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Is there a necessity for whole-leg lower-limb ultrasound in the setting of deep vein thrombosis?

E Bowen,[1,2] MB ChB, FC Path (Haem); **L Haupt,**[1,2] MB ChB, FC Path (Haem)

[1] *Department of Haematology and Cell Biology, School of Pathology, Faculty of Health Sciences, University of the Free State, Bloemfontein, South Africa*
[2] *National Health Laboratory Service, Universitas Academic Hospital, Bloemfontein, South Africa*

Corresponding author: *E Bowen (bowene@ufs.ac.za)*

Background. Isolated distal deep vein thrombosis (IDDVT) is thrombosis that occurs in the lower-limb venous system, limited to the calf veins, with no extension into the popliteal veins. Proximal propagation or proximal DVT (PDVT) has well-defined treatment protocols in which anticoagulation shows clear benefit. IDDVT, however, does not always require treatment because the risk-benefit relationship of anticoagulation is not well established. The divergence in IDDVT treatment has led to two ultrasound approaches: whole-leg and proximal-only ultrasound, with repeat examination when indicated.
Objective. To investigate the prevalence of IDDVT using the current ultrasound approach at Universitas Academic Hospital, in order to advise on possible adaptation and tailored approaches in distinct subpopulations.
Methods. A retrospective file review of ultrasound investigations performed from 1 January 2015 to 31 December 2020 at the vascular suite in Universitas Academic Hospital, Bloemfontein, South Africa. Demographic data, HIV status and the anatomical site and anatomical extent of the thrombosis were collected.
Results. In total, 2 208 files were reviewed, which included 1 203 (54.5%) cases negative for DVT, with an alternative diagnosis possible in 113 (9.4%) of the negative cases. Of the 1 005 (45.5%) positive cases, 983 had adequate data for analysis, with 845 (86.0%) PDVT and 138 (14.0%) IDDVT cases. A female predominance was observed, with a male-to-female ratio of 1:2.02. Black African and mixed-race patients had significantly less IDDVT than white patients. Nearly two-thirds (66.0%) of the patients were HIV positive. However, HIV as a risk factor for PDVT did not meet statistical significance (p=0.053).
Conclusion. The low prevalence of IDDVT in the study cohort suggests that a proximal-only ultrasound approach can be adopted. Additionally, black African and mixed-race ethnicity, as well as male sex, were associated with a higher incidence of PDVT. Further prospective evaluation of the propagation rate of IDDVTs might advocate for tailored ultrasound approaches in different demographic groups.

Keywords: deep vein thrombosis, DVT, isolated distal deep vein thrombosis, calf vein thrombosis, proximal deep vein thrombosis, ultrasound, South Africa

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Isolated distal deep vein thrombosis (IDDVT), a deep vein thrombosis (DVT) isolated to the infra-popliteal calf veins with no proximal extension or pulmonary embolism (PE), is a distinct subclass of venous thromboembolism (VTE), as it appears to have low embolic potential.[1,2] Unlike the well-studied entities of proximal DVT (PDVT) and PE, in which anticoagulation has been shown to be clearly beneficial,[3,4] the optimal treatment strategy for IDDVT is under debate.[5,6] The diagnosis of DVT is made by compression or duplex Doppler ultrasound, typically following the application of a pre-test clinical scoring system, such as the Wells criteria, combined with D-dimer testing.[7-9] The diagnosis of PDVT using ultrasound has excellent sensitivity and specificity (>95%). However, sensitivity in evaluating for IDDVT is notably lower (60 - 70%), which highlights the poor reliability of ultrasound in IDDVT.[9]

These controversies have led to variations in the sonographic diagnostic approach to DVT. Some society guidelines advocate for proximal-only ultrasound evaluation, with repeat imaging done 6 - 8 days later. The rationale for this approach is that potentially significant IDDVT would propagate to the proximal veins and be detected with the subsequent ultrasound.[10,11] Other groups recommend an initial whole-leg ultrasound, with either treatment of high-risk IDDVT or ultrasound follow-up to assess propagation.[12] Prospective studies comparing these two approaches have concluded that both are acceptable, and the preferred approach should be determined by the testing institution.[13]

The prevalence of IDDVT varies according to the population and the ultrasound approach. As a result of these confounders, significant variations in prevalence have been reported in the literature, with review articles citing IDDVT prevalence ranging from 15.3% to 70%.[14,15] Real-world data from the GARFIELD-VTE[16] and RE-COVERY DVT/PE[17] studies showed that despite multiple prospective studies highlighting that anticoagulant therapy can be safely omitted in the majority of IDDVT cases, most patients with IDDVT are still treated with anticoagulation (99% and 99.3%, respectively).[16,17] Furthermore, these studies revealed a significantly lower percentage of African-American patients with IDDVT. The IDDVT-to-PDVT ratios for African Americans, whites and Asians were 0.20, 0.59 and 0.55 in the GARFIELD trial,[16] and 0.20, 0.46 and 0.50, respectively, in the RE-COVERY trial.[17] No African countries were included in these studies, and African-American patients were in the minority (n=169 (2.9%) in RE-COVERY, and n=470 (4.7%) in GARFIELD).[16,17]

There are no South African (SA) studies investigating IDDVT, or guidelines on the approach to diagnosis or treatment of IDDVT. Risk factors for DVT include, but are not limited to, hospitalisation, immobilisation, active cancer, increasing age and major surgery.[18] Two additional independent risk factors, namely infection with HIV and tuberculosis, respectively,[19-21] are prevalent in SA. The treatment of DVT reduces the risk of complications (pulmonary embolism, recurrent DVT and post-thrombotic syndrome (PTS)), and initially consists of subcutaneous or intravenous heparin, followed by oral vitamin K antagonists (VKA) or direct-acting oral anticoagulants.[22] In many cases, IDDVT does not require treatment with anticoagulation, thus avoiding the possible complications associated with anticoagulation therapy.[14,23] Although uncommon, the risk of major bleeding in patients on VKA treatment cannot be overlooked and carries a significant mortality risk.[24] The risks associated with anticoagulation are weighed against the risks of complications of IDDVT, most notably the risk of DVT extension. The CALTHRO[14] and CACTUS[6] studies showed proximal extension of IDDVT in 3.1% and 5.4% of untreated patients, respectively. In a 2012 retrospective review, Masuda *et al.*[25] described significant variation in the reported extension of IDDVT to the popliteal veins (1.9 - 23.0%).

The current protocol in the vascular imaging suite of Universitas Academic Hospital in Bloemfontein, SA, is a single whole-leg compression ultrasound. The suite provides diagnostic vascular ultrasounds to various primary, secondary and tertiary institutions throughout the Free State Province.

The present study aimed to review the prevalence of IDDVT using the current ultrasound approach at Universitas Academic Hospital, with the objective being to advise on possible adaptation and tailored approaches in distinct subpopulations.

Methods

Study design

A retrospective file review was performed using the request forms and ultrasound reports archived at the vascular imaging suite from 1 January 2015 to 31 December 2020.

Study setting

The vascular imaging suite is located in Universitas Academic Hospital, which is a tertiary hospital in Bloemfontein, SA. Referrals to this centre are from throughout the Free State Province. The hospital comprises primary, secondary and tertiary level healthcare facilities.

Participants

All request forms and reports for lower-limb ultrasound for suspected DVT were screened. In cases that were negative for DVT, an alternative diagnosis was recorded, if applicable. However, no further data were collected from negative cases. The cases that were positive for DVT were further analysed to identify possible associated factors for IDDVT based on demographics (age, sex and race), the location of the thrombosis (proximal v. distal, and left v. right), the location of the referred patient (in- or outpatient) and the HIV status of the patient (positive, negative or unknown). Demographic data (including race) were obtained from the bioinformatics system during registration of the participant at Universitas Academic Hospital.

Cases were excluded if any information (excluding HIV status) on the data capture form was missing. If HIV status was not stated and not available on bioinformatic platforms, these patients were grouped into the HIV status 'unknown' group.

Statistical analysis

Categorical variables were summarised using frequencies, while numerical data were summarised using means and standard deviations. Medians were calculated for evenly distributed data, and interquartile ranges for skewed data.

To assess the effect of HIV infection, a multivariate logistic regression model was employed. Risk factors for IDDVT were evaluated using a multivariate model, adjusted for known confounders. Results were summarised into adjusted odds ratio (aOR) with a 95% confidence interval. $P<0.05$ was considered statistically significant.

Ethical considerations

Ethics approval for the study was obtained from the Health Sciences Research Ethics Committee (HSREC) of the University of the Free State (ref. no. UFS-HSD2021/1662/2903-0002). Owing to the retrospective nature of the study and the fact that only archived patient files were used for data collection, informed consent was not required.

Results

A total of 2 208 lower-limb ultrasounds were performed during the study period, of which 1 005 were positive for DVT (45.5%). Of the 1 203 negative cases (54.5%), 113 (9.4%) cases received an alternative diagnosis. Twenty-two of the 1 005 positive DVT cases were excluded owing to incomplete data sets. Consequently, 983 positive DVT records were included in the final data set, of which 845 (86.0%) had PDVT and 138 (14.0%) had IDDVT. Table 1 summarises the patient characteristics.

Table 1. Demographic variables of patients diagnosed with deep vein thrombosis (*N*=983)

Variable	*n* (%)
Sex	
Male	319 (32.5)
Female	664 (67.5)
Race*	
Black African	816 (83.1)
White	104 (10.6)
Mixed race	62 (6.3)
Sex and race combined*	
Black African	
Male	252 (25.7)
Female	564 (57.4)
White	
Male	50 (5.1)
Female	54 (5.5)
Mixed race	
Male	17 (1.7)
Female	45 (4.6)
HIV status	
Positive	452 (46.0)
Negative	246 (25.0)
Unknown	285 (29.0)
Position of DVT	
Proximal (PDVT)	845 (86.0)
Distal (IDDVT)	138 (14.0)

DVT = deep vein thrombosis.
*Excluding 'other' (*n*=1).

Demographic data revealed a female predominance, with a male-to-female ratio of 1:2.02. The site of thrombosis according to sex and race is shown in Figs 1 and 2, respectively. Most (83.1%) patients were of black African descent. The mean age of the cohort was 47 years, ranging from a 30-day-old infant to a 100-year-old patient. Male sex was shown to be a statistically significant risk factor for PDVT (p=0.034), with an aOR of 1.56 with multivariate analysis. The association between HIV status and the site of thrombosis is illustrated in Fig. 3.

When race and gender are combined as a risk factor, mixed-race males had the highest rate of PDVT (n=17; 94.1%), followed by mixed-race females (n=45; 93.3%), black African males (n=252; 90.9%), black African females (n=564; 85.3%), white males (n=50; 78.0%) and white females (n=54; 68.5%).

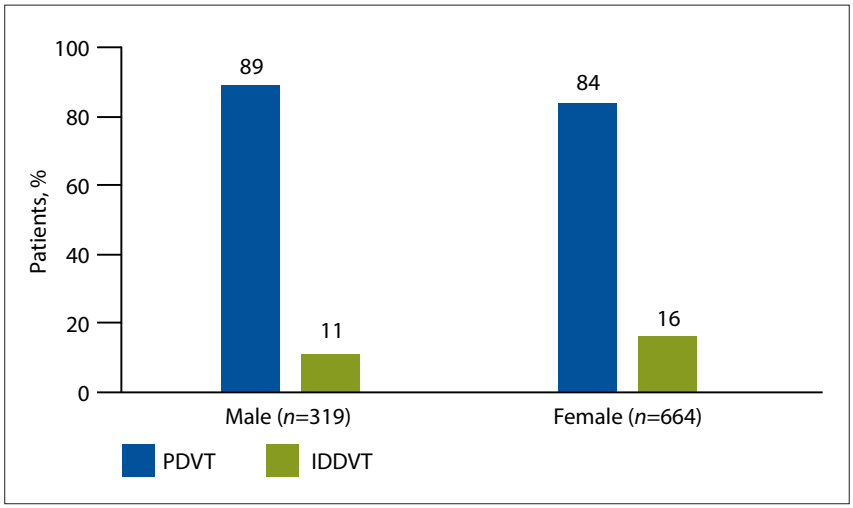


Fig. 1. Sex and site of thrombosis (N=983). (DVT = deep vein thrombosis; PDVT = proximal DVT; IDDVT = isolated distal DVT.)

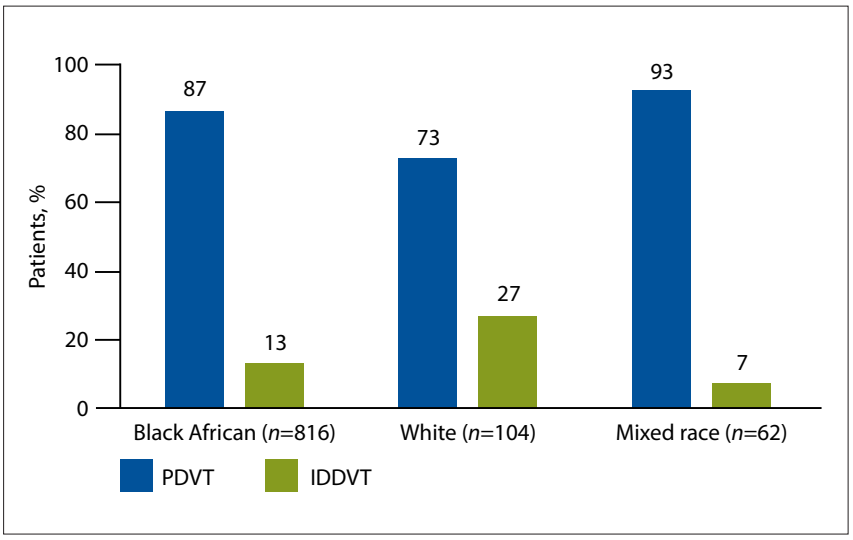


Fig. 2. Race and site of thrombosis (N=982, excluding 'other' representing a single case). (DVT = deep vein thrombosis; PDVT = proximal DVT; IDDVT = isolated distal DVT.)

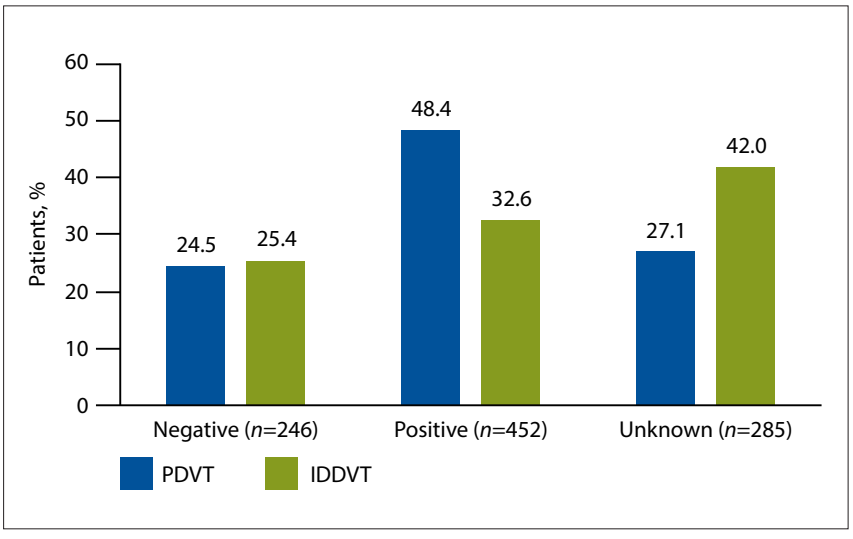


Fig. 3. HIV status in relation to isolated distal deep vein thrombosis (IDDVT) v. proximal DVT (PDVT).

Discussion

Historically, the treatment for IDDVT has been in favour of using anticoagulation therapy.[26] This has been questioned in large-scale, prospective studies, which showed that complications only occur following proximal propagation.[6,14] These controversies have led to divergent treatment guidelines, summarised in Table 2. Despite these recommendations, real-world data indicate that most patients with IDDVT do receive anticoagulation therapy.[16,17] In central SA, where there are no specialised thrombosis clinics, the nuances surrounding the treatment of IDDVT may very well be overlooked, leading to inappropriate anticoagulation initiation and treatment duration. The decision to initiate anticoagulation therapy impacts patients' bleeding risk and quality of life, and governmental healthcare spending.

The controversies surrounding the treatment of IDDVT are further illustrated in the various approaches to the diagnosis of DVT (Table 3). These guidelines and recommendations should be taken into consideration to inform the objective of this study to advise on a centre-based and possible personalised ultrasound approach in patients with DVT.

Whether or not to examine distal veins depends on what is considered the appropriate management of IDDVT. Our study showed a relatively low frequency of IDDVT of 14.0%, compared with 17.6% and 35.2% in the GARFIELD-VTE[16] and RE-COVERY[17] studies, respectively. A delay in seeking medical attention, as well as a delay in time to ultrasound, may explain why fewer IDDVTs were seen in this study.

Table 2. Summary of treatment approaches in IDDVT

Guidance body	Recommendation
NICE[10]	Anticoagulation therapy reserved for proximal extension
Cochrane review[27]	3-month anticoagulation for IDDVT
CHEST;[11] European Society of Cardiology[28]	Risk stratification: • low-risk patients: ultrasound follow-up • high-risk patients: anticoagulation

IDDVT = isolated distal deep vein thrombosis; NICE = National Institute for Health and Care Excellence; CHEST = American College of Chest Physicians.

Table 3. Summary of ultrasound approach by guideline

CDUS	Proximal-only ultrasound with D-dimer, followed by possible CDUS in 6 - 8 days	Either strategy acceptable
Society of Radiologists in Ultrasound[12]	NICE guidelines[10] CHEST[11]	European Society of Cardiology[28] American Society of Hematology[5]

CDUS = single complete duplex ultrasound; NICE = National Institute for Health and Care Excellence; CHEST = American College of Chest Physicians.

Some IDDVTs may already have propagated proximally at the time of diagnosis, and were therefore classified as PDVTs, which would lower the number of IDDVTs detected in our cohort.

When evaluating the rate of HIV, it is apparent that there was an over-representation of HIV-positive patients in the cohort, when taking into account the 12.7% national and 15.6% provincial prevalence of HIV.[21] These findings are comparable with other local studies by Moodley *et al.*[19] and Awolesi *et al.*,[29] who found HIV prevalences of 51.9% and 59.0%, respectively, in VTE cohorts. When comparing HIV positivity in PDVT with IDDVT, HIV appeared to be more common in PDVT patients (48.4% v. 32.6%), albeit not statistically significant (p=0.053). This finding suggests that the presence of HIV is associated not only with a greater risk for DVT, but likely also PDVT. Statistical evaluation of HIV status as a risk factor was limited by the significant proportion (29.0%) of patients in whom HIV status could not be established.

In the GARFIELD[16] and RE-COVERY[17] studies, African-American patients had a lower incidence of IDDVT than other ethnicities. Our study revealed similar findings, but is distinct in that black Africans represented the majority of patients in our cohort. The IDDVT-to-PDVT ratio in this study was 0.15 in black Africans, compared with 0.20 in the GARFIELD and RE-COVERY studies.[16,17] It was noteworthy that the mixed-race group showed an even lower incidence of IDDVT, with an IDDVT-to-PDVT ratio of only 0.08.

The majority (67.5%) of patients with VTE in this study were female. Possible explanations include female-specific risk factors such as pregnancy and combined oral contraceptive use.[18] However, in both the RE-COVERY and GARFIELD studies, gender representation was nearly equal (50.7% and 50.4% female, respectively), with no significant differences between IDDVT and PDVT.[16,17] In another SA study, Awolesi *et al.*[29] also found a female predominance of 72.8% in patients with DVT, revealing an apparent over-representation of female patients with DVT in SA cohorts.

The present study brings into question the possibility of tailoring an ultrasound approach to specific risk factors. We demonstrated that certain demographic groups showed lower rates of IDDVT. Whole-leg ultrasound could be reserved for groups where a significant IDDVT (i.e. one that may still propagate proximally) is more likely, who could then be risk-stratified further for anticoagulation or ultrasound follow-up should an IDDVT be found. Inversely, one could argue that male mixed-race patients should receive proximal-only ultrasound owing to the very low frequency of IDVVT found in this population. Lastly, HIV as an isolated risk factor could also weigh into an individualised approach.

The low frequency of IDDVT in our cohort suggests that a proximal-only ultrasound approach is acceptable. However, this could be confounded by the need for repeat ultrasound investigations, which will significantly add to cost and labour. Future prospective studies assessing the rate of propagation of IDDVTs in our setting would be valuable in choosing an appropriate ultrasound approach for our institution. It is an appealing prospect to remove the clinical decision of whether or not to treat IDDVT by adjusting the ultrasound approach. Ultimately, the individualised ultrasound approach, the decision to commence anticoagulation therapy and the duration thereof should preferably take place at a specialised thrombosis clinic, which is not currently available in the Free State public healthcare sector. Anecdotal experience from our local international normalised ratio (INR) testing facility suggests that many patients currently diagnosed with IDDVT are receiving inappropriate anticoagulation therapy. This should be formally documented in future studies to supplement international guidelines with local evidence.

Study limitations

Identifying race in the study was challenging. While the patient's race is supposed to be indicated on the bioinformatics system available, this was not the case in all patients, and race had to be concluded from the name and surname of the patient in a minority of cases, which might often be unreliable.

The lack of complete HIV data made specific risk-factor analysis challenging, and likely contributed to the lack of statistical significance in HIV status as a risk factor for PDVT.

Insufficient clinical and treatment data limited discussion regarding some of the statistically significant findings, such as the female predominance.

Conclusion

This study demonstrates a relatively low incidence of IDDVT (14.0%) in a central SA cohort. This low frequency is most likely explained by the composition of the study cohort, with a majority of black African patients, in whom IDDVT occurs less frequently.[16,17] Additionally, it has been shown that the SA mixed-race population has an even lower incidence of IDDVT. The lower incidence of IDDVT lends itself to a proximal-only ultrasound approach, which would diagnose the majority of DVTs in our centre and avoid the possibility of unnecessary treatment of IDDVT. Evaluation of the propagation rate of IDDVTs and the added burden of follow-up investigations is needed for conclusive decision-making.

Data availability. The data used in this study are available upon request from the authors.

Declaration. This study forms part of the requirements for EB's MMed (Haematology) degree at the University of the Free State.

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Author contributions. Both authors contributed to conceptualisation and design of the study, and interpreted the results. EB collected the data, wrote the first draft of the article and approved its final version. LH was the study supervisor, edited the article and approved its final version.

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