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Lower Extremity Deep Venous Thrombosis: Vascular Laboratory Quality Assurance Without Correlation Between Ultrasound and Venography

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Venography is rarely available for comparison with ultrasonography (US) as a means for quality assurance (QA) in the detection of lower extremity venous thrombosis. New QA methods must be implemented. We compared results of multiple serial studies performed in the same extremity as a QA indicator. From a 3-year sample of close to 9,000 venous tests, we obtained a subset of 44 patients who had 331 tests in 71 lower extremities throughout the years. A positive or negative study preceded or followed by another positive or negative study was considered as a confirmed study. A negative or positive study not preceded or followed by a negative or positive study was considered as unconfirmed. Explanations were then sought to explain unconfirmed results. There were 169 (51%) and 124 (37%) confirmed positive and negative studies, respectively, and 13 (4%) and 25 (8%) unconfirmed positive and negative studies, respectively. Of the 13 unconfirmed positive tests, 2 were preceded by negative tests, 3 were preceded and followed by negative tests, and 8 were followed by negative tests. Of these 13 tests, 4 documented extensive venous thrombosis. Of the 25 unconfirmed negative tests, 11 followed treatment for venous thrombosis, 6 had recurrent thrombosis with intermittent lysis, and 8 were followed by positive tests. Considering the low probability of extensive thrombosis being a false-positive test, positive predictive value was 95% (173/182). Excluding 11 negative tests following treatment for venous thrombosis, negative predictive value was 90% (124/138) and accuracy was 93% (297/320). US versus US and literature US versus venography comparisons of these statistics were similar.

Introduction

Noninvasive diagnosis of vascular diseases has enjoyed a period of significant growth with duplex ultrasonography being popularized among several medical specialties interested in vascular pathophysiology and imaging.^{1,2} Vascular laboratories have proliferated inside hospitals, in outpatient clinics, and in medical offices. Instrument availability and underutilization have enticed a business-like expansion toward applications that differed from the primary specialty of the original service. This multitude of medical and entre-

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preneurial objectives created inconsistent protocols and interpretation of results. To deal with this problem, medical associations in the United States organized the Intersociety Commission for Accreditation of Vascular Laboratories (ICAVL). This entity has created a set of rules related to patient safety, standard protocols, and consistent interpretation of results, reporting standards, and methods of quality control and quality assurance. As a subset of this entire process, we have been particularly interested in the accuracy of noninvasive testing and this paper deals specifically with detection of deep venous thrombosis in the lower extremities.³⁻⁵

Initially, venous ultrasonography was compared to venography.^{1,4,5} Although considered the "gold standard" for detection of venous thrombosis, this radiologic technique is expensive and its potential complications may not allow for evaluation of high-risk patients or repeat studies. As a consequence of increased quality and availability at relatively low costs, ultrasonography has become the practical standard for detection of deep venous thrombosis. Availability of venographic results for comparison and quality control has become rare. New methods of quality assurance have become necessary. For the purpose of fulfilling accreditation requirements, we investigated repeatability of venous ultrasonography in patients with multiple, serial tests.

Methods

The following hypothesis was examined: Analysis of multiple serial examinations performed in the same extremity should increase confidence in ultrasound venous testing if agreement is observed. Furthermore, if disagreement between sequential tests is noted, the case should be reviewed as a process of quality assurance and quality control.

Patient Population

Lower extremities with 2 or more ultrasound venous evaluations for venous thrombosis as recorded in the computer database for a 3-year period were entered in the study. For these extremities, all previous studies dating back to 1992 were analyzed also. A total of 331 venous ultrasound tests performed in 71 lower extremities of 44 patients were reviewed. There were 4.7 ultrasound scans per extremity or 7.5 scans per

patient. Patients with multiple venous ultrasound tests were a small sample of all patients seen in the vascular laboratory. For example, 3,054 venous tests were performed in 1 year either in the outpatient clinic (1,572) or the hospital (1,482). The number of multiple scans varied widely: 25 extremities had only 2 examinations, whereas, at the other end of the range, 1 lower extremity had 17 tests performed during a period of 5 years. Otherwise, in the midrange, the number of extremities submitted to 3, 4, 5, or 6 scans varied between 5 and 10 and the number of extremities submitted to 7, 8, 9, 10, 12, 15, and 17 scans varied between 1 and 3.

Justification for multiple test performance varied from patient to patient (Table I), and the same patient may have had several reasons for repeat examination. Time between 2 consecutive tests is summarized in Table II.

Table I. Venous ultrasonography: Justification for multiple tests (44 patients).

Disease progression	14
Chronic venous insufficiency	14
Recurrent thrombosis	12
Predischarge testing	8
Superficial thrombosis	3
Monitoring high-risk patient	3
Localized thrombosis	2
Popliteal (Baker's) cyst	1

Note: more than 1 reason existed per patient.

Table II. Venous ultrasonography: Time interval between tests.

Within 7 days	30% (100/331)
Within 30 days	60% (197/331)
Within 180 days	88% (291/331)
Within 365 days	96% (319/331)

Basic Ultrasound Venous Examination

The ultrasound examination for detection of deep venous thrombosis (DVT) followed standard protocol previously described.^{1,4,5} A complete examination included iliac, femoropopliteal, and calf veins. The great and small saphenous veins were also imaged. With rare exceptions due to obesity or excessive edema, the common femoral, femoral, and popliteal veins were examined in their entirety. Extensive segments of iliac, peroneal, posterior tibial, and muscular veins were commonly scanned. Imaging of the anterior tibial veins was limited to patients with localized symptoms.

The examination included B-mode visualization of the vein and compression maneuver with the transducer. Doppler spectral velocity analysis provided information about flow phasicity with respiration and flow augmentation with compression of distal muscles or release of proximal venous compression. Color flow imaging provided additional information about flow around nonobstructing clots, flow phasicity, or flow augmentation.

The diagnosis of deep venous thrombosis was made if thrombus echogenicity, venous incompressibility, flow around nonoccluding thrombus, and/or absence of venous flow was detected. Lack of venous coaptability or compressibility with the ultrasound probe, performed from multiple directions, was considered the most reliable finding for diagnosis of venous thrombosis.⁶ Although fresh thrombus may be hypoechoic and sometimes not differentiable from blood, echogenicity inside the vein, tending to echogenicity of the surrounding tissue, was a helpful indicator of venous thrombosis. Lack of Doppler flow signals, as opposed to a clear flow waveform phasic with respiration, confirmed the diagnosis of venous thrombosis. Continuous flow or lack of flow augmentation upon release of abdominal pressure was suggestive of proximal obstruction, either blood clot or external compression. Lack of flow augmentation upon distal compression suggested poor blood volume within the veins, probably limited by clot. Therefore, compressibility, local imaging, and lack of flow or presence of abnormal color flow channel were the indicators most relied upon for diagnosis of venous thrombosis. Although differentiation between acute or chronic thrombus was done in the clinical studies based on vein diameter, thrombus echogenicity, collateral development, venous recanalization, and presence of reflux, thrombosis was not sepa-

rated between acute or chronic, or deep or superficial, for the purpose of this study.

Data Analysis

All studies were classified as either negative or positive for venous thrombosis. Each test was classified as a confirmed positive or negative test or as an unconfirmed study. A positive (or negative) test was a confirmed test if preceded or followed by another positive (or negative) test for thrombosis. A positive (or negative) test not preceded or followed by another positive (or negative) test was classified as an unconfirmed test. As a corollary, a first test could be confirmed only by a second test, and a last test could be confirmed only by a next-to-last test while intermediary tests could be confirmed by either a preceding or a following test.

Results

There were 51 lower extremities with at least 1 positive test (72%). Table III summarizes the numbers of confirmed and unconfirmed positive and negative tests. Of the 25 (8%) unconfirmed negative tests, 11/331 (3%) followed treatment for deep venous thrombosis (Group A), 8/331 (2%) preceded positive tests (Group B), and 6/331 (2%) tests were preceded and followed by positive tests (Group C). Of the 11 extremities with unconfirmed negative tests following treatment for venous thrombosis (Group A), disease was extensive in 5, clot was localized in 5, and superficial thrombosis was detected in 1 extremity according to a preceding test. Of the 8 extremities with unconfirmed negative tests that

Table III. Venous ultrasonography: Agreement between serial tests.

Confirmed positive tests	51% (169/331)
Confirmed negative tests	37% (124/331)
Unconfirmed negative tests	8% (25/331)
Unconfirmed positive tests	4% (13/331)

preceded positive tests (Group B), thrombosis was extensive in 2, localized in 3, and superficial in 1 extremity. Two other of these negative tests were in patients with extensive contralateral venous thrombosis. Of the 6 unconfirmed negative tests "sandwiched" between positive tests (Group C), 5 extremities had localized thrombosis and 1 had superficial thrombosis. Of the 13 (4%) unconfirmed positive tests, 2 were preceded by negative tests, 3 were preceded and followed by negative tests, and 8 were followed by negative tests. Extensive thrombosis was present in 4, and clot was localized in 9 at the common femoral vein (3), femoral vein (2), and popliteal vein (4).

Based on 169 confirmed and 13 unconfirmed positive tests, the positive predictive value was 93%. Considering the low probability of an extensive thrombosis being a false-positive test, after reclassification of 4 cases, positive predictive value was 95% (173/182). Based on 124 confirmed and 25 unconfirmed negative tests, negative predictive value was 83%. If 11 negative tests following treatment were excluded, negative predictive value was 90% (124/138). The estimated accuracy based on ultrasound repeatability was 89% (293/331). Excluding 11 negative tests following treatment for venous thrombosis, accuracy was 92% (293/320) or 93% (297/320) if, in addition, unconfirmed extensive thrombosis cases were considered true positive instead of false positive.

Discussion

The lack of venography as a standard of comparison for venous duplex ultrasonography has created a complex problem for quality assurance in the vascular laboratory. The traditional calculation of statistics such as accuracy and predictive values is impractical nowadays. As the experience with, the confidence in, and the demand for duplex venous ultrasonography increased, the need and demand for venography decreased. Although this laboratory was formed in the early 1990s in an era of few venograms, the authors have had prior experience in the comparison of ultrasonography and venography. Correlation in the presence of extensive thrombosis was excellent. Detection of fresh thrombus in the calf in post-surgical patients was the greatest challenge. Several findings, however, favored the use of ultrasonography over venography. Indeed, pitfalls

in the comparison of venous ultrasonography with venography became evident.⁷ Dye dilution, nonvisualization of patent veins, and misidentification of thrombosed segments were findings that undermined the value of venography as a "gold standard." Dye dilution with blood, mainly in the femoral junction, precluded confirmation of femoral nonocclusive clot detected by ultrasonography. About half of the nonvisualized veins by venography were patent by ultrasonography. Rare but possible, depending on x-ray projection, misidentification of a deep for a superficial calf veins occurred. Furthermore, ultrasound proved to be more useful than venography in identifying nonvenous pathology such as popliteal aneurysms, cysts, hematomas, or other masses. Even if venography is available today, it is for a specific population of patients whose ultrasound examinations are deemed incomplete or of poor quality. These cases include extremities with severe edema, large patients, or incapacity to detect new thrombus in the presence of old deep venous obstruction.

A process of quality assurance is not, however, linked to achieving a specific goal as far as accuracy is concerned. The main objective is that a process is in place to continuously monitor performance aiming for improvements along the way. Some suggestions for quality assurance include the following: (1) comparison of test results with intent to treat, and (2) double-blind, sequential studies by 2 technologists in randomly selected patients. The latter option is too time consuming in busy vascular laboratories and has low yield owing to the low incidence of positive tests observed in modern series.⁸⁻¹⁰ We opted for multiple study analysis performed in a population with a prevalence of venous thrombosis close to 4 times greater than the average observed in our vascular laboratories.^{9,10} One strong reason to monitor these patients serially was a higher incidence of pulmonary embolism in patients with ultrasonic observation of disease progression.¹¹ The basic rationale is that for laboratories with accuracy over 90% for detection of extensive femoropopliteal thrombosis with ultrasound, the probability of error if 2 sequential tests are in agreement is minimal. In addition to the evaluation of extensive thrombosis, analysis of sequential tests should also focus on localized thrombosis or calf thrombosis, conditions that render inferior ultrasound accuracy. Our analysis demonstrated that almost 60% of all unconfirmed tests, 9 of 13 positive tests (69%) and 13 of 25 negative tests (52%) were associated with detection of localized

thrombosis in positive tests or tests preceding or following negative tests. Improved B-mode sensitivity impairs differentiation between slow flow and soft clot. False incompressibility at the inguinal ligament, adductor canal, popliteal tendons, and tibial bones may result in false-positive tests. Incomplete scans may result in missing small clots. Not all errors, however, may be ascribed to technical errors. During animal studies with hourly monitoring of the thrombotic process, we observed that the fight between thrombosis and thrombolysis is continuous at all locations with unpredictable results.^{12,13} In the initial process, clot location, propagation, and lysis vary widely. Other observations have linked superficial to deep venous thrombosis and to hypercoagulability.^{14,15} We have observed that these patients come back at different times with thrombosis in different systems and different limbs, including the upper extremity.

In summary, serial venous ultrasound examinations provided valuable information for quality assurance in the vascular laboratory. We observed agreement between ultrasound tests compatible with agreement between ultrasound and venography as reported in the literature. The learning process has expanded from ultrasonic detection of extensive femoropopliteal thrombosis to the analysis of localized thrombosis, propagation of contralateral or superficial venous thrombosis, lysis, and recurrence.

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