Sensitivity and Specificity of Thermal Imaging When Used to Detect Superficial Venous Reflux as Compared to Duplex Ultrasound

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Abstract: Objective: Vein disease is one of the most common circulatory disorders. The main diagnostic tool which is often considered the "gold standard" for vein disease is duplex ultrasound scanning (DUS). DUS is somewhat time consuming and requires highly skilled technologists to perform contact intensive and often laborious examinations to achieve complete venous mapping. Patients with obvious vein symptoms often forgo investigation and appropriate treatment for years in part due to the inaccessibility of an easier, less obtrusive methodology that may reliably uncover superficial venous insufficiency. Recently, the non-contact imaging modality of thermographic imaging (TI) has become widely available, it is mobile, quick to perform and inexpensive to use with little operator technical skill requirements. It has the added benefit to ultrasound technologists of focusing DUS examinations thus improving both scanning time and completeness. **Methods:** In a retrospective study of 101 patients (202 legs) the TI results were compared to DUS and analyzed for sensitivity and specificity, positive and negative predictive values and overall accuracy. **Results:** Sensitivity was 95.2% and Specificity 100%, positive predictive value was 100% and negative predictive value 88.5% and overall accuracy 98.5%. **Conclusions:** These Sensitivity and Specificity results suggest that TI is an excellent pre-screening tool which may help identify those likely to benefit from further investigation of leg symptoms and superficial vein treatment.

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Introduction

More than 80 million Americans suffer from chronic venous disease (CVD), which often is visually recognized as varicose veins.[1] If left untreated, these abnormal leg veins can progressively worsen and cause other complications.[2] Thus, optimizing non-contact, noninvasive imaging methods that can be useful in either earlier or more complete diagnosis of CVD may be beneficial. The gold standard for diagnosis for CVD is duplex ultrasound scanning (DUS). DUS is capable of detecting and quantifying incompetence in both the deep and superficial venous systems and is often able to detect the exact location of valve failure and sources of venous reflux from deep to superficial.[3] Inherently, venous ultrasound is very operator dependent and due to the variability of patient's body habitus and differing vein anatomy, it is often laborious and requires experienced technologists and often expensive machines. As with all ultrasound imaging it only shows anatomy directly beneath the ultrasound probe, thus in a disease such as varicose veins where the sources of reflux and distribution of veins is highly variable, inadvertent error and incomplete vein mapping is possible.

Duplex ultrasound requires direct physical patient contact, skilled operators and relatively expensive, less mobile equipment. Thermal imaging conversely; is non-contact, highly mobile, can be used by less skilled personnel and creates a complete superficial thermal image of the leg of interest. Thus, thermal imaging as a precursor to DUS has considerable benefit as it may identify most incompetent superficial veins which can then help guide the ultrasonography technician to optimize the efficiency of their scanning by easily identifying the sources of reflux that fill the identified varicosities.

TI has been adopted as part of investigational adjunctive routine examination of patients presenting for venous imaging in a series of high through-put venous offices. It is important to understand the benefits and limitations of this novel application of TI. The purpose of this report is to establish the sensitivity and specificity of TI when measured against DUS as the gold standard in this cohort of patients.

The goal of this retrospective analysis of 101 consecutive pa-

Table 1. Counts and percentages for venous incompetence diagnosis by TI and DUS.

		Ultrasound	
		Positive	Negative
Thermal	Positive	176 (98.4)	0 (0.0)
	Negative	3 (1.6)	23 (100.0)

Table 2. Test statistics comparing TI to DUS.

Measurement	Statistics
Accuracy	98.5% (95% CI: 95.7%,99.7%)
Prevalence	88.6% (95% CI: 83.5%,92.3%)
Sensitivity	98.3% (95% CI: 95.2%,99.4%)
Specificity	100.0% (95% CI: 85.7%,100.0%)
Pos Pred Value	100.0% (95% CI: 97.9%,100.0%)
Neg Pred Value	88.5% (95% CI: 71.0%,96.0%)

tients in an ICAVL (Intersocietal Commission for the Accreditation of Vascular Laboratories) accredited vascular laboratory setting was to determine the sensitivity and specificity of clinical thermal leg imaging for detection and mapping of clinically relevant superficial venous insufficiency when compared with subsequent DUS.[4]

Methods

This retrospective study of patients who underwent evaluation of their legs for venous disease with a combination of initial thermography and duplex ultrasound. The records of a single practitioner vein practice were reviewed from February 2019, consecutive series of records fulfilling inclusion criteria were drawn and examined, each leg was considered separately.

Patient inclusion criteria: Age between 18-75, First referral visit to the institution, had not had previous truncal vein intervention, but a past history of cosmetic venous sclerotherapy was not excluded. These patients where predominantly CEAP Clinical Classification C2 and C3, with very few having more severe disease. As such they had typical distribution of vein incompetence predominantly of the great saphenous vein. All cases had to have a complete ultrasound report within the EMR- eClinicalWorks™, have a complete set of stored thermographic and visual photographic images- via RxPhoto ™ (AppWorx, Boston Ma) cloud-based storage.

Thermographic images were created prior to ultrasound or consultation and included as a minimum 3 views of each leg, anteromedial, anterolateral and posterior. Visual photography was captured at the same time. Thermographic images were captured with the exposed leg with the patient standing, patients were not permitted to lie down prior to the image creation and walking was encouraged but not controlled. The images were captured by a FLIR One Pro™ (FLIR Systems, Inc. Wilsonville, Or) camera connected to an iPhone™ 8 or newer with iOS X or newer, and stored in a HIPPA compliant manner using RxPhoto™ software. Routine ultrasound was conducted by qualified sonographers following ICAVL guidelines.

DUS examination was considered positive if there was incompetence exceeding 0.5 seconds in any part of the superficial system. If transient reflux in the GSV was confined to a limited segment of the thigh this was considered negative as there was no propagation down the leg.

The charts were reviewed by 2 registered ultrasonography technologists who were familiar with evaluating thermal images. They determined if a leg was positive or negative for venous disease by visual inspection of thermal images and independently positive or negative for incompetence by review of DUS reports. If both assessors agree the result was entered but if there was a disagreement the case was referred to a physician skilled in both thermography and ultrasound to decide the status of the investigation, all data were uploaded to an Excel spread sheet for analysis.

Statistics

Simple demographics were determined for age (median and range) and sex and laterality.

Computation of sensitivity and specificity were calculated for thermography compared to ultrasound as the gold standard, confidence interval and p value were calculated. To look for agreement between TI and ultrasound, all vein measurements were combined into one group. A nested logistic regression analysis was then done. The independent variable was group (TI vs. DUS). Measurements for each leg were nested within the individual. We found no significant difference between measurement techniques. $X^2(1, N = 1{,}616) = 0.533$, $p = 0.463$. Table one provides the descriptive results and R version 4.0.1 (R core team 2020: R Foundation for Statistical Computing, Vienna, Austria) was used for all data analysis.[5]

Accuracy is the overall probability that a patient is correctly classified; Kappa is rater agreement; Sensitivity is the ability of a test to correctly identify those with the disease (true positive rate); Specificity is the ability of the test to correctly identify those without the disease (true negative rate); Positive predictive value is the probability that subjects with a positive screening test truly have the disease; Negative predictive value is the probability that subjects with a negative screening test truly don't have the disease.

Results

Of the 101 patients 87 (86.1%) were female, median age was 51 (range 30 to 70). Thermography identified 176 positive legs compared with 179 with ultrasound, there were 176 true positives, 23 true negatives, 0 false positives and 3 false negatives (**Table 1**). The computed sensitivity of Thermal imaging to detect superficial insufficiency compared with DUS was 98.3%, confidence interval (CI) 95.2% - 99.4% and specificity 100%, CI

Figure 1. Thermal Imaging right leg clearly shows hotter linear pattern suggestive of an incompetent vein, which was confirmed on DUS. Left leg shows no linear skin heating and is negative for incompetence on DUS.

85.7%-100%. Positive predictive value was 100% and negative predictive value 88.5%. Overall accuracy was 98.5% CI 95.7% - 99.7% (**Table 2**).

Discussion

Thermographic imaging is a relatively simple technique that can add significant value in the evaluation of the venous patient. Complete thermal images of both legs may be captured in a matter of minutes, while simultaneously obtaining the visual photographic images of the corresponding leg. Recording, storage and cataloguing of those anatomical and thermographic images in a HIPPA compliant manner is essential for future review and analysis. The images can be used for a variety of purposes such as to determine the need for ultrasound, to guide ultrasound examinations making them faster and more efficient as well as to educate patients. The creation of a varicose vein map may then be used in combination with ultrasound to facilitate optimal

Figure 2. Thermal image **(A)** and simultaneous optical image **(B)** of 62-year-old male with obvious superficial veins seen mid-calf. Notice no significant temperature differences on thermal imaging. Ultrasound confirmed that there was no venous incompetence as well.

individual treatment.

TI can display areas of increased heat relative to areas of adjacent skin temperature that usually represents incompetent superficial veins. These incompetent superficial veins stand out quite clearly (**Figure 1**) as irregular linear areas which follow vein patterns, whether they are visible or not to the naked eye. These areas of increased heat over the veins have previously been ascribed to inflammation in the varicose veins, which we do not believe to be correct.[6]

A much more plausible explanation is that blood in the deep veins has largely supplied the muscles and other structures deep to the deep fascia and is close to core body temperature (37°C), conversely venous blood in the normal superficial veins of the leg is blood that has been through the capillary network of the skin and subcutaneous tissue and so has equilibrated with skin temperature which is typically 29-30°C.[7,8] In thermal imaging normal superficial veins of the leg do not show up as different from the skin and are therefore not detected (**Figure 2**).

In superficial venous disease blood refluxes from the deep veins into the superficial veins and down the leg through incompetent valves, most commonly the great saphenous vein (GSV). The refluxing venous blood is substantially hotter than the skin (as it arrives from the deeper core heated venous pool) and heat is conducted to the surface and is detected as elevated temperature that overlies the course of the incompetent superficial vein and is easily seen

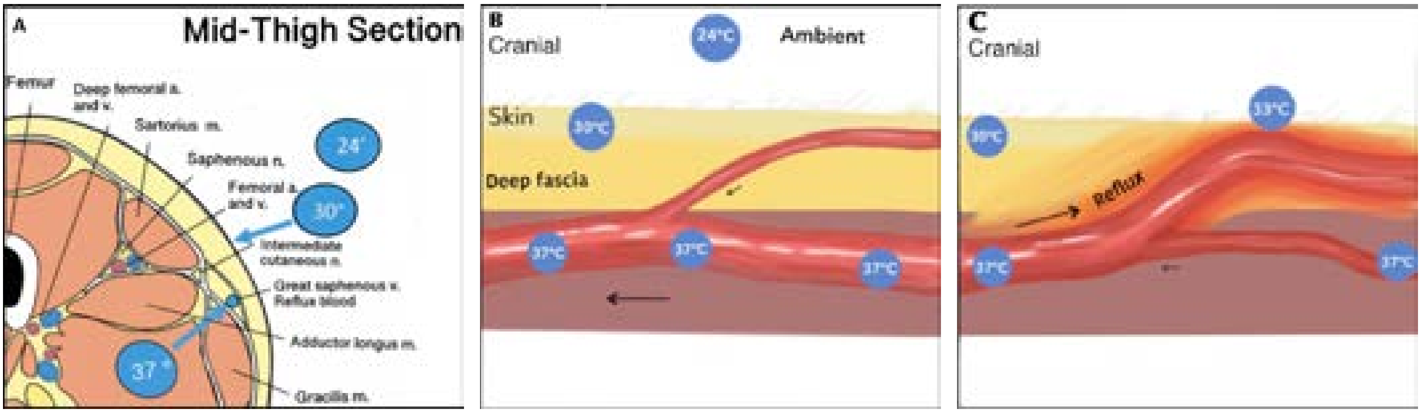

Figure 3. (A) Cross section of thigh, all deep structures at approximately 37° with relatively uniform insulating subcutaneous tissue and skin. Modified from Wright et al.[10] **(B)** Longitudinal view. Normal; no temperature gradient between superficial vein and skin. **(C)** Longitudinal view; venous incompetence. Reflexing blood from deep to superficial veins conveys "hot" (approximately 37°C) blood to subcutaneous veins, heat is conducted to the skin.

on TI (**Figure 1**). The incompetent trunk vein is not usually seen as it lies in its own fascial sheath and adjacent structures are also at core body temperature and equally conduct heat to the surface so no excess heat is detected. Once the incompetent vein escapes the deep fascia and travels closer to the skin, the surface temperature becomes elevated and is typically around 33°C, creating a localized elevation in temperature along the pathway of the incompetent vein of approximately 3°C (**Figure 3**). This temperature differential is easily detected with modern TI cameras that currently have a spot temperature resolution of 0.1°C.[9]

In this consecutive series of patients presenting to clinic for first referral for leg vein symptoms, TI when compared with DUS as a "gold standard" was both highly sensitive 98.3% and had 100% specificity. This high level of true positives and absence of false negatives is often considered sufficient to be considered an effective screening method. Sensitivity was a little lower than specificity as expected due to the incompetent vessels that may have been missed beneath the deep fascia and/or when the heat signature of the incompetent veins was being obscured by the constant warmth over the anterior tibial border. Specificity was 100% and illustrates that there are limited causes of endogenous relative skin warming of the leg other than venous incompetence that would be sufficient to yield such a clear and distinctive image. There are other areas of increased heat which might confuse an inexperienced observer. These areas are found to be over the anterior tibial border and the popliteal fossa and are easily distinguished as they are roughly elliptical areas that are easily identifiable to experienced observers. The hamstring tendons, especially in slim individuals can create a linear pattern as well, but these are easily distinguished from venous insufficiency as they arise from the medial and lateral aspects of the popliteal fossa and fade as the area extends superiorly. The pattern of common physiological thermographically heated areas as above were easily distinguished and did not give rise to false positives in this series. Visual light photography was assessed in a pilot study and had poor sensitivity and specificity when compared with DUS and as might have been predicted had little to offer in the diagnostic phase of venous examination. A specific definition of DUS observed incompetence was used excluding veins where a small amount of reflux was detected in the thigh portion of the GSV and was not conducted further down the leg. Such cases may be a prelude to future superficial vein incompetence but are not generally accepted as an indication for treatment.

Thermal imaging of legs for superficial vein incompetence is not proposed as a diagnostic tool in this study, but as a prelude to detailed duplex examination. Thus, a small proportion of false negative results (1.5%) is acceptable to the authors. The nature of superficial vein incompetence is not an acute occurrence. Therefore, the downside of delayed intervention in those small portions of false negatives, is very limited suggesting to the authors that there should lead to no objection to its widespread introduction and potential adoption as an adjunctive tool. Given the exceptionally high level of sensitivity and specificity when compared to the gold standard of duplex ultrasound, venous thermography should be considered for its potential additive benefits.

The relevance of thermal imaging in vein disease has not yet been fully established and additional prospective studies will need to be conducted to establish its benefits and limitations. This study is known to be limited by being retrospective analysis and will hopefully form the basis of future prospective multi-centered studies. ■

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