared to the control group, and lower shear wave elastic hardness in the observation group after 1, 3, and 6 months of treatment compared to the control group. This suggests that timely and effective anticoagulant therapy can impede the progression of MCVT to more proximal lesions, effectively reducing the incidence of pulmonary embolism.

The structure of thrombus tissue varies significantly at different periods post-formation, and this tissue structure is closely linked to the thrombus's softness and hardness [26]. Ultrasound elastography involves compressing the tissue under examination with a probe, collecting signals before and after compression, and evaluating the tissue's hardness based on echoes from the thrombus and blood in the lumen, flow filling, and homogeneity [27]. MCVT patients often exhibit thrombus plaques in their blood vessels. ARFI, used in the clinical efficacy evaluation of MCVT, utilizes pulses to induce slight local tissue deformation. The detection of transverse shear wave conduction velocity, closely associated with tissue elasticity, offers valuable insights [28]. Acoustic Radiation Force Pulse Imaging technology can measure plaque hardness, evaluate thrombus stability, and provide information on the type, location, and blood flow of the thrombus. This enables tailored treatment plans based on individual differences [29].

The necessity of anticoagulant therapy in the treatment of MCVT has been a subject of controversy. Some studies argue that anticoagulant therapy may elevate the recurrence rate of venous thrombosis and the incidence of pulmonary embolism [30]. Conversely, other studies suggest that anticoagulant therapy can promptly enhance blood flow, yielding superior therapeutic outcomes [31]. It has been observed that anticoagulant therapy administered for more than 6 weeks, tailored to the patient's condition, surpasses short-term anticoagulant therapy, leading to a reduction in bleeding events and other adverse reactions [32]. In the context of this study, the total clinical effective rates for the control group and the observation group after treatment were 83.33% and 95.00%, respectively. This indicates that superior clinical efficacy can be achieved with anticoagulant therapy. Furthermore, the thrombus disappearance time in the observation group was significantly lower than that in the control group, and the blood flow rate was notably higher. ARFI plays a crucial role in minimizing the impact of external factors on efficacy evaluation and treatment outcomes when assessing the therapeutic effect. It offers a more comprehensive reflection of the smoothness of bleeding flow, ultimately enhancing diagnostic efficiency.

Conclusion

In conclusion, as a prevalent vascular disease, MCVT demands careful consideration from both physicians and patients. Timely administration of anticoagulant therapy in MCVT treatment proves beneficial, enhancing clinical efficacy and addressing issues like blood stasis, ultimately aiding patients in their recovery. The integration of ARFI in the clinical efficacy evaluation of MCVT offers an effective means to reflect the hardness and location of the patient's thrombus tissue. This assists doctors in better understanding the condition of deep venous thrombosis, ensuring a high level of safety and positive outcomes through its painless and non-invasive nature.

Availability of Data and Materials

The data used to support the findings of this study are included within the article, and during the present study are available from the corresponding author on reasonable request.

Author Contributions

CFW designed the research study. YJZ and RHR performed the research. CFW, YJZ and RHR analyzed the data. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was approved by the medical ethics committee of the Second Affiliated Hospital and Yuying Children's Hospital of Wenzhou Medical University (2021-K-282-01), and the entire process of the experiment received informed consent from the patient or family member.

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Conflict of Interest

The authors declare no conflict of interest.

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