

Prospective study comparing the rate of deep venous thrombosis of complete and incomplete lower extremity venous duplex ultrasound examinations



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ABSTRACT

Background: A lower extremity venous duplex ultrasound (LEVDUS) examination positive for deep venous thrombosis (DVT) is an indication for anticoagulation. Incomplete examinations that fail to examine all lower extremity veins in patients not otherwise indicated for anticoagulation may be followed by repeated examination to exclude missed or progressing DVT. This study examined the frequency of incomplete LEVDUS studies, reasons for incomplete studies, veins incompletely examined, and follow-up LEVDUS after incomplete LEVDUS. The incidence of a positive finding of DVT was compared between initial complete LEVDUS and follow-up LEVDUS after an initial incomplete examination to determine whether improving rates of follow-up LEVDUS after an incomplete examination is a reasonable target for quality improvement.

Methods: At a single academic medical center from January 2017 to December 2017, incomplete LEVDUS studies were prospectively identified in patients who did not otherwise have an identified indication for anticoagulation. Rate of DVT in complete LEVDUS was also determined during the same time frame. Incomplete LEVDUS reports were reviewed for clinical setting, patient demographics, examination indication, ordering providers, reasons for incomplete examinations, anatomic locations of veins not visualized, rates of follow-up LEVDUS examinations within 30 days of the initially incomplete study, and rates of DVT identified in follow-up examinations of initially incomplete examinations.

Results: Of the 2843 LEVDUS examinations performed in 2017, 341 studies identified DVT and 197 incomplete examinations did not identify DVT. Veins not visualized on incomplete studies included tibial veins ($n = 170$ [86.3%]), femoral veins ($n = 73$ [37.1%]), and popliteal veins ($n = 76$ [38.6%]), with the most common reasons for incomplete studies being bandages or fixation devices (46.2%), intolerance of the patient for the study (14.7%), and body habitus or edema (17.4%). Only a minority of incomplete studies not identifying DVT (27.9%) had a follow-up examination performed. The majority of the repeated examinations were performed after incomplete LEVDUS examinations that were originally performed for high-risk screening (80%) as opposed to clinical suspicion for DVT (20%). There was no significant difference in demographic features of patients with initially incomplete studies who did or did not have a follow-up examination and no significant difference in the rates of DVT (13.1%) in complete LEVDUS examinations compared with the rate of DVT found in follow-up examinations of initially incomplete LEVDUS examinations (9.1%; $P = .33$).

Conclusions: The majority of patients with incomplete LEVDUS, even those with symptoms or signs suggestive of DVT, do not have a follow-up examination within 30 days of the incomplete study. The rate of DVT detected in initially complete studies was similar to that in patients with follow-up examinations whose initial study was incomplete and did not identify DVT. This suggests that to avoid missing DVT in patients with incomplete LEVDUS studies, quality assurance programs should be initiated to ensure that follow-up LEVDUS studies are performed after an incomplete LEVDUS examination. (*J Vasc Surg: Venous and Lym Dis* 2019;7:882-8.)

Keywords: Venous duplex ultrasound; Lower extremity incomplete venous thrombosis; Deep venous thrombosis; Superficial venous thrombosis

A complete lower extremity duplex ultrasound examination with visualization of the lower extremity veins bilaterally from the groin to the ankle is a definitive screening and diagnostic test for lower extremity deep venous thrombosis (DVT).¹ Sensitivity and specificity for

duplex ultrasound detection of DVT vary by the location of the venous thrombus and the population of patients.²⁻⁵ Overall, however, compared with venography, duplex ultrasound has shown similar or increased diagnostic efficacy with high clinical utility. Despite overall

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high sensitivity and specificity for identifying and excluding the presence of lower extremity DVT, patient-specific factors, such as obesity, open wounds, fresh surgical wounds, overlying bandages, fixators, braces, severe edema, and intolerance of the patient for the examination, may result in an incomplete study. Repeated duplex ultrasound performed after a study with nonvisualized veins potentially may identify venous thrombi for which initiation of anticoagulation treatment is indicated even if the previously nonvisualized veins were calf veins. The American College of Chest Physicians Guidelines for Antithrombotic Therapy suggest anticoagulation treatment for at least 3 months for high-risk patients with provoked venous thrombosis of calf veins and recommend anticoagulation treatment for at least 3 months for unprovoked venous thrombosis of calf veins, if the patient is treated with anticoagulation, recognizing that not all patients may be candidates for anticoagulation for calf vein DVT. Alternatively, a follow-up duplex ultrasound examination should be performed after 1 to 2 weeks or sooner if there is clinical concern to evaluate for extension of the DVT.⁶

A missed diagnosis of DVT from an incomplete lower extremity venous duplex ultrasound (LEVDUS) examination could therefore result in a failure to initiate anticoagulation treatment, which could subsequently lead to propagation and extension of DVT, additional DVT, or pulmonary embolism (PE). The objectives of this study were to determine the overall prevalence of incomplete LEVDUS examinations performed for evaluation of possible lower extremity DVT in patients not otherwise indicated for anticoagulation, to identify reasons for incomplete LEVDUS examinations, and to determine the frequency of performance of follow-up examinations should the incident LEVDUS examination be incomplete and the patient not otherwise have an indication for anticoagulation. An additional goal was to estimate the number of DVTs potentially missed because of a lack of a follow-up examination after an initial incomplete study to quantify the number of potential missed opportunities to initiate anticoagulation therapy. This information may help guide institutional practice and implementation of new policies to improve patient safety by decreasing the number of missed diagnoses of DVT.

METHODS

This study was both the initial phase of a quality improvement project and a prospective research study and therefore was approved by Oregon Health & Science University Institutional Review Board and conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Because of minimal risk to patients in this study, consent was not required by our Institutional Review Board. Patients with incomplete LEVDUS examinations performed to evaluate for DVT

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective observational study
- **Key Findings:** In 2843 patients, lower extremity venous duplex ultrasound (LEVDUS) was performed for deep venous thrombosis (DVT). Only 27.9% of incomplete LEVDUS studies for DVT had follow-up study. There were similar rates of DVT in repeated studies after incomplete examinations (9.1%) and in initially complete studies (13.1%; $P = .33$)
- **Take Home Message:** Follow-up studies after incomplete LEVDUS examination have the same rate of DVT as after complete studies; thus, repeated studies have the potential to identify initially missed or progressive DVT and should be performed after all incomplete studies.

and who did not have an indication for anticoagulation treatment were prospectively identified during the course of daily physician readings of LEVDUS examinations from January 1, 2017 to December 31, 2017 and recorded daily in a database generated and maintained by physicians. Upper extremity or abdominal duplex ultrasound examinations for venous thrombosis were not included as part of this study. Patients with known indications for anticoagulation, such as those with known DVT, PE, or atrial fibrillation, and patients with DVT identified in a visualized vein of an otherwise incomplete examination were excluded from analysis as they would have a potential indication for anticoagulation treatment despite having an incomplete LEVDUS study.

LEVDUS examinations at our institution are performed 24 hours a day and 7 days a week, almost exclusively at point of care, by registered vascular technologists from our Intersocietal Accreditation Commission-accredited vascular laboratory using Philips iU2200 or 5500 duplex scanners (Philips Healthcare, Best, The Netherlands). Examinations are, by protocol, bilateral unless otherwise specified by the ordering physician. Complete examination of the leg in unilateral studies was considered a complete examination for the purposes of this study. Deep veins examined include the bilateral common femoral, profunda femoral, femoral, and popliteal veins as well as the posterior tibial, peroneal, and gastrocnemius and soleal veins. Anterior tibial veins are not routinely studied, given the low prevalence of anterior tibial vein DVT.⁷ Bilateral examinations with anatomically present but not examined common femoral, profunda femoral, femoral, and popliteal or calf veins were classified as incomplete.

LEVDUS examinations at our institution are generally performed within 30 to 60 minutes of receiving the study request through the Epic (Epic Systems Corporation, Verona, Wisc) electronic medical record (EMR) or by direct contact from a requesting staff physician, midlevel

provider, or resident. Outpatient examinations were performed in the vascular laboratory, and inpatient examinations were performed at the point of care by the bedside. All examinations, whether they were in the outpatient or inpatient setting, were performed in an equivalent manner with the same protocols by the ultrasonographers. After performing the study and before leaving the point of care, the vascular technologist attempts to contact the referring provider or the patient's immediate provider or care giver to provide a verbal preliminary report. After completion of the examination and on returning to the vascular laboratory, the technologist authors a written preliminary report, using the MedStreaming Client PRD v.4 (Medstreaming, Inc, Redmond, Wash), to the EMR. All studies are then verified, edited, and signed by the reading physician within 24 hours of study completion, with most studies verified and signed as a final report within 4 to 6 hours of the completion of the examination.

Each included patient's EMR was then searched to determine whether the patient had a follow-up venous duplex ultrasound examination within 30 days of the initial incomplete study. Any repeated LEVDUS examination within 30 days was classified as a follow-up study as a low bar to maximize the possibility of identifying a follow-up study. Follow-up examinations were also classified as incomplete, complete, and negative for venous thrombosis (DVT or superficial venous thrombosis [SVT]) or complete and positive for DVT or SVT with the location of the venous thrombosis recorded.

The clinical setting in which the LEVDUS examination was ordered and subsequent follow-up examinations were noted. In addition, patients' demographics including age, sex, comorbidities, diagnosis, recent surgery (surgery in the operating room within 2 weeks) or traumatic injury, and referring services of patients with incomplete studies not excluded from the study were then determined through examination of the EMR chart. Demographics of patients with incomplete studies, with and without follow-up examinations, and referring services and clinical setting of the incident incomplete examination (inpatient, outpatient clinic, or emergency department) of patients with and without follow-up examinations were also compared.

All reports of duplex ultrasound DVT examinations include the study indication. Indications for LEVDUS were designated as either high-risk screening or clinical suspicion. At our institution, any patients without any lower extremity signs or symptoms were considered to be at high risk if they were admitted after traumatic injury or had a history of cancer, obesity, recent surgery, recent fractures, orthopedic injury, immobilization or nonambulatory state, intensive care unit admission, intubation, or prolonged hospitalization. By definition, a study was performed for clinical suspicion if the patient had lower extremity signs or symptoms of possible

DVT. LEVDUS reports also indicate the ordering medical provider. The training background (attending or resident) and type of medical degree (medical doctorate, doctor of osteopathic medicine, nurse practitioner, or physician assistant) of the providers who ordered the LEVDUS study were noted. Reports of incomplete examinations include a listing of the specific veins not examined and the reasons that they were not examined (including the presence of severe edema, bandages, wounds, incisions, casts, external fixators or devices, challenging body habitus or obesity, and intolerance or refusal of the patient for the examination). The rates of DVT were calculated and compared between initially complete studies and follow-up studies of initially incomplete duplex ultrasound examinations.

Statistical analysis was performed using SPSS version 25 (IBM, Armonk, NY).² Univariate analysis of age, clinical setting, thrombus incidence, and thrombus were analyzed and compared between the overall cohort of patients and those patients who had an incomplete study. Groups were compared using Student *t*-test, analysis of variance, and χ^2 analysis for either continuous or categorical variables as appropriate. Statistical significance was determined by a *P* value of <.05.

RESULTS

There were 2843 lower extremity duplex ultrasound DVT examinations performed in 2017. There were 2646 complete studies that did not identify DVT or were incomplete but identified DVT, with a total of 341 (12.9%) studies, complete or incomplete, that identified DVT (Table I) and 197 (6.9%) incomplete examinations that did not identify DVT. Patients with incomplete studies not identifying DVT were primarily inpatients (80.7%; *n* = 159/197), followed by outpatient clinic patients (*n* = 21/197 [10.7%]) and patients in the emergency department (*n* = 17/197; 8.6%). Table II summarizes the demographics of patients with incomplete lower extremity duplex ultrasound DVT examinations that did not identify DVT; 58% were male, with an average age of 51 years (standard deviation, 20 years).

Indications for studies that were incomplete and not identifying DVT were high-risk screening in 104 patients (52.8%) and lower extremity signs or symptoms or concern for PE in 93 (47.2%). Studies that were incomplete and not identifying DVT had been ordered by residents in 32% of patients (*n* = 63) and by attending physicians or midlevel providers (nurse practitioners or physician assistants) in 68% of patients (*n* = 134). Approximately 83.2% (*n* = 164) of incomplete DVT studies were ordered by providers with medical degrees (medical doctorate or doctor of osteopathic medicine), and 15.7% (*n* = 31) were ordered by advanced practice providers (nurse practitioners or physician assistants), with two unknown.

Table I. Results of all complete lower extremity venous duplex ultrasound (LEVDUS) studies

Lower extremity duplex ultrasound	Patients with thrombus identified on LEVDUS		Thrombus location	No.	%	Anatomic vein location of thrombus	No.	%
	No.	%						
Complete studies (N = 2646)	450	17	Deep	341	12.9	Femoral	178	52.2
						Popliteal	144	42.2
						Calf	274	80.3
			Superficial	109	4.1	Great saphenous	90	82.5
						Small saphenous	17	15.6

The most common reason for an incomplete examination was the presence of bandages or wounds (46.2%; n = 91/197), followed by a cast or a fixation device (16.3%; n = 32/197), excessive edema (13.2%; n = 26/197), inability of the patient to tolerate the study (14.7%; n = 29/197), and challenging body habitus (4%; n = 8/197), with 11 indeterminate. Veins not visualized on the initial 197 incomplete studies were calf veins (170 [86.3%]), popliteal veins (76 [38.6%]), and femoral veins in (73 [37.1%]).

Only 55 (27.9%) of the 197 patients with incomplete examinations that did not identify DVT had a follow-up study within 30 days, with no demographic differences in the patients with incomplete studies who did or did not have a follow-up examination (Table II). After an

incomplete initial examination, a minority of the repeated studies were incomplete, and the reason for the incomplete examination was usually the same for both studies. The most common reason for consecutive incomplete examinations was the presence of surgical bandages. In the 55 patients with repeated studies, the original study was in an inpatient, outpatient, or emergency department setting in 89%, 5.5%, and 5.5%, respectively. There was no significant difference in obtaining repeated examinations with respect to whether the initial incomplete study was obtained in an inpatient, outpatient, or emergency department setting (analysis of variance, P = .29).

The indication for the initial ultrasound study that was incomplete in the 55 patients with incomplete studies

Table II. Demographic comparison between patients with and patients without follow-up after initial incomplete lower extremity venous duplex ultrasound (LEVDUS) examination

Categorical demographic	No repeated ultrasound performed		Repeated ultrasound performed		χ^2 test
	%	No.	%	No.	P value
Female sex	43	61/142	39	21/55	.6
Current smoker	16.9	24/142	22.2	13/55	.846
Former smoker	31.7	45/142	29.6	16/55	.846
Nonsmoker	51.4	73/142	48.1	26/55	.846
History of venous ulcers	2.1	3/142	0	0/55	.496
Peripheral artery disease	8.5	12/142	3.7	2/55	.249
Arrhythmia or atrial fibrillation	12	17/142	3.7	2/55	.08
Coronary artery disease	14.1	20/142	3.7	5/55	.203
Angina	28.3	10/142	16.7	2/55	.384
Hypertension	50.7	72/142	35.2	20/55	.052
Hyperlipidemia	26.8	38/142	13	7/55	.04
Diabetes mellitus	44	35/142	14.8	9/55	.137
Chronic obstructive pulmonary disease	9.9	14/142	9.3	5/55	.899
Renal disease	17.6	25/142	7.4	4/55	.072
Obesity (body mass index >25 kg/m ²)	59.9	85/142	60	33/55	.960
History of cancer	9.9	14/142	9.1	5/55	.810
History of trauma	43	61/142	67.3	37/55	.002
History of fracture in last 3 months	38.7	55/142	41.8	23/55	.746
History of prolonged bed rest >7 days	20.4	29/142	23.6	13/55	.737
Current oral contraceptive use	2.1	3/142	1.8	1/55	.895

Table III. Results of repeated follow-up venous duplex ultrasound after initial incomplete lower extremity duplex venous ultrasound (LEVDUS) studies

Lower extremity duplex ultrasound	Patients with thrombus identified on LEVDUS		Thrombus location	Anatomic vein location of thrombus			
	No.	%		No.	%	No.	%
Repeated studies after initial incomplete examination (N = 55)	7	12.7	Deep	Femoral		1	20
				Popliteal		1	20
				Calf		3	60
				Superficial		2	3.6%
				Great saphenous		1	50
Small saphenous		1	50				

who had a follow-up examination was clinical suspicion of DVT or PE in 20% (n = 11) and high-risk screening in 80% (n = 44), indicating that a lesser proportion of patients with incomplete studies for whom the initial indication was signs or symptoms of DVT had a follow-up study vs those for whom the initial indication was high-risk screening (n = 11/55 [19.3%] vs n = 44/140 [31.4%]; $P = .08$).

In the 55 patients with a follow-up LEVDUS examination, 9.1% (n = 5/55) were found to have a DVT on follow-up examination, with DVT detected in a proximal vein in two patients and isolated to the calf in three patients (Table III). New thrombi of any kind, including SVT, were found in 12.7% (n = 7/55) of follow-up studies. The rate of finding DVT in a follow-up examination for an incomplete LEVDUS study was not different from that of finding DVT on an initial examination (n = 5/55 [9.1%] examinations vs n = 346/2646 [13.1%] examinations; $P = .33$). In this study, only 18 patients were evaluated with D-dimer studies, with only one positive result. In this patient, the positive D-dimer result correlated with a positive DVT finding on repeated duplex ultrasound examination. However, the other patients with a positive DVT or SVT finding on repeated duplex ultrasound had normal D-dimer levels.

Of the five repeated studies with positive findings, the physician ordering the repeated duplex ultrasound examination was in either the emergency department (n = 1) or an inpatient setting (n = 4). The majority of the repeated studies with positive findings were ordered by physicians in the inpatient setting (80%), and a minority were ordered by physicians in the emergency department (20%).

DISCUSSION

During the course of 1 year, our academic medical center completed 2646 ultrasound studies performed either for screening of lower extremity DVT or for clinical suspicion of lower extremity DVT in a predominantly inpatient setting with an overall DVT rate similar to that previously reported.^{8,9} Ultrasound is a validated tool with high

sensitivity and specificity for DVT diagnosis or exclusion.^{10,11} The potential for incomplete studies, however, is well recognized as patient-specific drawbacks, such as a patient's body habitus, can impair performance of lower extremity ultrasound to evaluate for DVT.¹²

Calf veins are considered more difficult to examine with duplex ultrasound than more proximal lower extremity veins and may not be routinely examined in some centers.¹ In our study, inability to examine calf veins occurred in 89% of the incomplete examinations. This is now clinically important in that the most recent 2016 iteration of the American College of Chest Physicians Guidelines for Antithrombotic Therapy recommend anticoagulation for calf vein DVT, postdating previous studies of the ramifications of incomplete venous duplex ultrasound for DVT and increasing the relevance of this study to current practice guidelines compared with previous studies.^{1,6} In addition, we also found that femoral veins and popliteal veins were unable to be evaluated in about 40% of the incomplete LEVDUS studies that did not identify DVT, indicating that both proximal and distal DVTs are potentially missed with incomplete examinations, and there is certainly little doubt about the value of anticoagulation for proximal DVT.⁶

Whereas there is controversy about the value of screening examinations for DVT and therefore the clinical importance of an incomplete screening DVT examination, screening duplex ultrasound DVT examinations are widely performed in high-risk patients but are likely to be of less value if the screening examination is incomplete.^{8,13} We found that incomplete screening examinations in high-risk patients were followed by a follow-up examination in a minority of patients (n = 44/104; 42.3%), potentially decreasing whatever value a screening program may have and arguing for methods to increase adherence to screening program protocols to maximize potential clinical utility. In this study, surprisingly, we found that the majority of the repeated examinations were performed after incomplete LEVDUS studies that were originally performed for high-risk screening in patients without signs or symptoms as opposed to clinical suspicion in patients with signs or

symptoms of DVT. Furthermore, there was an equivalent rate of positive findings on repeated examinations in those repeated examinations performed for the indication of high-risk screening and those performed for clinical suspicion of DVT. Thus, we recommend repeated examination after incomplete LEVDUS examination for both patients with the indication of high-risk screening and patients with clinical suspicion of DVT.

Of major concern is that in symptomatic patients with incomplete examinations that did not demonstrate DVT, only 19.3% of these patients with incomplete examinations had a follow-up study. This, coupled with the fact that we found follow-up studies in patients with incomplete examinations have statistically the same rate of identifying DVT as initial examinations and sometimes find proximal DVT, suggests methods of obtaining follow-up studies in symptomatic patients with incomplete duplex ultrasound DVT studies must also be found to enhance patient safety.

No particular provider group or examination setting was better or worse for obtaining follow-up examinations of incomplete LEVDUS studies. Thus, an institutional program to enhance the follow-up of incomplete LEVDUS examinations is probably best pursued on a system level rather than on an individual provider or patient setting level.¹⁴ Potential methods include EMR hard stops or reminders or addendums to vascular laboratory reports of incomplete studies.

There are some limitations to this study. We do not know why follow-up studies were not performed, and we may have missed some patients of interest. Patients with incomplete LEVDUS examinations were prospectively identified; however, identification was by a single surgeon reading >95% but not all of the vascular laboratory studies during the study year. However, conversely, this also means that the number of missed incomplete studies is likely to be small, with <5% of the examinations read off protocol by other physician readers. Overall numbers are also small compared with the number of duplex ultrasound DVT studies performed annually in the United States. A 30-day follow-up period is a low bar for classifying an examination as a follow-up study, and the patient population of an academic medical center in the Pacific Northwest with many previous publications on vascular laboratory topics may not reflect the vascular laboratory expertise or the patient population of the United States as a whole. On the other hand, the rate of positive studies at our institution is similar to previous reports, and thousands of vascular laboratories have gone through an accreditation process.^{8,9} This makes it highly likely that the problem of incomplete studies identified here is real and also exists at other centers, but possibly of a different magnitude (smaller or larger) in other centers, depending on whether they perform screening examinations, examine only patients with symptoms or follow protocols to

screen for actual performance of venous duplex ultrasound for evaluation of DVT, or examine calf veins routinely.¹⁵

CONCLUSIONS

Despite increased training of vascular technologists, improved technology of duplex ultrasound machines, and accreditation of vascular laboratories, incomplete LEVDUS examination remains a clinical problem, potentially missing diagnoses of DVT and denying the opportunity to anticoagulate patients with DVT. Our study suggests that an incomplete ultrasound examination is insufficient to rule out DVT and requires appropriate and timely follow-up with repeated examination to avoid missed DVT diagnoses, to prevent complications associated with increased morbidity and mortality, and to improve patient safety with indicated use of anticoagulation therapy for DVT.

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AUTHOR CONTRIBUTIONS

Conception and design: KN, GM
Analysis and interpretation: KN, JW, RS
Data collection: KN, JW, RS
Writing the article: KN, JW, RS, GM
Critical revision of the article: KN, JW, RS, GM
Final approval of the article: KN, JW, RS, GM
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