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Venous Doppler Combined With Thermography in the Management of Chronic Venousinsufficiency and Deep Venous Thrombosis- Prospective Analytic Study

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Abstract:***Introduction****Thermography is increasingly being utilizedin the management of chronic venous insufficiency and deep venous thrombosis (DVT). This study was done to determine the diagnostic importance of thermography and its efficacy when combined with Venous Doppler in the diagnosis of perforator incompetence.****Methodology****Patients attending the Department of Surgery with diagnosis of varicose vein over a period of twelve months were included in this study. The study excluded the patients requiringadditional procedure and those who had injection sclerotherapy prior to surgery. Venous Doppler and Thermography of leg were performed. The thermo grams were compared with the venous Doppler alone andin combination of thermography. The sensitivity, specificity and predictive values were compared. Perforator incompetence diagnosed by imaging (Doppler and Thermography) were compared with true positive cases (identified during surgery).****Results****A total of 80 patients were included in the study. All the baseline parameters like age, sex, comorbities and body mass index (BMI) were comparable between the groups.Thermography had high sensitivity (93.59%) and negative predictive value (96.65%) in diagnosing chronic venous insufficiency. Similarly ithad high specificity (82.05%) and positive predictive value (81.21%) in diagnosing DVT Preoperatively identified perforator incompetence (using Venous Doppler alone) (mean) was not identified [9.1 vs. 6.9; p= 0.001] during surgery. Similarly, preoperatively identified perforator incompetence using both (Venous Doppler and thermography) (mean) was not identified during surgery [5.4 vs. 5; p= 0.231].*
Conclusion*A combination of thermography and venous Doppler has a higher accuracy in detecting perforator incompetence and can reduce the number of negative explorations. The advantages of thermography are that it is a radiation-free, non-invasive, and cost-effective method for diagnosing varicose veins. Thermography could also be used in follow-up cases of DVT and postoperative cases of varicose veins.*
Keywords: *varicose veins, deep venous thrombosis, thermography, sensitivity, specificity*

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I. Introduction

Varicose vein is the commonest vascular disease accounting for 10% of the volume of surgical outpatient department. Venous Doppler is considered to be the investigationof choice to identify perforatorincompetence [1-3]. It carries a risk of radiation exposure, and is an expensive investigation. A major limitation is that it leads to a significant number of negative explorations as the specificity is low. Also, it causes a considerable cosmetic disfigurement due to scaring.

Thermography is a form of radiography that images the skin surface temperature and thermograms are pictorial representations of thermal maps of the outer surfaceof the body. The principle of thermography is to detect and measure variations in the heat emitted by the body in the form of infrared radiation and convert them into electrical signals [4]. The electrical impulses are fed into the computer, which analyses the temperature and vascular changes, producing high-resolution images [4-6].

Thermography can serve as an additive tool with Venous Doppler to improve the specificity, thereby avoiding negative exploration [4]. To the best of our knowledge,there is nostudy available in the literature, to compare the efficacy of Thermography combined with Venous Doppler versus Venous Doppler, alone to identify the perforator incompetence during surgery. Hence this study was planned to compare the concordance

of Thermography with Venous Doppler vs. Venous Doppler alone to identify the incompetent perforator with accuracy

In this study, thermography was utilized in attempt toprove its usefulness in the diagnosis of perforator incompetence in patients planned for varicose vein surgery.

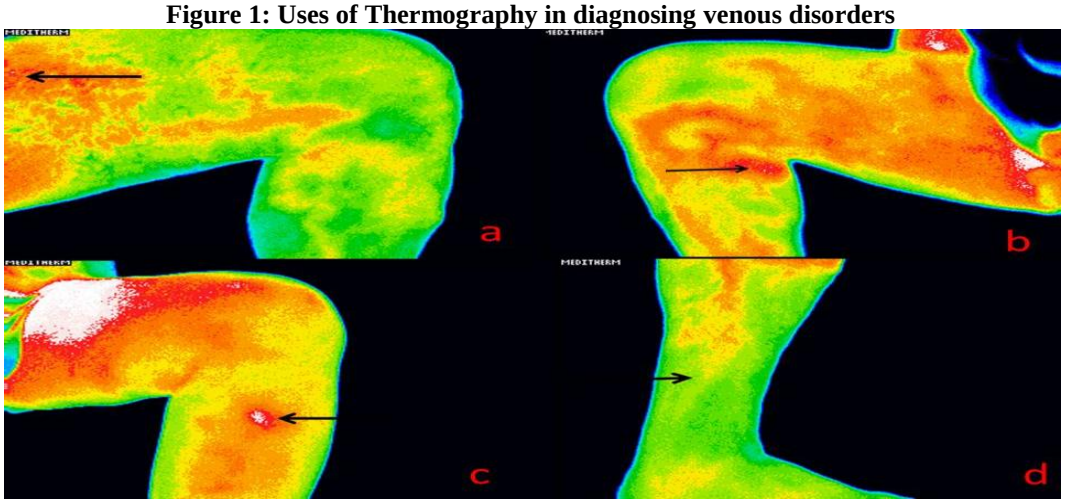
II. Methodology

This was a prospective observational study was carried out in tertiary care center in South India over a period of one year. All primary varicose vein patients who belong to CLASS 4-6 of Clinical-Etiology-Anatomy- Pathophysiology (CEAP) were included. The study excluded the patients who required additional vascular or nonvascular procedure, recurrent varicose veins and those who had injection sclerotherapy prior to surgery. Institute Human Ethics Committee (IEC) approval was obtained for the study. The nature, methodology and risks involved in the study were explained to the patient and informed consent was obtained. All the information collected was kept confidential and patients were given full freedom to withdraw at any point during the study. All provisions of the Declaration of Helsinki were followed in this study.

As an initial investigation, Venous Doppler was done followed by thermography of the leg.Prior tothermographic imaging, patients were allowed to rest at a room temperature of 28^{o}C. This was to achieve body temperature equilibrium with the surrounding ambient temperature and to nullify all the confounding variables that might influence the thermal imaging of leg.

An infrared thermal camera was positioned one meter away from the patient's leg. Thermography of the leg was performed using a high-resolution digital, non-contact thermographic camera, MED2000 Elite Iris (Meditherm Inc. Digital Infrared Thermal Imaging, Cheyenne, WY, USA). The standard views – anterior, posterior and lateral were taken. A thermal difference of 0.5°C between the homologous regions of the leg or a difference of 0.5°C compared to the surrounding area with colour change was taken as the criterion for abnormality [7]. Venous Doppler was taken in all other study group patients. Each perforator was studied separately, and data were collected. In Doppler, incompetence was identified by standard radiological methods. In thermography, incompetence that showed red was considered positive for venous insufficiency (Figure 1).

Figure 1: Uses of Thermography in diagnosing venous disorders



a) Sapheno femoral incompetence b) Popliteo femoral incompetence c) Perforator incompetence d) DVT (Cut off sign)

The perforators were marked as 'T' to indicate Thermographically positive perforator incompetence. Patients were then examined with Venous Dopplerby anotherconsultant radiologist and the incompetent perforators identified with Venous Doppler were marked as 'D'. Those perforators with an outward flow of duration of $\geq$ 500 ms, and with a diameter of >3.5 mm are considered pathological. Two differentradiologists performed the Thermography and Venous Doppler investigation. The consultant surgeon operated the patients who needed surgical intervention. Standard preoperative preparation was done and standard surgical procedure was carried out for sapheno-femoral junction incompetence. Surgical management of perforator incompetence was done in the form of stab ligation, where the incision was made in the site marked preoperatively.

All the Venous Doppler ('D') marked sites were explored surgically by mini-phlebectomy incisions for the presence of incompetent perforator as per the standard protocol. The incompetent perforators were ligated at the base after identification of "T" junction by stab phlebotomy technique. The number of incompetent perforator

identified during surgical exploration were categorised as 'D' positive or 'T' and 'D' positive and were recorded. Postoperative care and discharge were performed as per the standard.
Patient information, including age, gender, symptoms, complications and duration of the symptoms were recorded. Diagnostic properties like sensitivity, specificity and predictive values were analysed in Doppler (alone) group, Thermography (alone) group and both (Doppler and Thermography).

III. Statistical analysis

Assuming that sensitivity of Colour Doppler with Thermography is 80% with precision of 10% and the desired confidence interval is 95% the minimal sample size required to accurately identify the varicose veins was calculated as 80 lower limbs.

Statistical analysis was done by using SPSS 19.0 software version for windows. Categorical variable like gender was expressed as proportion. Continuous variables such as total number of varicose vein identified by Venous Doppler alone and those by a combination of Venous Doppler and Thermography were expressed as mean with standard deviation. Similarly, the continuous variables like number of varicose vein identified during surgery by venous Doppler alone and those by a combination of Venous Doppler and Thermography were expressed as mean with standard deviation. It was tested using Student T test. A p value of less than 0.05 was considered as statistically significant.

IV. Results

The study population consisted of 80 patients being 40 in each group. Mean age of the study population was 38.6 years. The most common symptoms reported by the patients were leg swelling, which was present in all 80 patients (100%), followed by painin lower limb 78 patients (97.5%). Tenderness was present in 70 patients (87.5%). All the base line parameters like BMI, comorbidities and recurrence were comparable between the groups (Table1).

Table 1: Basic demographic parameters of the study population

Demographic parameters	Doppler alone (n=40)	Thermography + Doppler (n=40)
Age (Mean)	58.6	54.3
Unilateral (N)	30 (75%)	20 (50%)
Comorbities (N)	50 (62.5%)	20 (25%)
BMI (Mean)	32.8	31.6
Recurrent disease	22 (52.5%)	18 (47.5%)

Comparison of Diagnostic properties of Doppler alone vs. Doppler +Thermography

DVT was identified in 95% (n=38) of the patients by Venous Doppler alone, whereas it was identified in all patients (100%) by using both Venous Doppler and Thermography. Similarly, chronic venous insufficiency was identified in 90% (n=36) of the patients by Venous Doppler alone. Contrastingly, it was identified in all patients (100%) using both Venous Doppler and Thermography. This difference was not statistically significant (Table 2).

Table 2: Comparison of Diagnostic properties of Doppler alone vs. Doppler and thermography

No.	Clinical diagnosis	Doppler alone (n=40)		Thermography + Doppler (n=40)	
		Present	Absent	Present	Absent
1.	DVT	38 (95%)	2 (5%)	40 (100%)	0
2.	CVI	36 (90%)	4 (10%)	40 (100%)	0

Comparison of Diagnostic properties of Doppler alone vs. Thermography alone

DVT was identified in 95% (n=38) of the patients by Venous Doppler alone but was identified only in 30 patients (75%) by using Thermography alone. Chronic venous insufficiency (Both SFJ and Perforator incompetence) was identified in 90% (n=36) of the patients by Venous Doppler alone. This drastically reduced to a mere 31 patients (77.5%) by using Thermography alone. This difference was significant (Table 3).

Table 3: Comparison of Diagnostic properties of Doppler alone vs. Thermography alone

No.	Chronic venous insufficiency	Doppler alone (n=40)		Thermography alone(n=40)	
		Present	Absent	Present	Absent
1.	SFI alone	40 (100%)	0	32 (49)	8 (50)
2.	Perforator incompetence alone	39 (97.5%)	1(2.5%)	35 (87.5%)	5 (12.5%)
3	Both SFJ and Perforator incompetence	36 (90%)	4(10%)	31 (77.5%)	9 (22.5%)
4	DVT	38 (95%)	2 (5%)	30 (75%)	10 (25%)

Venous Doppler positive (Preoperative vs. Intraoperative)

Venous Doppler positive varicose veins were compared with the true positive (identified during surgery) which revealed that preoperatively identified (using Venous Doppler alone) perforator incompetence

(mean) was not identified [9.1 vs. 6.9; p= 0.001] during surgery. This difference was statistically significant (Table 4).

Table 4: Comparison of Doppler (alone) positive vs. Intra-operatively identified Doppler (alone) positive for chronic venous insufficiency

Doppler alone positive (n=40)	Mean	SD	P value (Students t test) (Paired Samples Statistics)
Preoperative	9.1967	3.23472	0.001
Intra-operative	6.9672	2.97457	

Venous Doppler + Thermography positive (Preoperative vs. Intraoperative)

Similarly, preoperatively identified (using both Venous Doppler and thermography) perforator incompetence (mean) was not identified during surgery [5.4 vs. 5; p= 0.231]. This difference was not statistically significant. It was observed that the Doppler group required more number of negative explorations, which were unrewarding (Table 5).

Table 5: Comparison ofDoppler and Thermography positive varicose veins pre-operative vs. Intra-Operative

Doppler+ thermography positive (n=40)	Mean	SD	P value (Students t test) (Paired Samples Statistics)
Pre-operative	5.4754	2.32422	.231
Intra-operative	5.0984	2.33797	

The Venous Doppler on an average lead to 2 unnecessary explorations per patient (20 negative explorations per 10 patients). Compared to this, the Colour Doppler combined with Thermographyon an average result in less than one negativeexploration per 10 patients.

On analysing the concordance of Thermography with Venous Doppler 100% of incompetent perforators identified by Venous Doppler were also identified positively by Thermography, indicating 100% concordance between the Venous Doppler and Thermography in the identification of varicose veins.

Sensitivity, specificity, and predictive values of Doppler

Venous Doppler had high sensitivity **(**99.46%**)** and negative predictive value **(**98.43%**)** in diagnosing chronic venous insufficiency. Similarly ithad high sensitivity**(**98.99%) and positive predictive value **(**98.53%) in diagnosing DVT (Table 6).

Table 6: Sensitivity, specificity, and predictive values of Venous Doppler

No.	Venous Doppler	Sensitivity	Specificity	PPV	NPV
1.	CVI	99.46 (98.06-99.92)	98.88 (98.02-99.48)	97.67 (98.79-99.71)	98.43 (98.66-99.78)
2.	DVT	98.99 (98.81-99.13)	98.85 (98.09-99.99)	95.65 (96.91-98.09)	98.53 (97.00-99.23)

Sensitivity, specificity, and predictive values of thermography

Thermography had high sensitivity **(**93.59%**)** and negative predictive value **(**96.65%**)** in diagnosing chronic venous insufficiency. Similarly, ithad high specificity **(**82.05%) and positive predictive value **(**81.21%) in diagnosing DVT (Table 7).

Table 7: Sensitivity, specificity, and predictive values of thermography

No.	Thermography	Sensitivity	Specificity	PPV	NPV
1.	CVI	93.59 (86.06-96.2)	78.88 (72.02-82.8)	67.67 (58.79-73.71)	96.65 (91.66-97.78)
2.	DVT	74.61 (65.81-80.13)	82.05 (74.89-85.99)	75.65 (66.91-81.09)	81.21 (74.00-85.23)

V. Discussion

Varicose veins are prominent, tortuous vessel which occurs due to damage or incompetence of connecting valves. The symptoms may be dull aching pain, heaviness of leg, black discolouration of limb, non-healing ulcer and severe bleeding. Any complication is there, it will affect the patient's quality of life and is the most important indication for surgical management [5][6][7].

Venous Doppler has been conventionally used to diagnose varicose vein pathology. 2.5% of the annual health care budget in the developed countries like France and Belgium is spent on treating varicose vein. [8] In this study, it was found out that age and sex were equally distributed. A similar findingwas observed in a research done in Edinberg, England (9% men and 7 % of women in general population) [6-9]. Men are frequently engaged in work related to have longer hours of standing and hence needed early intervention.

Venography is an invasive imaging modality to diagnose venous disorder. Its use has declined in the last decade because of its invasive nature and complications like post phlebographic syndrome. [10-12]Ambulatory venous pressure monitoring was considered asa gold standard technique. Nowadays it is notpreferred because of its invasive nature and poor localization of incompetent perforator. (10). Non-invasive Imaging modalities like Duplex scanning possesses high sensitivity and specificity. They can be repeated because of its non-invasive nature [12-15]. However, though Venous Doppler is highly sensitive, the specificity remains low (40%) [16]

Venous Doppler investigation has its own limitation which includes longer duration for complete assessment of varicosities difficult interpretation in obese patients, requirement of radiologist with reasonable expertise in vascular imaging and higher cost. Marking of the perforators with the help of Venous Doppler the day before surgery is routinely practice in many centres [11-14].A study in Australia showed that Venous Doppler ultrasound when used alone led to 6 false positives in 165 limbs whereas clinical examination revealed none. [11-13]

The present study demonstrated that the conjoint usage of the two modalities would combine the high sensitivity of Venous Doppler and the high positive predictive value of Thermography. Venous Doppler when used alone would result in large number of unnecessary explorations. In contrast, Venous Doppler combined with Thermography produced a dramatic decline in the number of unnecessary explorations.

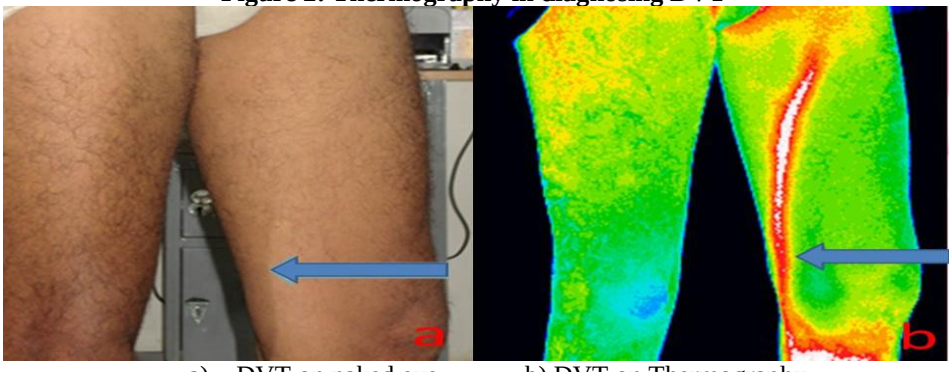
Open subfacial ligation or stab phlebotomy is still the most commonly performed surgery for perforator incompetence. [10-13] Thus, considering the high sensitivity of Venous Doppler,the addition of Thermography would improve the specificity can reduce the number of negative explorations. This advantage can reduce the duration of surgery by avoiding needless exploration. Thereby, it alsoreduces the cost of surgical treatment and better cosmetic outcome of the scar.

Thermography provides information only about physiology, not the morphology. It is the investigation of choice for screening and follow-up of venous disorders especially DVT treatment[9-10]. The use of thermography in the diagnosis of varicose veins has been seldom reported in the literature. Published work provides evidence relating use in DVT[4,11].

The role of thermography is only supplementary to other investigation, as it relies mainly on physiology of the disease that would not confirm a diagnosis. The advantages of thermography include early detection of disease and it is radiation-free, non-invasive, painless, and cost-effective. A precisely done thermography providesuseful information about venous diseases without the risk of radiation exposure. Thermography does not supersede venous Doppler or other time- tested methods of diagnosis. Infrared thermography is a good supplemental test and further large-scale research is necessary to determine whether it can besolely used as a diagnostic tool for diagnosing chronic venous insufficiency. The limitations of the thermography are the need of expertise to interpret the results and low specificity, but its efficacy can greatly be improved by correlating with other investigations.

Various studies reported the sensitivity and specificity of venous Doppler in diagnosing varicose vein, which range from 41%-95% and 30%-85%, respectively [12-16].The diagnostic ability of thermography with respect to individual perforator incompetence has not been studied. In this study, we elaborate that thermography combined with Venous Doppler is superior to colour Doppler alone in diagnosing varicose vein. This is because of the location of the venous system in comparison with the skin surface. Thermography is as effective as Venous Doppler as an investigative tool in diagnosing DVT (Figure 2).

Figure 2: Thermography in diagnosing DVT



a) DVT on naked eye b) DVT on Thermography

However, thermography failed to pick up a minority of cases. This is because of the deeper location of the deep venous system with respect to the skin surface. Concordant use of Doppler and thermography offer a very reliable diagnostic method in chronic venous insufficiency.

The limitation of the study was the relatively smaller sample size of the study population. It was conducted as a prospective observational study involving singlestudy group. A large scale randomised control trial comparing two group of patients with high sample size are required to substantiate our results.

VI. Conclusions

Colour Doppler combined with thermography carries a higher detection rate and a lower false positive rate in the diagnosis of perforator incompetence.This combinationwould reduce the number of negative explorations and improve the functional outcome in terms of a cosmetically acceptable scar.

Thermal imaging is a harmless non-invasive method that can be easily implemented in routine clinical practice. Though not a standalone diagnostic tool, we conclude that thermography shows promise supplementary investigation in providing informationon chronic venous insufficiency.

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