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Original Research Article

Clinical versus radiological assessment of patients treated for deep vein thrombosis

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ABSTRACT

Background: Clinical versus radiological assessment of patients treated for deep vein thrombosis. Aims and objectives of this study were to evaluate the patient treated for deep vein thrombosis (DVT) with reference to clinical examination and radiological imaging. To compare the predictive value of clinical methods versus radiological methods in the assessment of recovery of a patient following treatment of DVT. To study the sensitivity and specificity of the clinical and radiological methods used in assessing the effectiveness of treatment of DVT.
Methods: A prospective observational study was conducted on 80 patients of 18-50 years age groups with deep venous thrombosis treated with standard treatment protocol at Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pune over a period of 2 years. All patients were assessed clinically and radiologically using colour Doppler, post treatment at an interval of 3 months and 6 months.
Results: At the end of 3 months of treatment, to detect complete recovery, the clinical assessment was found to have a lower sensitivity (56.25%) and specificity (81.25%) on comparison with radiological assessment. At the end of 6 months of treatment, to detect complete recovery, the clinical assessment was found to have a relatively better sensitivity (100%) but lower specificity (65.31%) on comparison with radiological assessment when compared to assessment after 3 months of treatment.
Conclusions: The study has suggested that clinical assessment of patients after treatment of DVT has a varied value as far as complimenting radiological assessment of the same series of patients is concerned. When assessing patients after 3 months of treatment, clinical methods were found to be far inferior to radiological methods while after 6 months of treatment they were found to be on par with radiological methods. Hence, clinical methods can be used along with radiological methods for assessment, but radiological methods remain gold standard.

Keywords: Clinical methods, Deep vein thrombosis, Doppler

INTRODUCTION

In a recent global epidemiological study, 52% (42% medical and 64% surgical) of 68,183 (55% medical and 45% surgical) inpatients in 358 hospitals across 32 countries were found to be at risk for developing venous thromboembolism (VTE). India contributed 2058 patients (46% medical and 54% surgical), where 54% (45% medical and 61% surgical) of hospitalized patients had risk factors for VTE the same as in the rest of the world.[1]

Extensive radiological evaluation causes more financial burden on the patient. Radiological assessment is also very subjective and changes according to the radiologist and the type of machine that is used. Added to that, it only covers the vascular component of deep vein thrombosis (DVT) sequelae. The dermatological

manifestations as well as the other local sequelae including arthropathy is not covered in radiological evaluation conventionally used, i.e., colour Doppler. However, radiological evaluation is the main and important investigation post DVT which is very frequently advised and is the current backbone of post-DVT evaluation.

Clinical evaluation in current era has taken a backseat because of overuse and over-reliance on radiological modalities of assessment. Proper use of clinical evaluation will not only reduce financial burden on patients but also add to evaluation of post-DVT sequelae in terms of dermatological and local complications. It is therefore, the need of current era to compare both the methods and to select a proper method or to select both the methods complimenting each other in assessing post-DVT syndrome. A good study is required to compare all the post DVT parameters and to assess both the methods to conclude to an effective post-DVT assessment. Also, the study should form the guidelines about the frequency of evaluation by clinical and radiological methods so as to ultimately reduce financial burden on patient.

Aim of this study were to evaluate the patient treated for deep vein thrombosis (DVT) with reference to clinical examination and radiological imaging. To compare the predictive value of clinical methods versus radiological methods in the assessment of recovery of a patient following treatment of DVT. To study the sensitivity and specificity of the clinical and radiological methods used in assessing the effectiveness of treatment of DVT.

METHODS

The study was conducted at Dr. D. Y. Patil Medical College and Hospital, DPU University, for a period of 2 months from May 2015 to September 2017 and is a prospective type of study using 80 cases.

Inclusion criteria

- Age group - 18-50 years
- Symptomatically positive patients
- Freshly diagnosed cases of DVT

Exclusion criteria

- Alcoholic Patients
- Patients taking NSAIDS (5)
- Acute Abdominal pain
- Immunocompromised patient
- Active TB

Plan of study

Written and informed consent of all patients was taken prior to their enrolment in the study.

All patients diagnosed with DVT and managed for the same were enrolled into the study for clinical and radiological assessment.

Management guidelines for DVT

Patients were started on LMWH (1.5mg/kg daily) along with oral Warfarin 5mg on Day 1.[2] They were overlapped for the next 5 days. After assessing the PT/INR of the patient following 5 days of treatment, patients were shifted onto oral Warfarin alone was continued for the next 3-6 months.

Clinical assessment

- History and clinical examination

Radiological assessment

- By using the following Probes

1. 7-11 MHz linear transducer with B-mode (grey scale) and colour spectral Doppler, in case of non-obese patients
2. For obese patients, author used 3.5MHz convex transducer to assess superficial femoral vein in the mid and distal portion of thigh.
3. When necessary, the author used power Doppler in cases where it is indicated.

Scanners

- Sonosite Micromax (Portable)
- Siemens Acusson X300

Figure 1: Sonosite micromax (portable).

Position of the patient supine with 15-20 degree flexion at the knee and slight external rotation at the hip. The Doppler for all the patients was performed by the same vascular sonologist. Expected duration of stay at the hospital was 2 weeks with assessments on Day1 and the time of discharge with reference to clinical examination and radiological assessment using colour Doppler. All

patients were followed up at the time of discharge, after 3 months and after 6 months with reference to clinical examination and radiological assessment. At the time of follow-up, the outcome of the patient was defined as to whether the patient, recovered, i.e., clinically (symptomatically) and radiologically relieved off DVT, either Completely, Partially or not at all, as per following observations. All the findings were recorded as per proforma.

Statistical analysis

The sensitivity and specificity of each method was calculated separately for each patient and appropriate statistical analysis was done.

RESULTS

Outcome by clinical assessment

After 3 months: In the study, after clinical assessment of patients being treated for deep vein thrombosis the outcome was found to be that 27 patients had complete recovery (33.75%), 51 patients had partial recovery (63.75%) and 2 patients had no recovery (2.5%) after 3 months of treatment.

Table 1: Outcome by clinical assessment after 3 months of treatment.

Outcome after 3 months	No. of cases	Percentage
Complete recovery	27	33.75%
Partial recovery	51	63.75%
No recovery	2	2.5%
Total	80	100%

After 6 months

In this study, after clinical assessment of patients being treated for deep vein thrombosis the outcome was found to be that 48 patients had complete recovery (60%), 31 patients had partial recovery (38.75%) and 1 patient had no recovery (1.25%) even after 6 months of treatment.

Table 2: Outcome by clinical assessment after 6 months of treatment.

Outcome after 6 months	No. of cases	Percentage
Complete recovery	48	60%
Partial recovery	31	38.75%
No recovery	1	1.25%
Total	80	100%

Outcome by radiological assessment

After 3 months

In this study, after radiological assessment of patients being treated for Deep Vein Thrombosis the outcome after 3 months of treatment was found to be that 32 patients had complete recovery (40%), 45 patients had partial recovery (56.25%) and 3 patients had no recovery (3.75%).

Table 3: Outcome by radiological assessment after 3 months of treatment.

Outcome after 3 months	No. of cases	Percentage
Complete recovery	32	40%
Partial recovery	45	56.25%
No recovery	3	3.75%
Total	80	100%

After 6 months

In the study, after radiological assessment of patients being treated for Deep Vein Thrombosis the outcome was found to be that 31 patients had complete recovery (38.75%), 47 patients had partial recovery (58.75%) and 2 patients had no recovery (2.5%) even after 6 months of treatment.

Table 4: Outcome by radiological assessment after 6 months of treatment.

Outcome after 6 months	No. of cases	Percentage
Complete recovery	31	38.75%
Partial recovery	47	58.75%
No recovery	2	2.5%
Total	80	100%

Statistical analysis

At 3 months

For partial recovery, to detect partial recovery of the patient, the sensitivity of the clinical method was 80%, specificity was 57.14%, positive predictive value was 70.59% and negative predictive value was 68.97%. The Likelihood ratio of a positive test was 1.867 and Cohen's kappa was 0.3786.

For complete recovery, to detect complete recovery of the patient, the sensitivity of the clinical method was 56.25%, specificity was 81.25%, positive predictive value was 66.67% and negative predictive value was 73.58%. The Likelihood ratio of a positive test was 1.867 and Cohen's kappa was 0.3786.

At 6 months

For partial recovery, to detect complete recovery of the patient, the sensitivity of the clinical method was 100%, specificity was 65.31%, positive predictive value was 64.58% and negative predictive value was 100%. The Likelihood ratio of a positive test was 2.882 and Cohen's kappa was 0.5933.

Table 5: Statistical analysis for partial recovery after 3 months of treatment.

	Positive	Negative	Total
Positive	36	15	51
Negative	9	20	29
Total	45	35	80

Sensitivity - 80%; Specificity - 57.14%; Positive Predictive Value - 70.59%; Negative Predictive Value - 68.97%

Table 6: Statistical analysis for complete recovery after 3 months of treatment.

	Positive	Negative	Total
Positive	18	9	27
Negative	14	39	53
Total	32	48	80

Sensitivity - 56.25%; Specificity - 81.25%; Positive Predictive Value - 66.67%; Negative Predictive Value - 73.58%

Table 7: Statistical analysis for partial recovery after 6 months of treatment.

	Positive	Negative	Total
Positive	30	1	31
Negative	17	32	49
Total	47	33	80

Sensitivity - 63.83%; Specificity - 96.97%; Positive Predictive Value - 96.77%; Negative Predictive Value - 65.31%

For complete recovery, to detect partial recovery of the patient, the sensitivity of the clinical method was 63.83%, specificity was 96.97%, positive predictive value was 96.77% and negative predictive value was 65.31%. The Likelihood ratio of a positive test was 21.06 and Cohen's kappa was 0.567.

Table 8: Statistical analysis for complete recovery after 6 months of treatment.

	Positive	Negative	Total
Positive	31	17	48
Negative	0	32	32
Total	31	49	80

Sensitivity - 100%; Specificity - 65.31%; Positive Predictive Value - 64.58%; Negative Predictive Value - 100%

DISCUSSION

Outcome following clinical assessment

The final outcome by clinical assessment after 3 or 6 months of following the treatment protocol was assessed as complete recovery, partial recovery and no recovery.

Complete recovery was defined as patients having no clinical symptoms, signs or signs of complications of deep vein thrombosis following the 3 or 6 months of treatment.

Partial recovery was defined as patients having one or more of the clinical symptoms, signs or signs of complications of deep vein thrombosis following 3 or 6 months of treatment.

No recovery was defined as patients having no signs of recovery and instead having all the clinical symptoms, signs and signs of complications of deep venous thrombosis following 3 or 6 months of treatment.

In the study, after 3 months of treatment, the final outcome following clinical assessment shows 27 patients (33.75%) have completely recovered, 51 patients (63.75%) have partially recovered and 2 patients (2.5%) have not recovered.

After 6 months of treatment, the final outcome following clinical assessment shows 48 patients (60%) have completely recovered, 31 patients (38.75%) have partially recovered and 1 patient (1.25%) has not recovered. Hence in present study, more patients are seen to have completely recovered (60%) after 6 months of treatment than after 3 months of treatment (33.75%) following clinical assessment (Table 1,2). According to Hirsch J et al, the sensitivity of clinical diagnosis is low because many potentially dangerous venous thrombi are clinically silent. The specificity of clinical diagnosis is low because the symptoms or signs of venous thrombosis all can be caused by non-thrombotic disorders.[3]

Outcome following radiological assessment

The final outcome by radiological assessment after 3 or 6 months of following the treatment protocol was assessed as complete recovery, partial recovery and no recovery.

Complete recovery was defined as patients having none of the above radiological findings suggestive of deep venous thrombosis or it's complications following 3 or 6 months of treatment.

Partial recovery was defined as patients having one or more of the above radiological findings suggestive of deep venous thrombosis or it's complications following 3 or 6 months of treatment.

No recovery was defined as patients having all the above radiological findings suggestive of deep venous thrombosis and its complications following 3 or 6 months of treatment.

In this study, after 3 months of treatment, the final outcome after radiological assessment shows complete recovery in 32 patients with a frequency of 40%, partial recovery in 45 patients with a frequency of 56.25% and no recovery seen in 3 patients, i.e., 3.75%.

Hence in present study, after 3 months of treatment, 56.25% of patients showed partial recovery and 40%

showed complete recovery to treatment on radiological assessment as shown in table 3.

After 6 months of treatment, the final outcome after radiological assessment shows complete recovery in 31 patients with a frequency of 38.75%, partial recovery in 47 patients with a frequency of 58.75% and no recovery seen in 2 patients, i.e., 2.5%.

Hence in present study, after 6 months of treatment, 58.75% of patients showed partial recovery and 38.75% showed complete recovery to treatment on radiological assessment as shown in table 4.

Statistical analysis

During each interval, author further analyzed the sensitivity, specificity and predictive value for clinical methods versus radiological methods based on the ability of each method to detect partial recovery and complete recovery, separately, which is shown as follows.

At the end of 3 months

- To detect complete recovery of the patient, the sensitivity of the clinical method is 56.25%, specificity is 81.25%, positive predictive value is 66.67% and negative predictive value is 73.58%. The Likelihood ratio of a positive test is 1.867 and Cohen's kappa is 0.3786.
- To detect partial recovery of the patient, the sensitivity of the clinical method is 80%, specificity is 57.14%, positive predictive value is 70.59% and negative predictive value is 68.97%. The Likelihood ratio of a positive test is 1.867 and Cohen's kappa is 0.3786.

Hence present study showed that at the end of 3 months of treatment, the clinical assessment was found to be an inferior method as compared to radiological assessment of the patient's recovery from deep venous thrombosis (DVT).

102 patients with suspected DVT who presented to the outpatient departments of 2 tertiary-care hospitals underwent a clinical assessment and venography. The sensitivity of the clinical examination in this study was 66% (95% CI, 50%-82%) and the specificity only 53% (95% CI, 38%-69%).[4]

At the end of 6 months

- To detect complete recovery of the patient, the sensitivity of the clinical method is 100%, specificity is 65.31%, positive predictive value is 64.58% and negative predictive value is 100%. The Likelihood ratio of a positive test is 2.882 and Cohen's kappa is 0.5933.
- To detect partial recovery of the patient, the sensitivity of the clinical method is 63.83%, specificity is 96.97%, positive predictive value is 96.77% and negative predictive value is 65.31%. The Likelihood ratio of a positive test is 21.06 and Cohen's kappa is 0.567.

Hence present study showed that at the end of 6 months of treatment, the clinical assessment was found to be on par with the radiological assessment of the patient's recovery from deep venous thrombosis (DVT).

According to Huisman MV and Klok FA, non-compressibility of either the femoral or popliteal vein, or both, is diagnostic for a first episode of acute proximal DVT in patients suspected of having clinically manifest DVT, with a sensitivity of 94% (95% CI, 92-95) and specificity of 98% (95% CI, 97-98).[5] The inter-observer agreement of CUS is excellent, with a kappa of 1 for proximal DVT of the leg.[6,7]

According to Kraaijenhagen RA, Lensing AW et al, ultrasonography is considered to be the best non-invasive diagnostic method and has been evaluated against venography in many studies, showing an average sensitivity and specificity of 97% for proximal deep vein thrombosis.[8]

CONCLUSION

At the end of 3 months of treatment, the clinical assessment methods for patient being treated for DVT was inferior when compared to radiological methods in terms of sensitivity and specificity as well as positive predictive and negative predictive value.

At the end of 6 months of treatment, the clinical assessment methods were at par with radiological methods, with regards to sensitivity and negative predictive value but it still had an inferior value with regards to specificity and positive predictive value.

At the end of present study, the conclusion that is attained is that radiological methods of assessment are more sensitive and specific and hence more superior when compared to clinical methods of assessment of patients treated for deep venous thrombosis (DVT) after 3 months but can be useful in making the same assessment after 6 months of treatment, especially in financially constrained populations.

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PROFORMA

	Day 1	After 3 months	Result after comparing	After 6 months	Result after comparing
Clinical assessment					
Inspection Pre-tibial edema Hyperpigmentation Redness Venous ectasia Joint mobility Palpation Skin induration Signs of acute venous insufficiency: Homan's sign - present/absent Moses' sign - present/absent Signs of Complications Varicose veins Varicose ulcers Eczema					
Radiological assessment					
DVT Screening - spontaneous flow - present/absent - compression of the vein possible/not possible - color filling of the lumen by color flow dus - present/absent - respiratory flow variation - present/absent - venous distention - present/absent Signs of complications -varicosities -sf/sp incompetence -perforator incompetence					