Diagnostic Accuracy of Color Doppler Ultrasonography among Patients Having Deep Vein Thrombosis by Taking Venography as Gold Standard

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Authors’ contributions

This work was carried out in collaboration among all authors. Author GS designed the study and collect the data. Authors KK and MK performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors AH and NR managed the analysis and manuscript formatting. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2020/v32i1830682

Received 15 April 2020
Accepted 20 June 2020
Published 25 August 2020

ABSTRACT

Objective: To assess the diagnostic accuracy of Color Doppler ultrasonography in patients with Deep Venous Thrombosis by using venography as gold standard at Radiology department of Civil Hospital Karachi.

Methodology: This cross-sectional study was carried out from August 2014 to March 2015 at Radiology Unit, Civil Hospital Karachi. Patients of either gender with deep venous thrombosis were included based on clinical examination and observation. For Doppler ultrasound, the combinations of spectral scanning, color compression, and grey scale were used. Potential anomalies including existing or non-existing thrombus along with its magnitude were evaluated. Color Doppler Sonographic results included incompressible, lack of phasicity, site of flow space and absence of

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increasing trend. Scan diagnosis was subsequently contrasted with venographic reports and recorded in self-made proforma. Data was analyzed by using SPSS version 20.

**Results:** Total 104 patients were studied and their average age was 52.4±9.4 years. Males and females were 56% and 44% respectively. Color Doppler ultrasonography findings showed 99% sensitivity and 80% specificity. Positive predictive value 99% and negative predictive value 80% and accuracy was 98%.

**Conclusion:** Color Doppler ultrasonography is cost-effective, efficient, safe, and non-invasive method to diagnose the deep venous thrombosis of acute nature.

**Keywords:** Color Doppler ultrasonography; venography; deep venous thrombosis.

### 1. INTRODUCTION

Deep vein thrombosis (DVT) of lower extremities is among the factors that cause most deaths due to pulmonary embolism [1]. Several surgical and medical conditions are complicated due to DVT. Clinically, most of the venous thrombi remain asymptomatic [1]. DVT is development of blood clot in deep veins, which mostly affects the lower limbs and varies between asymptomatic condition (redness, swelling, pain, warmth) to a classical symptomatic state. Burden of the disease linked to thromboembolism is raised in western countries, as intimately 100 patients per 100,000 patients [2,3]. However the prevalence of venous thromboembolism in the Asian countries is lesser, while overall burden of venous thromboembolism in Asian has been considerably underestimated [2]. DVT development risk factors include surgery, malignancy, immobilization, trauma, paralysis or paresis, obesity, advanced age, anesthelia, varicose veins, long journeys, superficial vein thrombosis, central venous catheters, pregnancy, oral contraceptives, puerperium, and several hormone replacement therapies [4,5]. A local comprehension of the burden, pathogenesis, and etiology of disease as well as successful therapeutic and preventive interventions are highly import [6]. DVT is an acute disorder that should be diagnosed and treated promptly [7]. For DVT diagnosis, the venous ultrasonography (a popular imaging tool) has largely substituted the contrast venography, which is an invasive benchmark. [7] Venous ultrasound has been the preferred diagnostic procedure for acute deep venous thrombosis (DVT) suspected patients [8]. There is heterogeneity and controversy among influential groups about the constituents of the test needed. Some guidelines suggest the scanning of whole lower extremity, while others advise scans that are restricted to the knee and thigh accompanied by serial tests [3]. Many procedures involve gray-scale ultrasound only, while others use Doppler probing [8]. Doppler ultrasonography (DUS) remains a first line intervention in the DVT diagnosis because of its wide availability, non-invasiveness, low cost, no contrast material and ionizing radiation involved, 100% specificity and 76.1% sensitivity [9]. Even though venography is a benchmark for DVT demonstration, its invasive approach has post-contrast complications and radiation hazards [7]. Thus it may not be conveniently practiced as an OPD alternative for every patient. The purpose of color DUS was to authenticate or discount DVT and to determine thrombus (type and degree). In a government tertiary care facility, we decided to contribute to the findings reported in international and local publications on this subject on a large scale. Earlier reported local studies showed Doppler's less sensitivity to DVT diagnosis in comparison to international estimates [2,9]

### 2. MATERIALS AND METHODS

This cross-sectional research was carried out from August 2014 to March 2015 at Radiology Unit, Civil Hospital Karachi. Patients of either gender with manifestation of deep venous thrombosis, who were referred to the Department of Radiology, Civil Hospital Karachi were included based on clinical investigation and observation. Patients with certain factors of leg swelling including arthritis/infection, or platelet inhibitor/anticoagulant treatment, were excluded for obvious reasons. Doppler imaging was undertaken by specialist radiologist with minimum 5 years of experience with Doppler ultrasonography using a range of gray scale, colour, and compression spectral sonography. Potential anomalies were examined, such as the existing or non-existing thrombus, its magnitude and classification
(internal vascularity, free floating, partly or completely occlusive or attached). Venography in all patients was then accomplished by expert radiologist with five years of experience. All the data including Doppler scanning and venography findings were entered in the self-made proforma. Data was analyzed by using the SPSS version 20. Mean and standard deviation were estimated for numerical data like age. Frequency and percentage were calculated for categorical variables. 2X2 table was used to represent the calculations of the specificity (SP) negative and positive predictive values (NPV and PPV respectively) and Sensitivity (SE) of Color Doppler Ultrasonography by taking venography as gold standard.

3. RESULTS

Majority of the patients were in 41 to 60 years of age group. Mean age of patients was 52.41±9.43 years. Mean duration of DVT symptoms was 6.5±1.77 months. There were 58 (55.8%) males and 46 (44.2%) females Table 1.

Color Doppler scanning showed high rates for True positive (TP) and low rates for True Negative values. It indicates 99% positive predictive value and 80% negative predictive value. Sensitivity and specificity were 99% and 80% respectively. Diagnostic accuracy was 98% by taking venography as gold standard Table 2.

| Variables          | Statistics       |
|--------------------|------------------|
| Age (mean+SD)      | 52.41±9.43 years |
| Duration DVT       | 6.5±1.77 months  |
| Gender             |                  |
| Male               | 58(55.8%)        |
| Female             | 46(44.2%)        |

4. DISCUSSION

The timely diagnosis for deep venous thrombosis (DVT) is critical as it is associated with acute pulmonary embolism (PE), which happens in nearly half of the untreated DVT cases and has a mortality rate of 30%. Though, the location and clinical diagnostic accuracy of DVT is usually poor. Doppler ultrasound is a preferred procedure for the diagnosis of deep vein thrombosis (DVT) by reflected ultrasound waves showing venous blood flow. This non-invasive approach is much prevalent and effective to detect blood clots. This study intended to describe DVT cases under Doppler ultrasound among those who were clinically suspected for DVT. In this study males were 56% and females were 44% with average age of 52.4±9.4 years. Similarly Saeed IO et al. [10] reported that the rate of deep venous thrombosis was higher among patients aged >50 years and most of the positive cases were female. Study of Sanjay M et al. [11] also found comparable findings as; the highest prevalence of DVT was found in patients with 50 years of age. Hill et al. [12], observed a higher occurrence of DVT among males, these findings were similar to this study. However DeCosta L et al. [13] found 57% females and remaining 43% were males, while mean age was slightly lower as compared to this study. This gender difference may because difference in sample size.

In our findings, venography confirmed the DVT in 95.2% of cases indicating high True positive (TP) and low True Negative (TN) rates. It shows 99% positive predictive value (PPV), 80% negative predictive value (NPV), 80% specificity, 99% sensitivity and 98% accuracy. In comparison to our results, study conducted by Mohammad SH et al [13] reported that in 50 patients, color Doppler flow imaging showed 90% sensitivity, 96.7% specificity, 94.7% PPV, 93.5% NPV, and 94% accuracy rate, where most cases (26%) were aged around 50 years.

Markel et al. [14] conducted a study on 116 patients to assess the effectiveness of Doppler US in DVT suspected cases and results compared with venography. Out of 116 patients who had diagnosis of DVT on clinical ground and Doppler ultrasound, both the venography and Doppler ultrasound were performed in 40 patients. Doppler ultrasound had 89% sensitivity, 100% specificity and 94% accuracy in DVT diagnosis which was higher than venography. Amin et al. [15] conducted a prospective study on 100 DVT suspected cases with color-coded duplex sonography and venography and concluded that ultrasonography (US) was simple, highly accurate and noninvasive technique to detect femoropopliteal thrombosis, where further venography was un-necessary. Naz R et al. [9] reported in their study that doppler ultrasonography (DUS) has 76.1%, 100%, 100%, 44.45% and 80.00% of sensitivity, specificity, PPV, NPV and accuracy.
Table 2. Color doppler ultrasonography and venography (true negative and true positive outcome for deep venous thrombosis detection)

| Color Doppler Ultrasonography | Venography for Deep venous Thrombosis detection | Total |
|-------------------------------|-----------------------------------------------|-------|
| Yes                           | 1(FP)                                         | 98    |
| No                            | 4(TN)                                         | 1(FN) |
| Total                         | 5(4.8%)                                       | 99(95.2%) |

Sensitivity: TP/(TP+FN)x100 = 99%, Specificity: TN/FP+TNx100 = 80%, PPV: TP/TP+FPx100 = 99%, NPV: TN/FN+TNx100 =80%, ACC: TP+TN/TP+TN+FP+FNx100 =98%

respectively. Color DUS is safe, cost-effective, efficient and non-invasive method in acute DVT diagnosis of lower extremity however it is yet not 100% accurate. Theodorou et al. [16] conducted study on 136 suspected patients of DVT, they used Sonography and contrast-enhanced venography for the diagnosis, they found 93% sensitivity, 98% specificity (98%) and 97% accuracy. Lensing, et al. [17] found specificity, sensitivity and PPV of compression ultrasonography test (with 95% confidence interval) for proximal DVT at 96% (92%-99%), 60% (39%-81%), and 71% (48%-89%) respectively. The specificity, sensitivity and PPV (with 95% confidence interval) of compression ultrasound for calf vein thrombosis detection were 91% (83%-96%), 33%(18%-52%) and 58% (34%-80%) respectively. Magnusson et al. [18] reported that color DUS showed satisfactory sensitivity among symptomatic DVT patients in proximal region. However Özbudak Ö et al. [19] also found 76% sensitivity and specificity 100% of Doppler ultrasonography, with 100% positive predictive value and 81% negative predictive value. Color duplex Doppler is very sensitive to DVT diagnosis in femoropopliteal system, however has constraint, such as operator dependency and low sensitivity in evaluating thrombus level with inferior venal cava and iliac veins [1]. Color Doppler flow allows risk-and pain-free direct imaging of the lower extremities in deep venous system, to decide the value of color Doppler flow imaging in identification of DVT of the femoropopliteal system.

5. CONCLUSION

It was observed that Color Doppler ultrasonography is a cost-effective, efficient, safe and non-invasive method with 99% sensitivity and 80% specificity in diagnosis of deep venous thrombosis of acute nature. This imaging tool can be used instead of venography. Further large sample size and multicenter studies are required on this diagnostic tool.

CONSENT

All patients underwent verbal explicit consent to conduct procedure and for participation in the study.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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