TO DETERMINE WELLS CRITERIA AS A RELIABLE CLINICAL TOOL IN DIAGNOSIS OF DEEP VEIN THROMBOSIS

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DISSERTATION

Submitted to the

KLE Academy of Higher Education and Research, Belagavi, Karnataka

In partial fulfilment

of the requirements for the degree of

M.S. (MASTER OF SURGERY)

IN

GENERAL SURGERY

Department of General Surgery

J.N.MedicalCollege,

Belagavi – 590010, Karnataka, India.

APRIL 2020

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI, KARNATAKA

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Sir/Madam,

The softcopy of thesis entitled "WELLS CRITERIA AS A RELIABLE CLINICAL TOOL IN DIAGNOSIS OF DEEP VEIN THROMBOSIS" has been submitted for Anti-Plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of 5% (Five percentage) which is within the acceptable limits of 10% as per the guidelines given by UGC.

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Yours sincerely,

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Guide.

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ABBREVIATIONS

ABG	**–**	Arterial Blood Gas Analysis
Anticoag	–	Anticoagulant.
APTT	–	Activated Partial Thromboplastin Time.
BBB	**–**	Bundle Branch Block
CHF	–	Congestive Heart Failure.
CI	**–**	Confidence interval
CT	**–**	Computed tomography
CTPH	**–**	Chronic Thrombo-embolic Pulmonary Hypertension.
DEC.	**–**	December
Dept.	**–**	Deparment
'DVT'	**–**	Deep Vein Thrombosis
ECG	**–**	Electrocardiogram
Esp.	–	Especially.
F/U	–	Follow Up.
Fig.	–	Figure.
Grp	**–**	Group
Gen.	**–**	General
i.e.	–	That is.
IL	**–**	Interleukin
Inj.	–	Injection.
IVC	–	Inferior Vena Cava.
JAN.	**–**	January
MI	–	Myocardial Infarction.
mm Hg	**-**	Millimeter of Mercury
MRI	**–**	Magnetic Resonance Imaging
NCPE	–	National Colloborative study of prospective investigation diagnosis of Pulmonary Embolism.
No.	–	Number.
NPV	**–**	Negative predictive value
OCP	–	Oral Contraceptive Pill.
'PE'	**–**	Pulmonary Embolism

PA	**–**	Pulmonary Angiography
PaO2	**–**	Partial Pressure of Oxygen
Pl.	–	Pleural.
Plt	–	Platelet
PPA	**–**	Pretest Probability Test
PT	–	Prothrombin Time.
R/F	**-**	Risk factors
RAV	–	Radionuclide Ascending Venography.
RVH	**–**	Right Ventricular Hypertrophy
SN	**–**	Sensitivity
SP	**–**	Specificity
Subj	–	Subject.
THR	–	Total Hip Replacement.
TKR	–	Total Knee Replacement.
USG	**–**	Ultrasonography.
V/Q	**-**	Ventilation perfusion scan
-VE	–	Negative.
+VE	–	Positive.
Vit.K.	**–**	Vitamin K
VKA	**–**	Vitamin K antagonists
Yrs.	**–**	Years.

ABSTRACT

Background: Thrombosis refers to the formation of an abnormal mass within the vascular system from constituents of blood. When it occurs in deep veins, it is known as Deep Vein Thrombosis In our day-day experience, it was unveiled that due to lack of a reliable tool or criteria to diagnose Deep Vein Thrombosis earlier, either patient suffered more with morbidities or reached a stage of moribund condition

Objectives: To determine accuracy of Wells criteria as a predictive tool in diagnosis of deep vein thrombosis in patients with suspected deep vein thrombosis in our clinical setup.

Methodology: The present study was a prospective study from January 2018 to December 2018. In my study 40 subjects were included which had patients more than 18 years of age, any gender, came with complain of limb swelling and importantly gave valid consent but pregnant patients, already known case of DVT or Bleeding diathesis were excluded. Risk will be calculated according to the wells criteria tool and confirmed with color Doppler of the affected limb.

Result: Results was well established in favor of Wells criteria to diagnose DVT as higher frequency of people were more than 50 years with male preponderance and history of smoking present. Subjects had leg swelling with edema and calf tenderness

with paresis or paralysis or immobilization/bedridden. Criteria showed 100% sensitivity with NPV of 100% and accuracy of 90%.

Conclusion: This criteria can help the clinicians to treat the disease before it takes a violent course and help the patients live a healthy life.

Key words: Deep Vein Thrombosis, Wells Criteria, Color Doppler

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INTRODUCTION

Clotting of blood (= thrombus) in deep veins of human body, usually leg is known as Deep Vein Thrombosis ('DVT').[1]

Complications like post phlebitic syndrome, pulmonary embolism ('PE'), pulmonary hypertension can occur and can even cause death. Venous insufficiencies of long duration (= 'Post Thrombotic Syndrome') can lead to calf swelling, ankle swelling and dull aching pain in leg with ulcerations.[2] The mean incidence of first 'DVT' in people is (5 per 10000 person-years).[2]

Predisposing risk factors like surgery, estrogen exposure, prolong immobilization like in hospitalisation, cigarette smoking, obesity, kidney disease, air travel, OCP or permanent factors like stroke worsens it.[2,3] Deep leg veins constitutes more than 90% of thrombophlebitis and phlebothrombosis.[4]

Genetic mutations (autosomal dominant) which are common:[4]

1. Leiden (factor5) mutation: leads to resistance of endogenous anticoagulant – which activates proteinC which plays role in inactivation of the factor 5 and 8.
2. Prothrombin gene mutation resulting in increaseprothrombin.

Factors favouring formation of 'DVT' known as Virchow's Triad consist of[5,6]

1. Venous stasis.
2. Hypercoagulable state
3. Endothelial wall damage.

This venous stasis brings a low oxygen tension with induction of proinflammatory genes.[7]This thrombi if dislodge from its site of formation, can embolise vena cava, right atrium & ventricle subsequently to pulmonary arterial system,leading to pulmonary embolism.

Clinical scoring system has been developed viz., Well's Score which counts history and various clinical signs to help the clinicians draft a clinical diagnosis of the 'DVT'.

Objective of this study is to determine effectivenessof "Wells criteria as a predictive tool in the diagnosis of 'DVT' in patients suspicious of 'DVT' in our clinical setup".

OBJECTIVES

The objective of the study was to determine Wells Criteria as a reliable clinical tool in evaluation of Deep Vein Thrombosis (DVT).

REVIEW OF LITERATURE

ANATOMY

Vein:

Like their counterparts i.e. arteries, veins are differentiated into small, medium and large,with no clear demarcations because they blend into one another. Three layers are present which are tunica media intima and adventitia. But they are not as well defined as in arteries. In largeveins the adventitia is much larger than the media whereas in large arteries thetunica media is much thicker. Due to this very reason veins are not able to retaintheir shape. The amount of elastic tissue in veins is also much less compared toarteries. Even in some larger veins the internal elastic membrane may not bewell developed or even absent. Valves are an important part of veins whichserve to prevent backflow especially from the lower extremities.[8]

Categories of peripheral veins:

1)Suprafacial (superficial)

2)Perforating Veins

3)Subfascial Veins (Deep)

The Superficial (suprafascial) system of veins

It consists of a web like network whichare interconnected at various places and intricately arranged and the veins thatform this system are mostly unnamed.But there consist of a few superficialveins,the position of which fairly remain constant and like the deep veins.

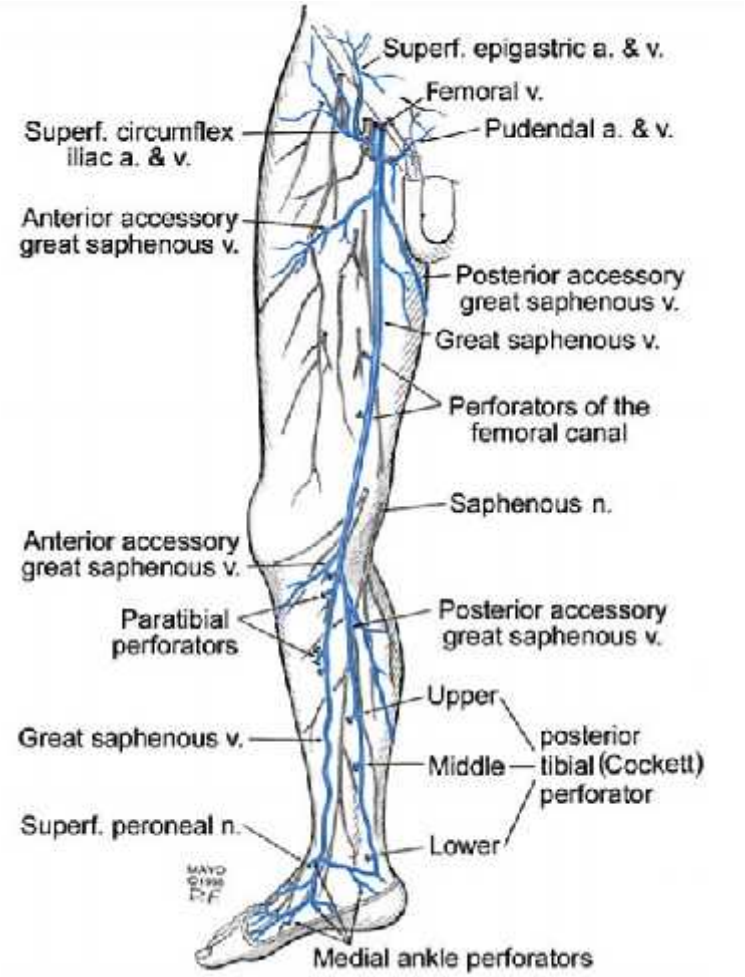


Figure 1 showing superficial and perforating veins of leg

Perforating vein:

Most of the veins in the superficial compartment collect and carry blood to great as well as the small saphenous veins, following which these inturn supply their blood into the deep system. There are number ofperforating veins that connect the superficial veins in deep fascia to join with the deep veins.[8]

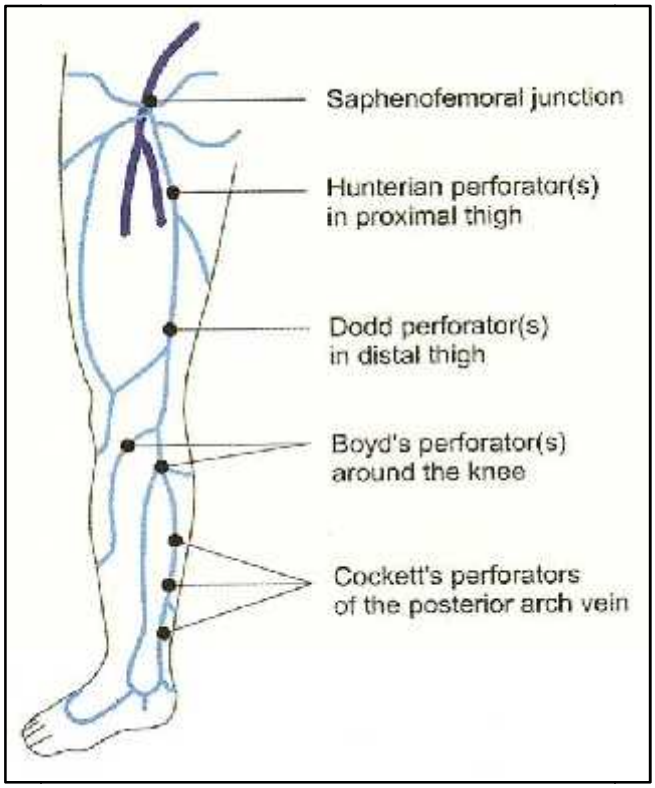


Figure 2 showing perforators of leg

Deep Venous System[8]

Primary veins includes as depict in diagram

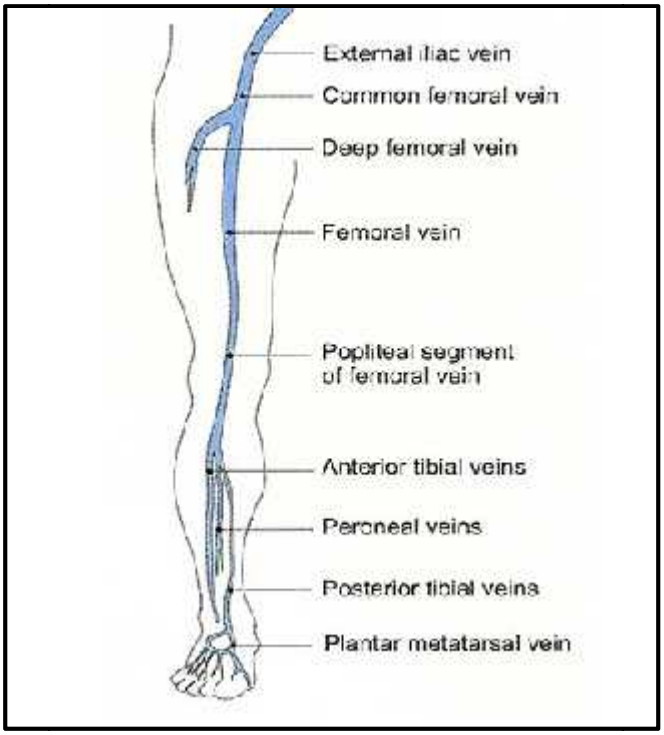


Figure 3 showing deep veins of lower limb

EPIDEMIOLOGY:

Most common population which got effected by 'DVT' is elder population. It is one of the most common disease was first reported in the Middle Age in the year 1271 in a patient named Raoul who suffered from unilateral edema proliferating to his leg.[8,9]

Mean adjusted incidence of thevenous thromboembolism (VTE) is-117 per 1 lakh annually with higher age among males than females.[9] Sex equally afflicted by VTE but men are more prone for recurrence. [10,11]

Afro-american race are more prone for VTE but recurrence rates are more in Caucasian race than others[12]Young age child have less incidence with percent of (0.07 -0.14) per 10,000 children.[13,14] Neonatal period has highest incidence which is followed by another spike during adolescence with more incidence found in adolescent females due to pregnancy and OCP usage.[15,16]

In paediatric age group, fatal infections, sickle cell, anti-phospholipid syndrome,trauma associated with hypercoagulable state.[25]

Pregnant women are more prone for 'VTE' as compared to non pregnant of same agegroup with caesarean section at a greater risk than vaginal delivery.[17]Postpartum period has highest incidence.[18]

Approximate risk of 'DVT' after undergoing general surgery – 15-40% and knee and hip replacement – 40-60%.[19]

In Indian population, due to inaccurate reporting, incidence of 'VTE' is expected to be similar to western population.[20] Improper management of 'DVT' result in recurrence of 'VTE' which accounts for 20-50%[21]

NATURAL COURSE

After clinching the diagnosis and management of 'DVT', 25% can develop post thrombotic syndrome after a period of two years.[22]

A study[23] suggests people having higher level of IL-8 are more prone for 'VTE' support interleukin role in the etiology and pathology.

A study showed powerful relationship between 'DVT' in one month and risk of 'PE' in a 3 month following recent respiratory tract infection.[24]

RISK FACTORS

Injury to endothelium ,blood flow stasis, and hypercoagulation of blood are main responsible factors.

Risk factors which are genetic are classified into:[26]

A) Strong factor: deficiency of protein C, S and anti – thrombin.
B) Moderate: Leiden (factor 5), blood grp (non O grp),fibrinogen factor, prothrombin factor
C) Mild : fibrinogen, factor XI and XIII variants.[1]

Risk factors related to patient

A)Inherited patient-specific factors[21]

- Factor V Leiden and activated protein C resistance
- mutation of prothrombin gene
- deficiencies of Antithrombin III, Protein C and S
- Dysfibrogenaemia
- Increase homocysteine level
- Idiopathic VTE.

Acquired patient-specific factors

- Previous attack of thromboembolism
- Malignancy
- age>40 years
- obesity
- varicose vein
- prolonged immobilization
- dehydration,
- heart failure, nephrotic syndrome, stroke
- pregnancy, puerperium, oral contraceptives, hormone replacement therapy
- antiphospholipid antibody syndrome.[21]

Figure 4 showing risk factors associated with DVT

Classify as under:[21]

Surgery-specific risk factors

Table 1:Factors predisposing for 'DVT' postsurgery:[21,27,28]

Factor	Mild risk	Moderate risk	High risk
Routine surgery (age)	<40yrs	>40yrs	>40yrs
Surgery duration (mins)	<60	>60	>60
Orthopaedic surgery			THR,TKR
Trauma			Extensive soft tissue injury fracture
Medical conditions	pregnancy	postpartum period, MI, CHF	Stroke.

Table 2:Incidence(%) of DVT AND PE after surgery.[21,27,28]

Event	Mild risk	Moderate risk	High risk
'Without Prophylaxis'	(2)	(10-40)	(40-80)
'PE(Symptomatic)'	(0.2)	(1-8)	(5-10)
'PE(Fatal)'	(0.002)	(0.1-0.4)	(1-5)

CLINICAL FEATURES

Patients with DVT may or may not be symptomatic.

If symptomatic, they may present with complaints of pain, swelling of the lower limb associated with calf tenderness.[36,39]

Homans' sign may be positive.

DVT may be suspected based on these features and patient can be further evaluated

"*Phlegmasia alba dolens*" shows edema, pain, and blanching without cyanosis and "*phlegmasiaceruleadolens*"shows these features in addition to cyanosis, which progresses proximally and leads to formation of bleb/bulla.

Signs and Symptoms[21]:

- Tenderness
- Palpable thick veins
- Distended veins
- Discoloration of the limb/ cyanosis

DIAGNOSIS

To diagnose a case of DVT, commonly accepted evidence based approach standardising is clinical assessment using risk factors and clinical features.[1]

The model which is most accepted made by Well's and his colleague[29] dividedpatients in the following manner:

1. If score is less than one- unlikely of 'DVT'
2. If score is more than or equal to two- likely of 'DVT'[30]

An initial model based of clinical presentation and risk factors,grouped people into following group

A) Low risk group- had 5% risk of 'DVT'

B) Moderate risk group- had 33% risk of 'DVT'

C) High risk group - had risk of 85% of 'DVT'

Figure 5: Pretest probability assessment (Well Score)[29]

Clinical Variable	Score
Active cancer	1
Paralysis, paresis, or recent cast	1
Bedridden for >3 days; major surgery <12 weeks	1
Tenderness along distribution of deep veins	1
Entire leg swelling	1
Unilateral calf swelling >3 cm	1
Pitting edema	1
Collateral superficial nonvaricose veins	1
Alternative diagnosis at least as likely as DVT	−2

Low risk group if Point Score is 0 or less

Moderate- risk group Is 1 to 2

High- risk group Is 3 or Greater

NON-INVASIVE TEST

1)'D-DIMER ASSAY'

Fibrin degraded products formed as soon as plasmin degrades fibrin clots which are thrombin generated.[30]In suspected VTE, 'D-Dimer assay' is the most reliable biomarker for early detection of it.

Therefore, together 'D-Dimer' assay and clinical risk stratification excludes 25% VTE cases.[31] This combination has good exclusion for recurrent DVT and in subject group who has low chance or probabilities.[8]

Types of assay for evaluation of D-Dimer:[8]

- Enzyme-linked Immunoassay
- Latex-Agglutination Assay
- Red blood cell whole blood agglutination assay(simpli RED)

This assay has high sensitivity upto 95 percent but lack in specificity for diagnosis of VTE. Nearly NPV is 100%.

False negative results seen:

1. In cases or subjects on heparin use

2. late presentation that is if symptoms are for more than 14 days

3. Below knee 'DVT'.[1]

2)'VENOUS USG'

A safe, non – invasive, reliable, available and inexpensive gold standard tool for patients with diagnosis as 'DVT' likely.[32]

There are 3 types of venous ultrasonography:

- Colour Doppler image
- B-mode image also known as **Compression-USG**
- B-mode image and Doppler-waveform analysation also known as **Duplex ultrasound**

Pulse doppler signal produces images in color doppler sonography.[33]

In vein, flow of blood is spontaneous augmented by manual pressure and phasic with respiration.

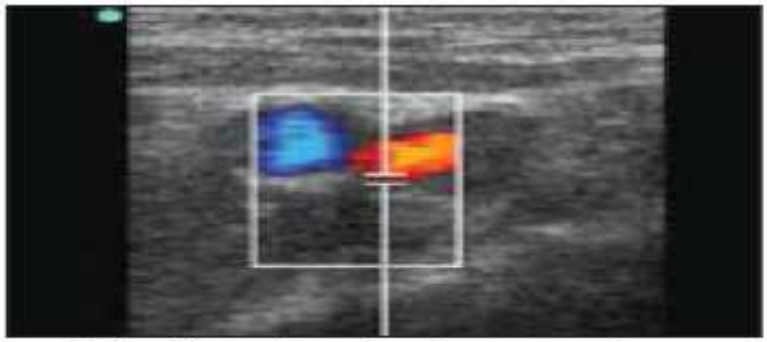
Compression ultrasonography is performed on deep veins which are proximally like:

- Common-femoral vein,
- Popliteal vein
- Femoral vein

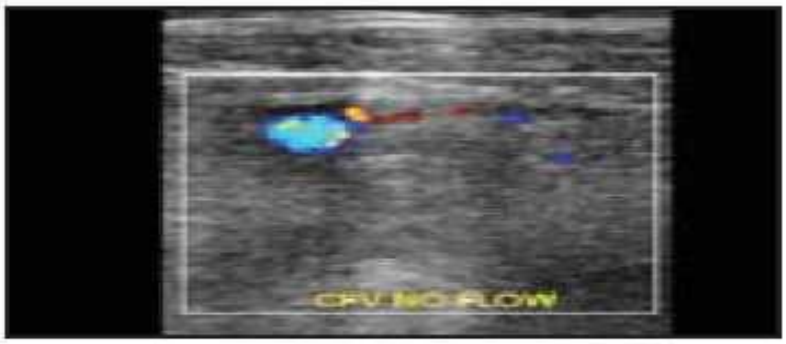
For distal venous system combined colordoppler and duplex usg clinch the diagnosis.[34]

Criteria to detect venous-thrombosis on USG are -

- Lumen of vein fails to compress under gentle probe pressure.
- Absent phasic flow pattern
- Responds to valsalva
- Complete loss of signals either spectral and color-doppler from lumen of veins.[35]



Color-flow Doppler in normal vessels.



Color-flow Doppler in deep vein thrombosis.

Figure 6: Color Doppler flow in normal vein and thrombosed vein

Advantage of ultrasonography of veins is that no contact to radiation and disadvantage of venous ultrasonography is it is less efficacious to detect thrombosis distally[36].

Sensitivity of venous ultrasound for 'DVT' in veins of calf region is 73%.[37]

To diagnose symptomatic 'DVT' proximally, B-mode imaging (compression ultrasound) alongwith or without Duplex scan imaging has 95% sensitivity and 96% specificity.[37]

Non compressibility of veins help to identify DVT

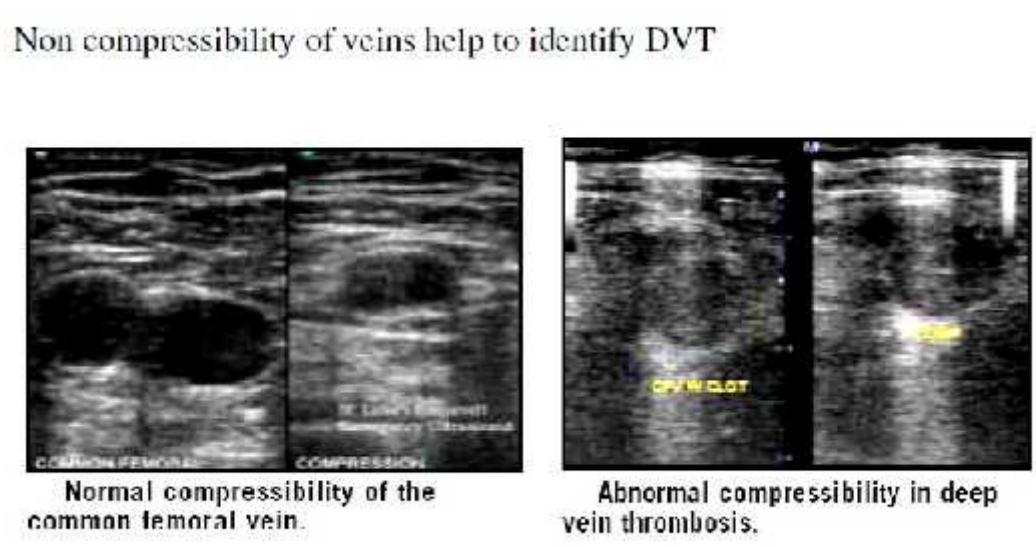


Figure 7: Sign on colordoppler

INVASIVE TEST

1) 'CONTRAST VENOGRAPHY'

It is the definitive confirmatory tool to clinch the condition of 'DVT' but it is invasive. So non-invasive tests like venous usgand D-dimer is better, ideal and precise in case of acute/sudden episode of DVT.

In this test, a contrast dye is injected which is non iodinated andcannulated in a pedal vein.

Omnipaque diluted in normal saline in large volume results in improved image quality and better deep venous filling.[38]

The cardinal sign which is most reliable for identifying using venography: persistent intral-luminal filler defect in ≥2views.[38]

Second dependable criteria is a sign – sudden cut-off of a deep vein[39]

This is highly specific[8] as well as highly sensitive especially in recognising extent, and clot localisation[8]

Disadvantages:

- Exposure to irradiation.
- Painful
- Invasive
- Renal dysfunction.
- Allergic reaction risk.
- Induction of new DVT by sonography.[40]
- Thrombogenic.

2) IMPEDANCE PLETHYSMOGRAPHY

Basis of measurement of this technique is two electrodes on the calf is applied and after the venous occlusion cuff is deflated, rate of change in impedance is noted.

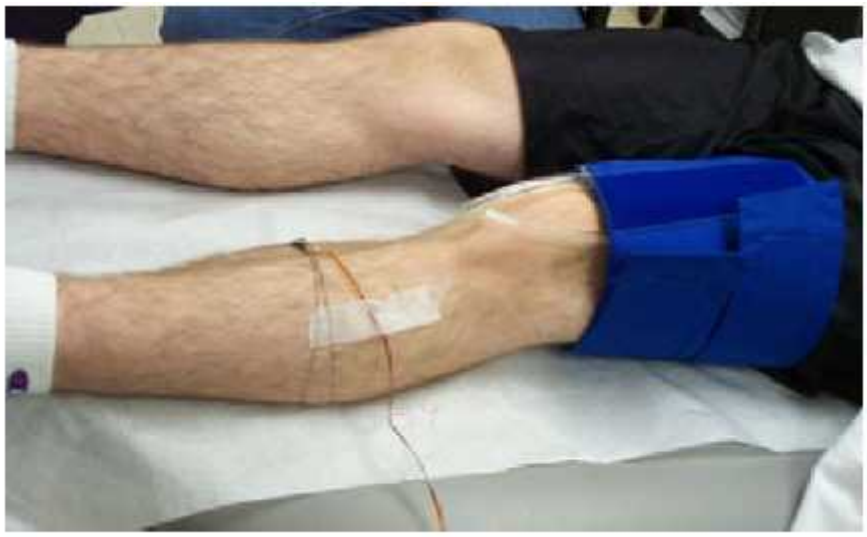


Figure8: Technique of Impedance plethysmography

Advantages :

- Safe
- Reliable
- Portable
- Non invasive

Disadvantages:

- Undetects calf-thrombi and small non–obstructing thrombus of proximal veinsIn presence of DVT, delay in outflow of venous blood results in more gradual change in impedance and vice-versa in free-flow.[41]

3) MAGNETIC RESONANCE IMAGING

Diagnostic test of option:- for suspicious IVC and iliac-vein thrombosis when CT-venography is technically inadequate/contraindicated.

It is modality having high sensitivity in detecting pelvic and calf DVT[42] and upper extremity venous thrombosis.[43]

Advantages:

- No risk of ionising radiation.

Disadvantages:

- Expertise required
- Scarce
- Costly.

DVT Diagnosis:

1. Impedance plethysmography has sensitivity 96%,50% &38% to diagnose acute-DVT in proximal,popliteal&distal veins respectively.
2. Plasma D-dimer - A negative value can exclude DVT and PE.
3. Contrast Venography- gold standard to diagnose ‘DVT’.

It can determine all forms of DVT.

4. Duplex or compression ultrasonography of popliteal and femoral veins has specificityand sensitivityof 97% to detect DVT.

   It has sensitivity for proximal-DVT but less calfDVT.

5. RAV can assess"thrombusburden"inpulmonary,femoral,caval and iliac circulatory-flow.[44] Sensitivity and specificity of 90% and 92% respectively to detect DVT of proximal leg veins.

VTE diagnosed, so now tests to be done:[21]

1. Recognise inherited R/F with lifelong or extended period of management but this is not possible for life saving situations.
2. Baseline tests –platelet,APTT,PT before starting anticoagulants.

PULMONARY EMBOLISM

Wells Diagnostic Scoring System based on clinical manifestations helps in diagnosis of PE.

These clinical features areseen in most of the patients.[21,45.]

Diagnostic criteria:

1. ABG:- PaO2 ≤80 mmHg seen in 26%patients.[21,45]
2. CT/MRI/Spiral CT-angiography – have high specificity to identify embolus.
3. Electrocardiogram– salient features which can be seen on ecg are:
   A) leadI-appearance of S-wave
   B) lead III-Q-wave and inverted T wave

In some cases patient having arrythmias, strain, P-pulmonale, RVH and right BBB may be present.

ST segment or T wave may show some nonspecific changesfound in 49% cases.[45]

4. Plasma D Dimer - A negative value can exclude DVT and PE.[1]

5. X-Ray Chest – 68% of patients may have pulmonary parenchymal abnormality and atelectasis.

Pulmonary edema, raised diaphragm and pl.effusion might exist.[21]

6. Pulmonary angiography- gold standard test, but performed less due to the availability of CT/MRI/spiral CT angiography. A diagnostic strategy that includes clinical evaluation, V/Q scan and evaluation for DVT would decrease the number of patients who require pulmonary angiography from 72% to 33%.[21]
7. "Ventilation/Perfusion scan (V/Q scan)" : Within normal limit V/Q scan entirely excludes PE.[21]

"PIOPED-criteria" – It is indicated PE in 87%patients. (NCPE).

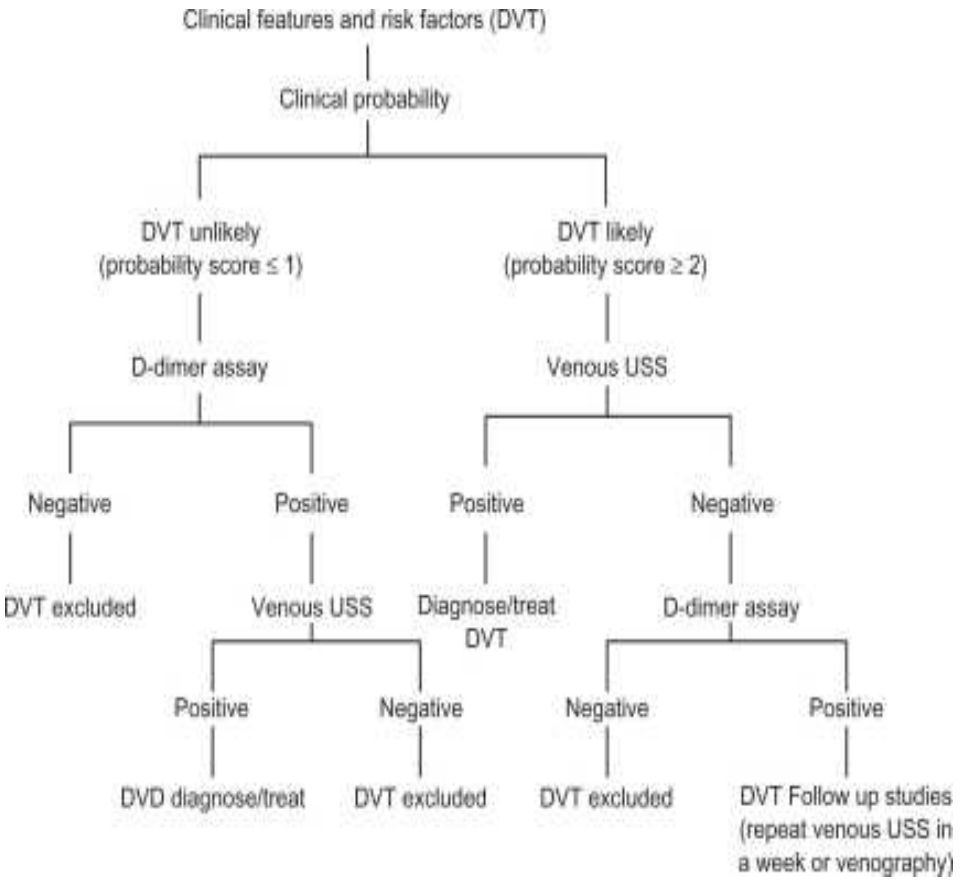


Figure 9: Flow chart to diagnose DVT

PPA uses a secure exemplary such as Well Score.

If outcome≤1, D-Dimer performed.

If nugatory," DVT" ostracized.

If evaluation +ve, Venous-USG suggested which rules-out "DVT".

While "DVT" diagnosed is made if ultrasound is unambiguous.[8]

If result≥2 , venous-USG indicated else D-dimer assay.

So, positive D–Dimer result indicates follow – up studies while negative D-dimer result excludes DVT as diagnosis.

In F/U study, USG in 6–8days or "venography".

The flow chart is not asked-for in gravid as D-Dimer is maliciously elevated.[8]

TREATMENT

The major breakthrough in treatment of DVT was made in last 100 years where first half century was marked with the discovery of anticoagulants and 2nd half marked with the easier way out of anticoagulant treatment, end of bed rest dogma and allowance of ambulation.

Complementary treatments are developed. New oral anti coagulants decrease illness via safe and protracted cure.

Optional method: micro bubbles developed for safe early removal of thrombus. Antiplatelet drugs and statins use to reinforce DVT therapeutic arsenal.

Emergence of oral anticoagulants[46] reduced PE mortality from (18%) to (0.4%)

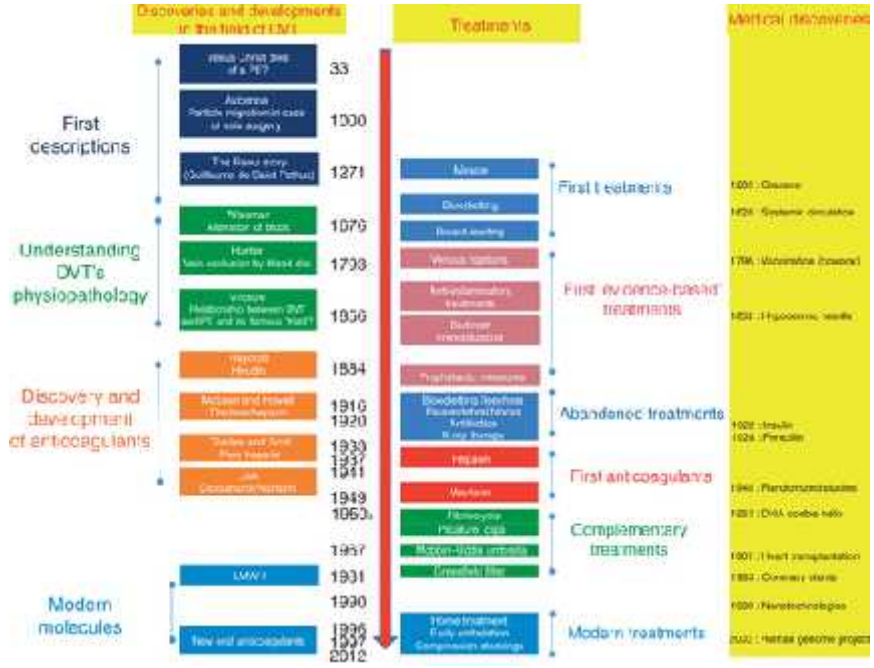


Figure 10:Brief summary of 'DVT' history and treatment

Heparin was widely used in 1940s with variable duration of treatment like 7-10 days.[46,47.] Introduction of oral vit.K antagonists (VKAs) in led to lengthened cure.[8]

VITAMIN K ANTAGONISTS (VKAs)

In 1939yr, Link and his co workers proved "coumarin" antagonised by Vit.K.

After 2 yrs, this 'dicoumarol' as inaugural to cure "DVTs".

"Link" commenced the tale of warfarin[8] .It was thoughtful to be very toxic for humans which in 1954 was commercialised as therapeutic agent.

Heparin and VKAs proved to be complementary to each other rather than competing with each other.

VKA's per oral with prolonged management and heparin is parenteral with immediate effect.[35]

Thereafter, a sequence was classic which was heparin plus "VKAs" .

Due to Jorpes[4],subjects benefitted from this curative schema in absence of all contra indications. 31 out of 37 patients got admitted in Cleveland University hospital for DVT and were prescribed heparin followed by VKAs.[8,46,48]

In this modern era, treatment of DVT is ambulation with complementary treatment.

METHODOLOGY

The present study was done in the KleDr. P.K and M.R.C, Belgaum from Jan.2018 to Dec. 2018.

Study- Design

The study-design was cross-sectional.

Duration and period

one year (Jan.2018 to Dec. 2018)

Place

This study was carried out in the Dept. of Gen.Surgery, KlesDr. P.K. and M.R.C, Belgaum.

Source of Data

Patients attending General Surgery OPD with lower limb swelling, and clinically suspected to have DVT, diagnosed and confirmed by a Colour Doppler of affected lower limb, and getting admitted to KlesDr. P.K. and MRC, Belgaum for the treatment.

Sample size

The study sample was comprised of 40 patients

Sampling procedure

Since no similar studies have been reported in the literature regarding prevalence of Deep Vein Thrombosis applying thumb rule 40 cases were included

Selection criteria

i) Inclusion criteria

- Patients with Lower limb swelling
- Patients giving valid consent
- Patient≥18 yrs.
- Male / Female patients

ii) Exclusion criteria

- Patients who refuse to give consent
- Pregnant woman
- Previously diagnosed as deep vein thrombosis
- Patients with bleeding diathesis

Ethical clearance

Prior to the commencement, the Ethical Clearance was obtained from the Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belagavi

Informed Consent

After sorting out according to criteria, consent taken on paper.(Annexure I).

Collection of data

Parameters like peer-group, gender, past medical history, personal history of smoking, side affected, pain in affected limb, symptoms of chest pain or dyspnea on minor exertion, unambulated>3days due to extensive operations, and medically restricted mobility of lower-limbs(LL) were noted. The patients were subjected to clinical examination and evaluated for ability to walk, and signs of pitting oedema.

Also vitals and weight were noted. Results plotted on a pre-designed pro-forma(Annexure- II).

Investigation

All selected patients underwent following investigation

- Colour doppler of affected lower limb

Procedure

Patient who came with lower limb swelling were clinically examined and suspected patient based on well's criteria were split up as low, inter-mediate and high-risk categories.

The assessment score is as follows:

	Points
Active cancer (treatment ongoing or within previous 6 months or palliative)	1
Paralysis, paresis, or recent plaster immobilization of the lower extremities	1
Recently bedridden for 3 days or major surgery within 12 weeks requiring general or regional anaesthesia	1
Localized tenderness along the distribution of the deep veins	1
Entire leg swollen	1
Calf swelling 3 cm > asymptomatic side (measured 10 cm below tibial tuberosity)	1
Pitting edema limited to the symptomatic leg	1
Collateral superficial veins (non-varicose)	1
Alternative diagnosis as likely as or more likely than DVT	−2

Low risk group if Point Score Is Zero or Less;

Moderate- risk group Is 1 to 2;

High- risk group Is 3 or Greater

Subjects will have to undergo colour doppler for confirmation so that efficiency of the test can be determined i.e the correlation between the wells score and doppler will be checked.

Safety Considerations:

In every step of the study patient safety will be given topmost preference. All procedures will be done under strict aseptic precautions and only necessary investigations will be carried out after carefully evaluating the patient.

-Any procedure will be done only after getting consent of the patient or the attender.

Quality Assurance:

Strict care will be taken to ensure that the study is done in the best quality possible right from patient admission which includes interaction with the patient history taking ,clinical examination and while subjecting to the necessary investigations

Expected Outcome:

This study is basically to test the effectiveness of Wells criteria as a diagnostic tool in Deep Vein Thrombosis.

Wells score application will allow the clinician to be prepared for the diagnosis even before the confirmation by a Venous Doppler ultrasound thus saving time in initiating treatment and thereby enabling faster patient recovery.

STATISTICAL METHODS:

DVT (by colordoppler) was considered as primary outcome variable.

Secondary outcome variable

Primary-explanatoryvariables

For quantitative variable, descriptive analytical method was applied with help of Standard deviation and mean and for categorial variables with help of proportion and frequency.Box plots; bar diagram and pie chart like diagrams are used to explain data

Percentage comparisons and cross tabulations used to explain connection between categorial outcomes and explantory variables. Statistical significance testing done with help of Chi-square test

DVT (by colordoppler) was considered as gold standard. Wells score was considered as screening test. Screening test specificity and specificity, diagnostic and predictive value along with their 95% CI were presented.

If Pvalue is <0.05 then consider as statistically significant.

RESULTS

Final survey encompasses forty(40) subject

Table(3): Descriptive-analysis of age (years) in research section

Parameter	Mean ± SD	Median	Minimum	Maximum	95% C. I	
					Lower	Upper
Age (In Years)	48.93 ± 18.75	50.50	16.00	81.00	42.93	54.92

The mean age was 48.93 ± 18.75 in the study population, ranging between 16 years to 81 years (95% CI 42.93 to 54.92). (Table 3)

Table (4): Descriptive-analysis of age distribution in the research section

Age distribution	'Frequency'	Percentage (%)
up to 30	9	22.50%
31 to 50	11	27.50%
51 to 70	15	37.50%
>70	5	12.50%

Among the study population, 9 (22.50%) participants were aged 30 years, 11 (27.50%) participants were aged between 31 to 50yr, participants15 (37.50%) aged between 51 to 70 yr and 5 (12.50%) participants were aged >70 years. (Table 4&Graph 1)

Graph1: Bar chart of age distribution in the study population (N=40)

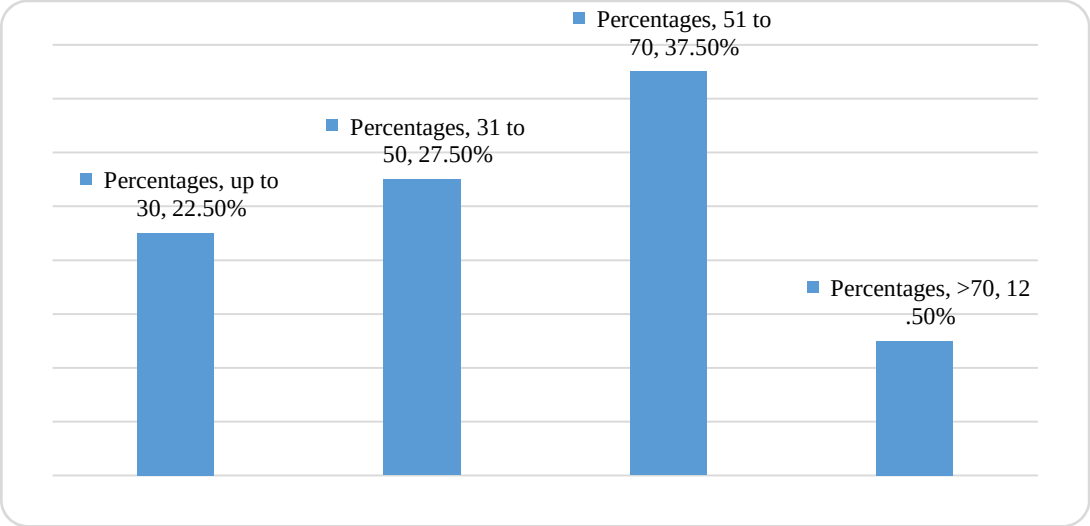


Table (5): Descriptive-analysis of gender in the research section

Gender	'Frequency'	Percentage(%)
Male	33	82.50%
Female	7	17.50%

In thisresearch 33 (82.50%) subjects were male while 7 (17.50%) participants were female. (Table 5&Graph2)

Graph2: Pie chart of gender in the study population (N=40)

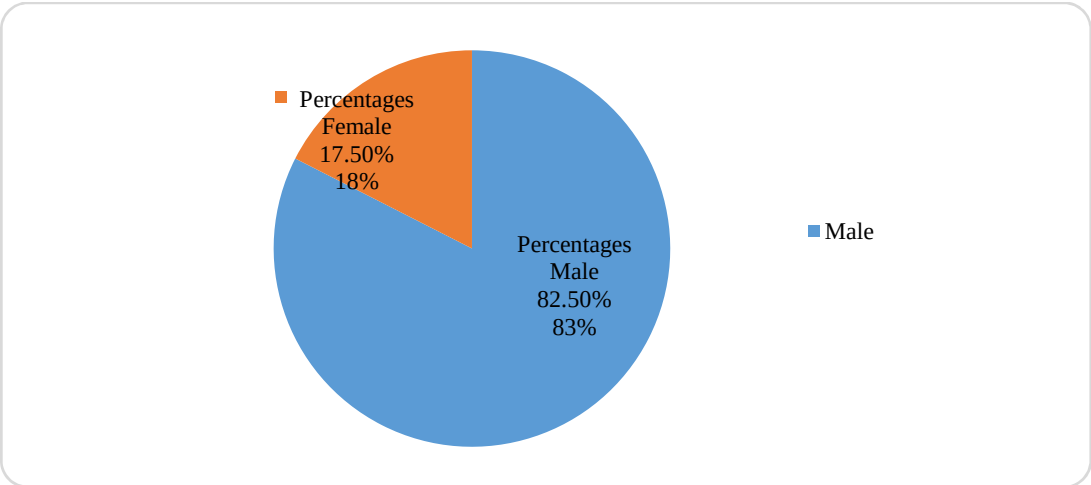


Table (6): Descriptive analysis of duration of swelling in leg (days) in study population (N=39)

Parameter	Mean ± SD	Median	Minimum	Maximum	95% C. I	
					Lower	Upper
Duration of Swelling in Leg (Days)	5.97 ± 3.24	4.00	2.00	12.00	4.92	7.02

The mean duration of swelling in leg (Days)was 5.97 ± 3.24 in the study population, ranging between 2 to 12 days (95% CI 4.92 to 7.02). (Table 6)

Table (7): Descriptive analysis of pain in lower limb in the study population (N=40)

Pain in lower limb	Frequency	Percentages
Yes	38	95.00%
No	2	5.00%

Among the study population, 38 (95%) participants had pain in lower limb. (Table 7&Graph 3)

Graph 3: Bar chart of pain in lower limb in the study population (N=40)

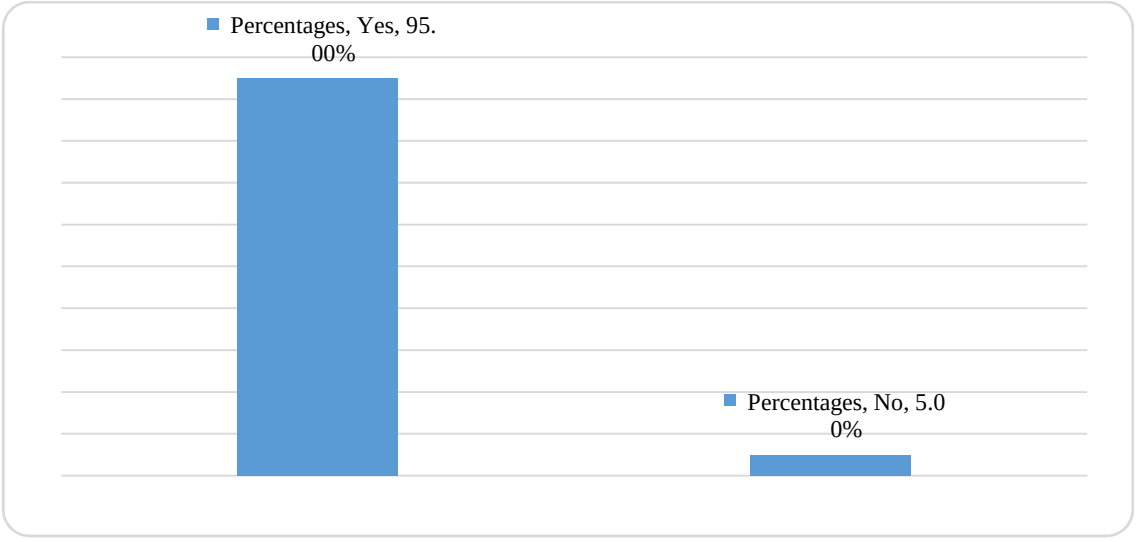


Table (8): Descriptive-analysis of h/o trauma in research section

H/O Trauma	'Frequency'	Percentage(%)
Yes	8	20.00%
No	32	80.00%

Among the study population, 8 (20%) participants had h/o trauma. (Table 8 & Graph4)

Graph 4: Pie chart of h/o trauma in the study population (N=40)

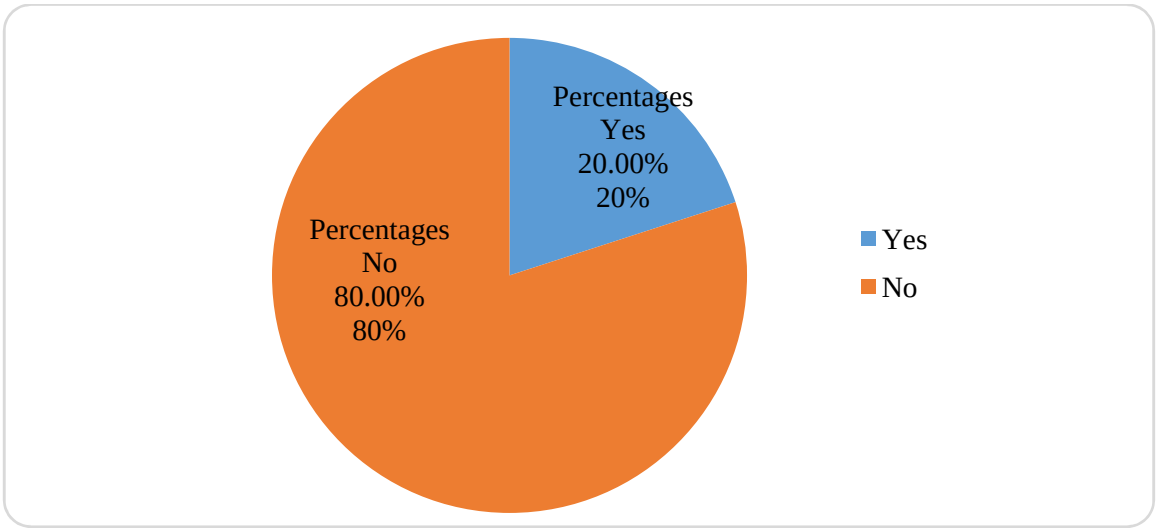


Table (9): Descriptive analysis of chest pain or dyspnoea or Minot exertion in the study population (N=40)

Chest pain or dyspnoea or Minot exertion	'Frequency'	Percentage(%)
Yes	4	10.00%
No	36	90.00%

Among the study population, 4 (10%) participants had chest pain or dyspnoea or Minot exertion. (Table 9&Graph 5)

Graph 5: Bar chart of chest pain or dyspnoea or Minor exertion in the study population (N=40)

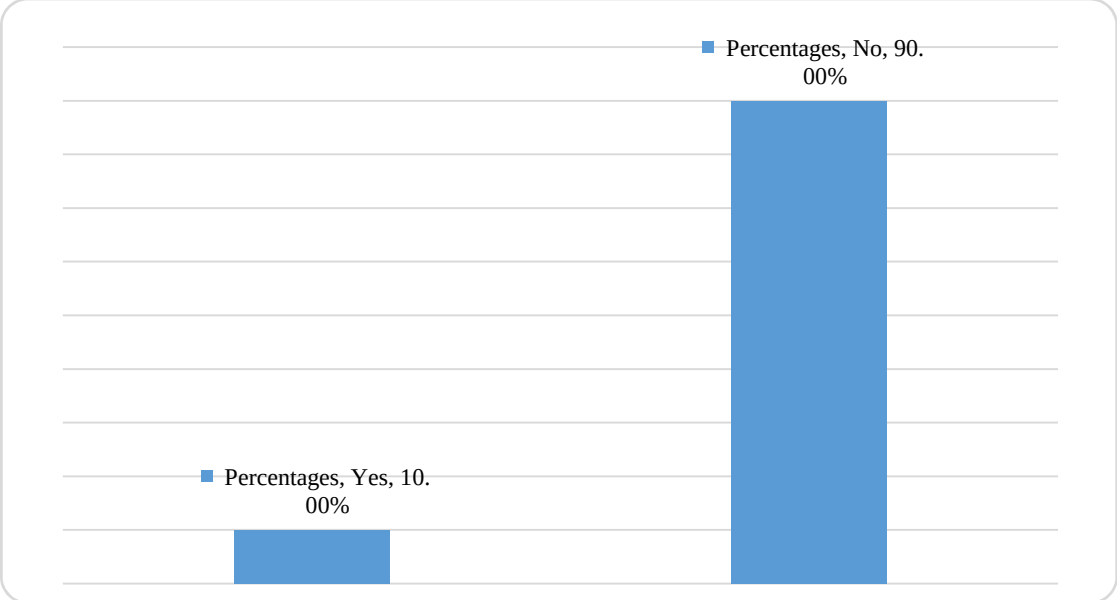


Table (10): Descriptive analysis of ability to walk in research section

Ability to walk	'Frequency'	Percentage(%)
Yes	37	92.50%
No	3	7.50%

Among the study population, 37 (92.50%) participants had ability to walk. (Table 10&Graph 6)

Graph 6: Pie chart of ability to walk in the study population (N=40)

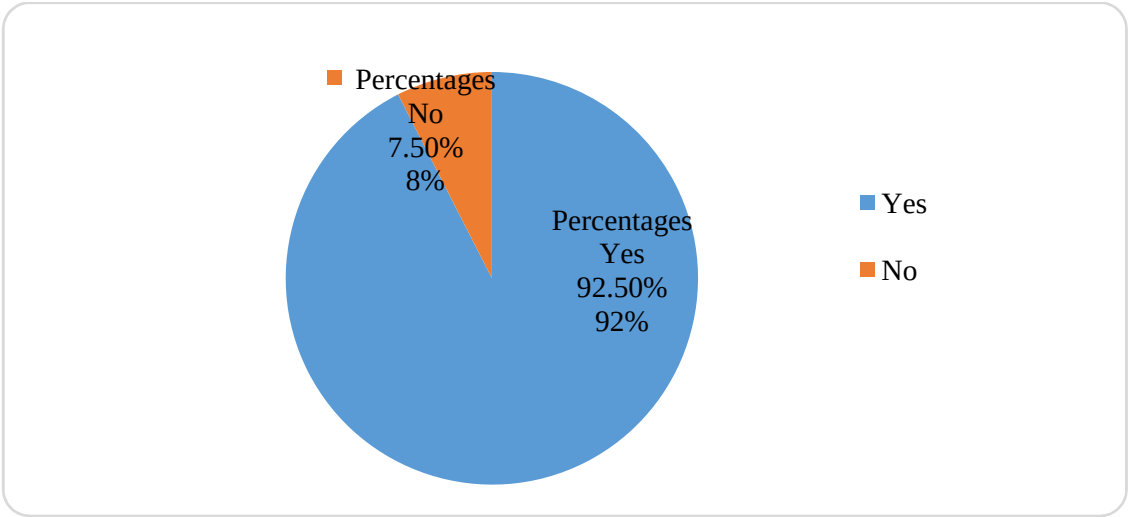


Table (11): Descriptive analysis of is the patient a smoker in the study population (N=40)

Is the patient a smoker	Frequency	Percentages
Yes	23	57.50%
No	17	42.50%

Among the study population, 23 (57.50%) were smokers. (Table 11&Graph7)

Graph 7: Bar chart of the patient is a smoker in the study population (N=40)

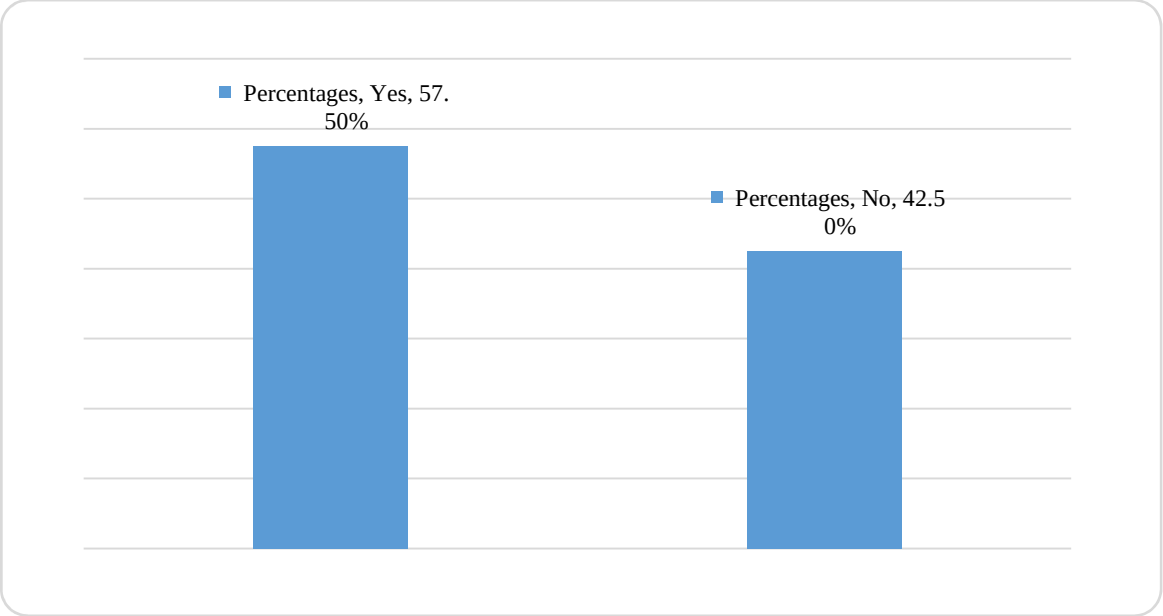


Table (12): Descriptive-analysis of edema in research section

Edema	'Frequency'	Percentage (%)
Present	39	97.50%
Absent	1	2.50%

In this research 39 (97.50%) subjects were having edema. (Table 12 &Graph 8)

Graph 8: Pie chart of edema in the study population (N=40)

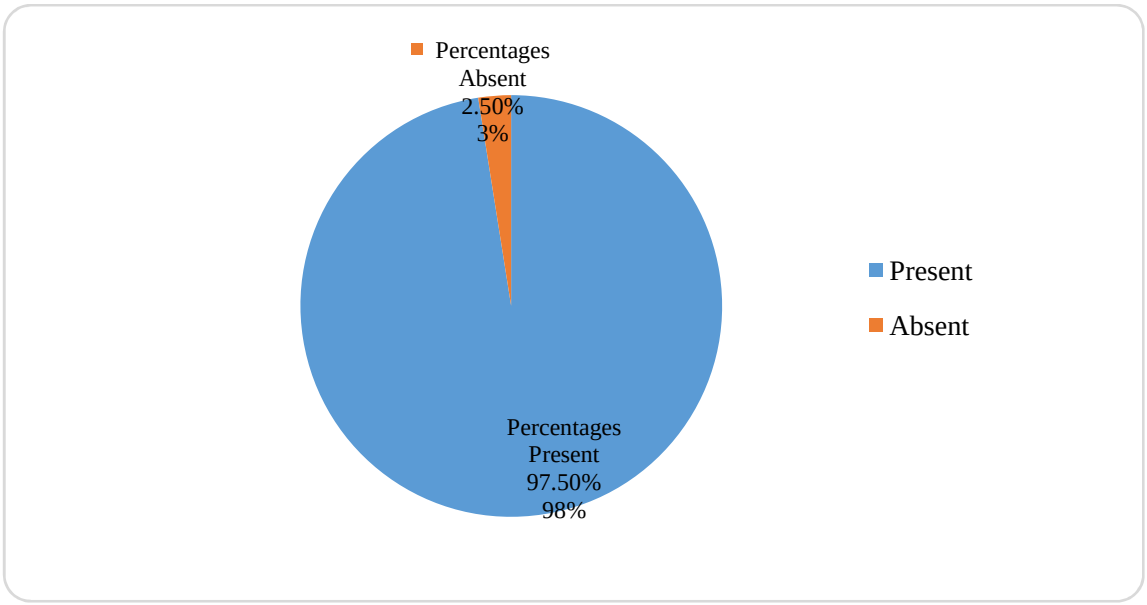


Table (13): Descriptive-analysis of swelling in research section

Swelling	'Frequency'	Percentage(%)
Present	40	100.00%

Table (14): Descriptive-analysis of calf tenderness in research section

Calf tenderness	'Frequency'	Percentage (%)
Present	38	95.00%
Absent	2	5.00%

In this research, 38 (95%) subjects were having calf tenderness. (Table 14&Graph 9)

Graph 9: Pie chart of calf tenderness in the study population (N=40)

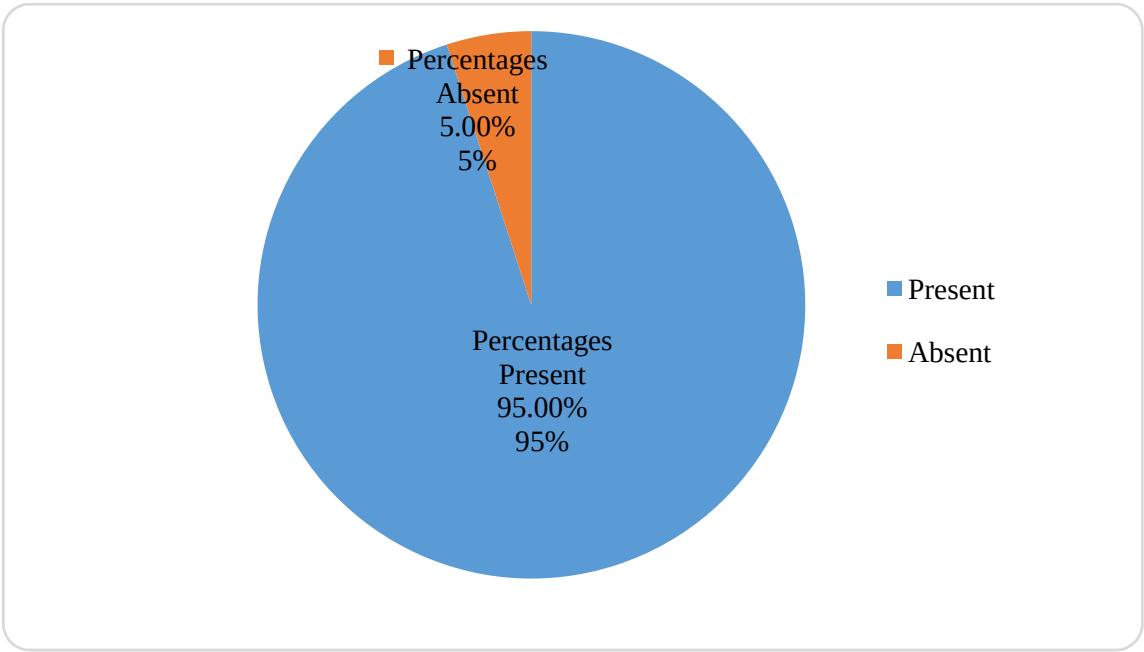


Table (15): Descriptive-analysis of redness in research section

Redness	'Frequency'	Percentage(%)
Present	22	55.00%
Absent	18	45.00%

In this research, 22 (55%) subjects were having redness. (Table 15&Graph10)

Graph 10: Bar chart of redness in the study population (N=40)

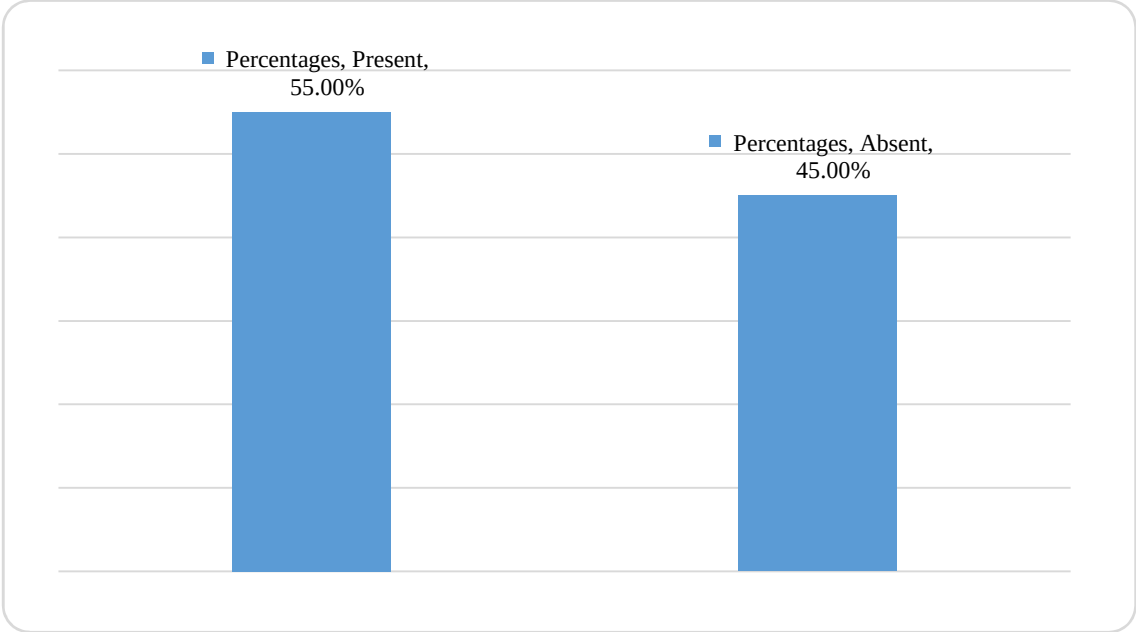


Table 16: Descriptive-analysis of local rise of temperature in the study population (N=40)

local rise of temperature	'Frequency'	Percentage(%)
Present	34	85.00%
Absent	6	15.00%

Among the study population, 34 (85%) participants had local rise temperature. (Table 16&Graph11)

Graph 11: Bar chart of local rise of temperature in the study population (N=40)

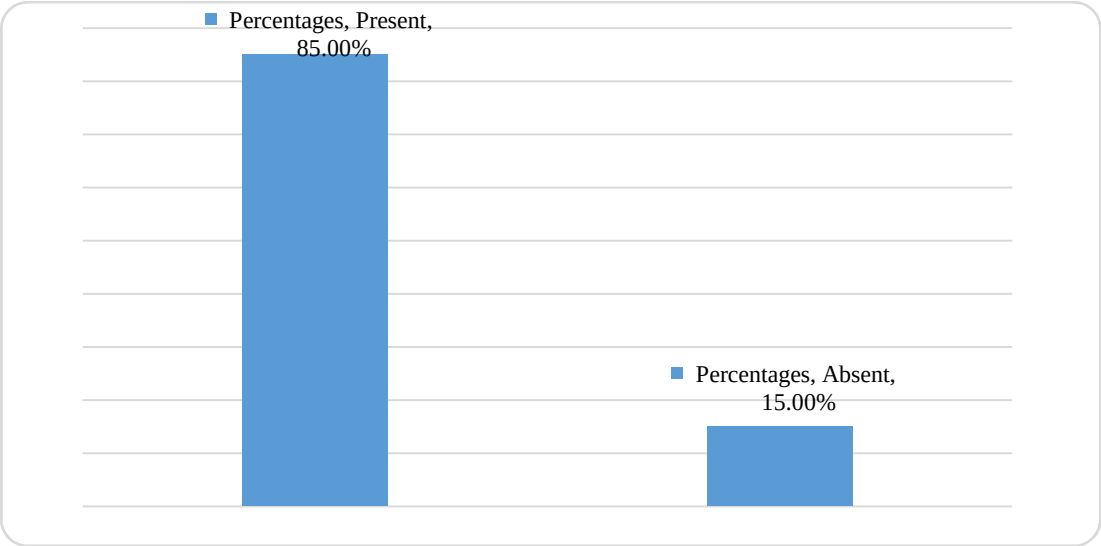


Table (17): Descriptive-analysis of peripheral pulsation in research section

Peripheral pulsation	'Frequency'	Percentage(%)
Present	39	97.50%
Absent	1	2.50%

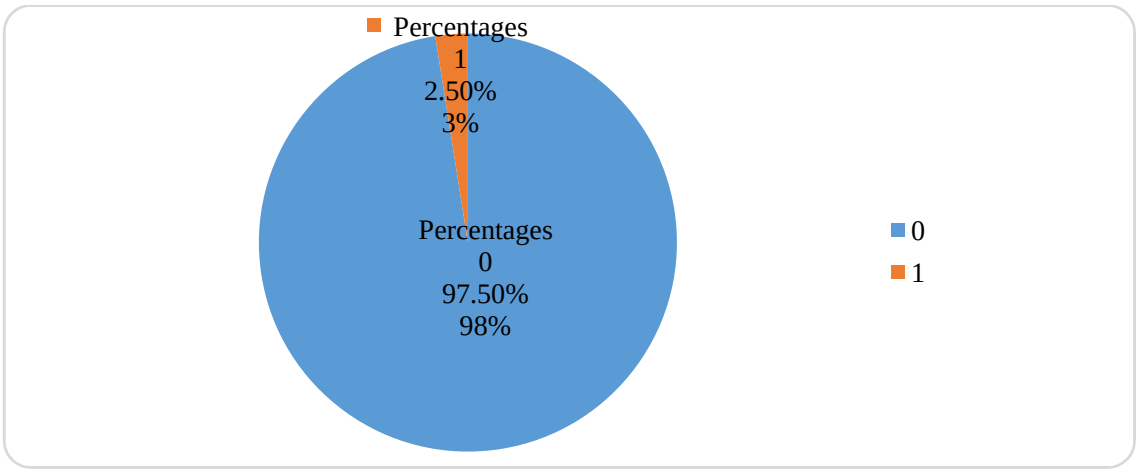
Among the study population, 39 (97.50%) participants had peripheral pulsation. (Table 17)

Wells Criteria

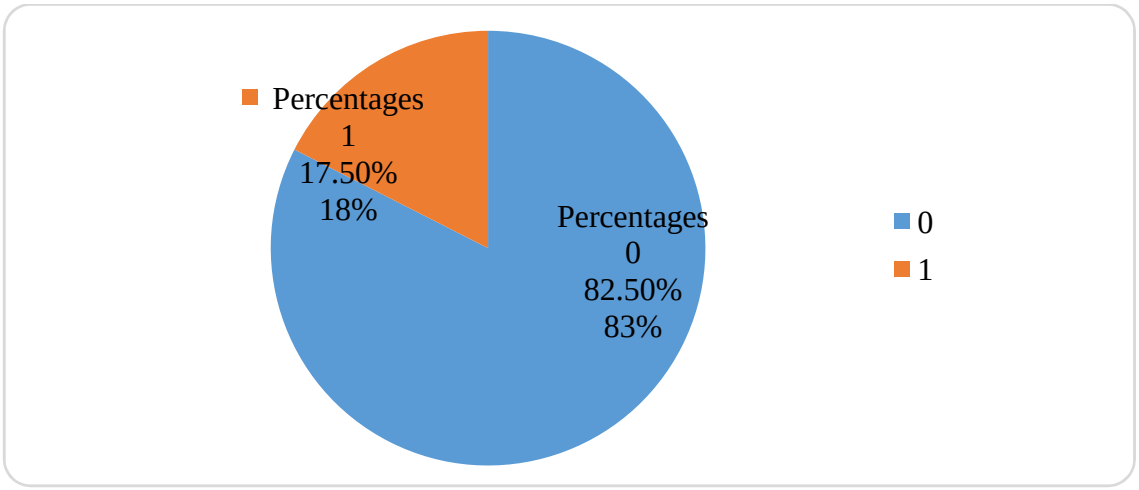
Table (18): Summary of Wells Criteria in research section (N-40)

Wells Criteria	'Frequency'	Percentage(%)
Active cancer (treatment ongoing or within the previous 6 months or palliative)		
0	40	100.00%
Paralysis, paresis, or recent plaster immobilization of the lower extremities		
0	39	97.50%
1	1	2.50%
Recently bedridden for more than 3 days or major surgery within 4 weeks		
0	33	82.50%
1	7	17.50%
Localized tenderness along the distribution of the deep venous system		
0	2	5.00%
1	38	95.00%
Entire leg swollen		
0	1	2.50%
1	39	97.50%
Calf swelling by more than 3 cm when compared to the asymptomatic leg		
0	5	12.50%
1	35	87.50%
Pitting edema (greater in the symptomatic leg)		
0	6	15.00%
1	34	85.00%
Collateral superficial veins		
0	40	100.00%
Alternative diagnosis as likely or greater than that of DVT		
-2	7	17.50%
0	33	82.50%

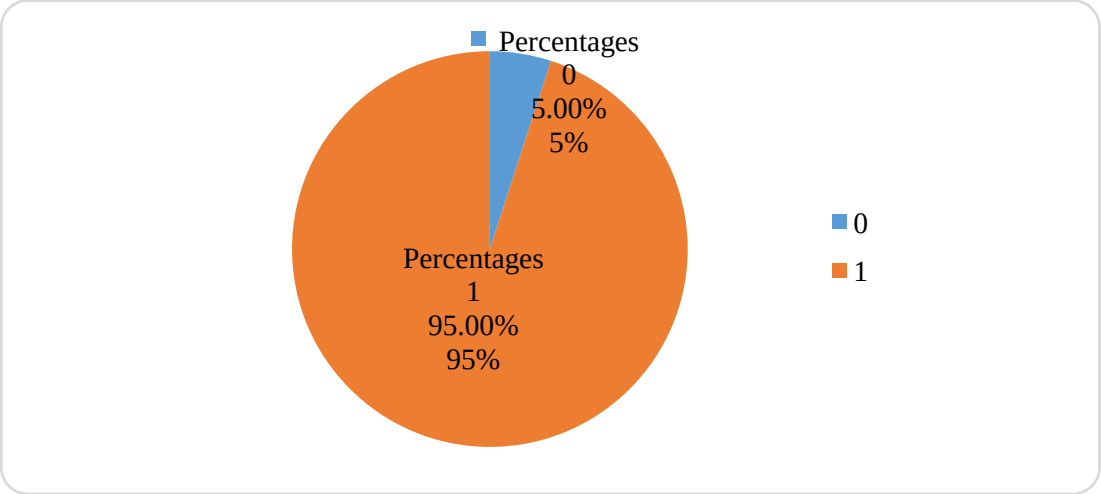
Graph 12: Pie chart of (paralysis, paresis, or recent plaster immobilization of the lower extremities)in the study population (N=40)



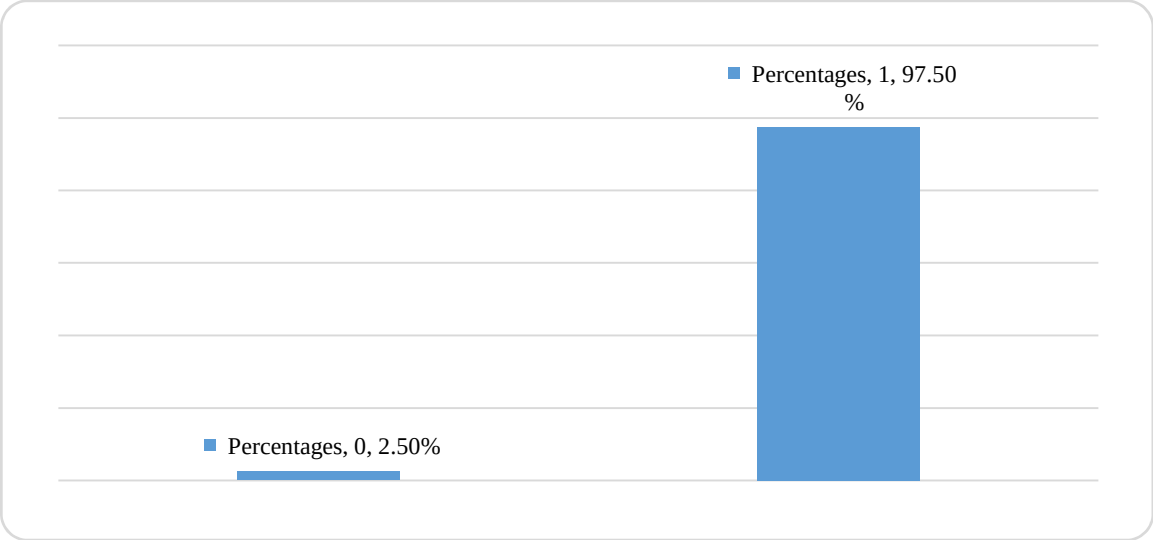
Graph 13: Pie chart of (major surgery within 4 weeks or recently bedridden for more than 3 days or) in study population (N=40)



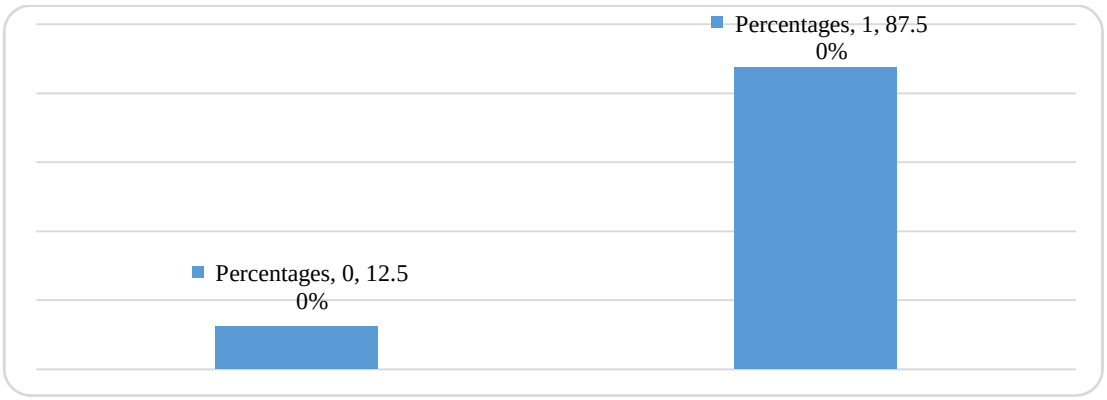
Graph 14: Pie chart of (localized tenderness along the distribution of the deep venous system) in the study population (N=40)



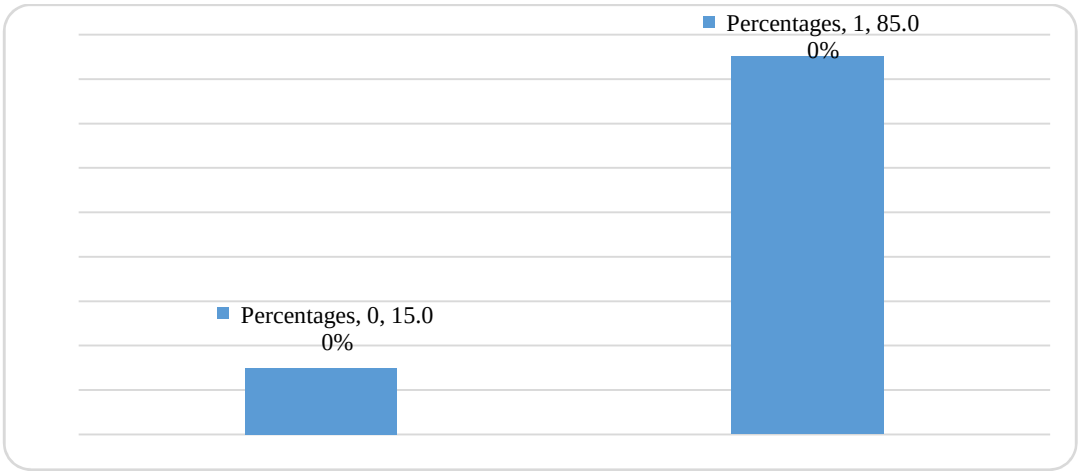
Graph 15: Bar chart of (entire leg swollen) in the study population (N=40)



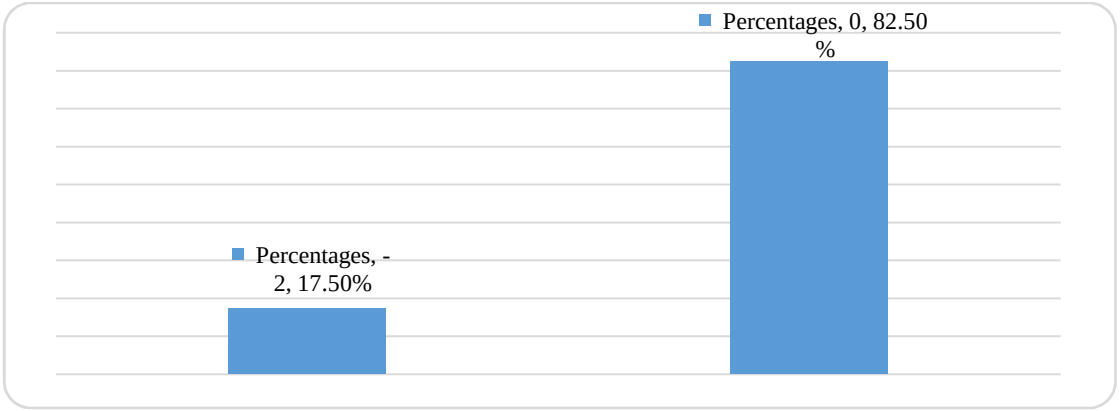
Graph16: Bar chart of (calf swelling by more than 3 cm when compared to the asymptomatic leg) in the study population (N=40)



Graph 17: Bar chart of pitting edema (greater in the symptomatic leg) in study population (N=40)



Graph18: Bar chart of (ALTERNATIVE DIAGNOSIS AS LIKELY OR GREATER THAN THAT OF DVT) in the study population (N=40)



Table(19): Descriptive analysis of total score (out of 8) in the study population (N=40)

Total score (out of 8)	'Frequency'	Percentage(%)
0	3	7.50%
1	3	7.50%
2	1	2.50%
3	4	10.00%
4	23	57.50%
5	5	12.50%
6	1	2.50%

Graph 19: Pie chart of total score (out of 8) in the study population (N=40)

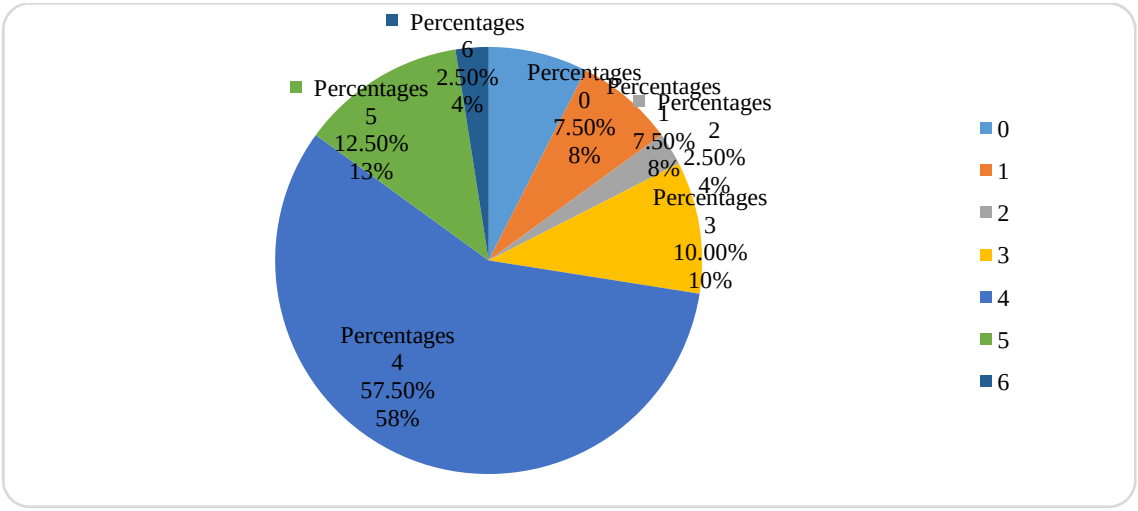


Table 20: Descriptive analysis of DVT (by colordoppler) in research section

DVT (By Colordoppler)	'Frequency'	Percentage(%)
Yes	33	82.50%
No	7	17.50%

Among the study population, 33 (82.50%) participants had DVT (by colordoppler). (Table 20 & Graph 20)

Graph 20: Bar chart of DVT (by colordoppler) in the study population (N=40)

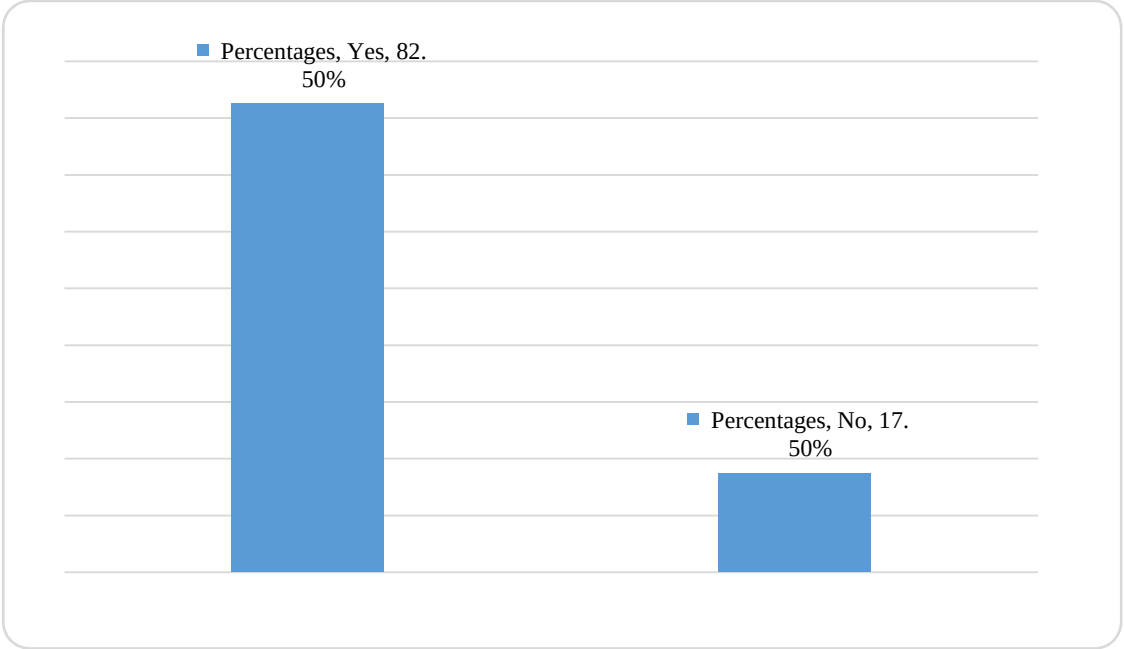


Table 21: Descriptive analysis of wells score criteria in research section

Wells score criteria	'Frequency'	Percentage(%)
Low-risk (0)	3	7.50%
Intermediate-risk (1-2)	4	10.00%
High-risk (≥3)	33	82.50%

Graph 21: Bar chart of wells score criteria in the study population (N=40)

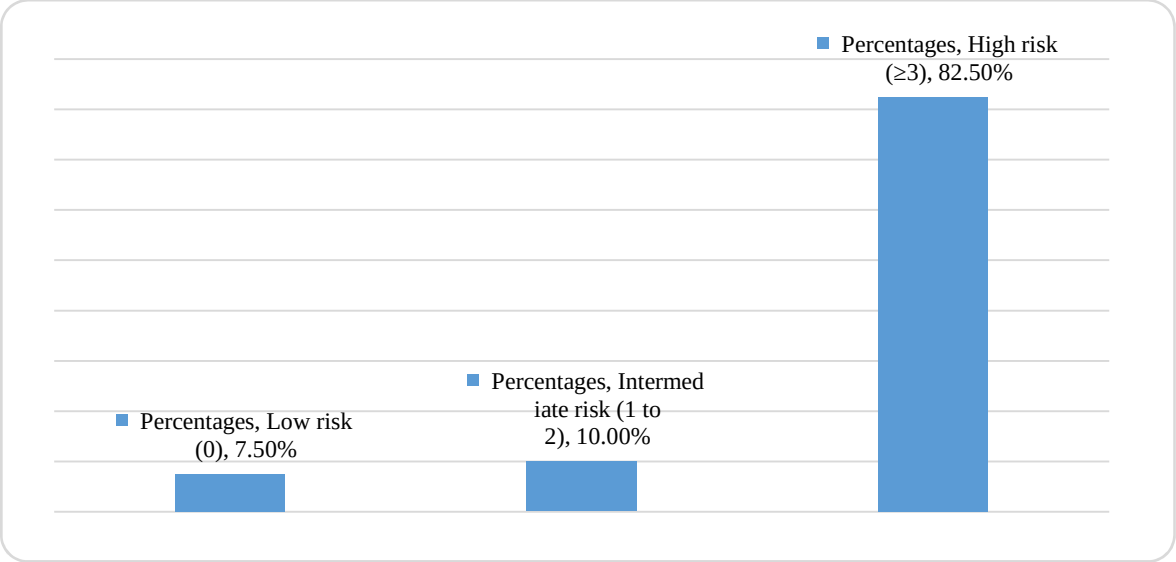


Table-22: Descriptive analysis of wells score category in research section

Wells score category	'Frequency'	Percentage(%)
Low risk (0)	3	7.50%
Intermediate risk & High risk	37	92.50%

Among the study population, 3 (7.50%) participants had low risk and 37 (92.50%) participants had intermediate and high risk. (Table 22)

Table 23: Comparison of DVT (By Colordoppler) with Wells score category (N=40)

Wells score category	DVT (By Colordoppler)	
	Yes (N=33)	No (N=7)
Intermediate Risk & High Risk	33 (100%)	4 (57.14%)
Low Risk (0)	0 (0%)	3 (42.86%)

**** statistical test was not applied as zero subjects in the cell***

Among the people with DVT all33 (100%) had intermediate and high risk. Among the people without DVT 4 (57.14%) had intermediate and high risk and 3 (42.86%) had low risk. (Table23)

Table-24: Predictive validity of Wells score in predicting DVT (By Colordoppler) (N=40)

Parameter	Value	95% CI	
		Lower	Upper
'Sensitivity'	100.0%	89.42%	100.0%
'Specificity'	42.86%	9.90%	81.59%
'False positive rate'	57.14%	18.41%	90.10%
'False negative rate'	0.00%	0.00%	10.58%
'Positive predictive value'	89.19%	74.58%	96.97%
'Negative predictive value'	100.0%	29.24%	100.0%
'Diagnostic accuracy'	90.00%	76.34%	97.21%

Wells score category had sensitivity of 100.00% (95% CI 89.42% to 100.00%) in predicting DVT , Specificity was 42.86% (95 CI 9.90% to 81.59%), False positive ratewas 57.14% (95 CI 18.41% to 90.10%), False negative ratewas 0.00% (95 CI 0.00% to 10.58%), Positive predictive value was 89.19% (95 CI 74.58% to 96.97%), Negative predictive valuewas 100.00% (95 CI 29.24% to 100.00%), and the total diagnostic accuracy was 90.00% (95 CI 76.34% to 97.21%). (Table24)

The study showed that frequency in the age group between 51-70 years was more with mean age being 48.93 + 18.75 years in the population (Table 3&4; Graph 1).Significantly higher frequency (33) of "DVT" was revealed by the study in males than females.(Table 5, Graph 2).

Duration of leg swelling(in days) ranged between 2-12days,where mean duration demonstrated is 5.97 + 3.24 days(Table 4).Pain in the lower limb was seen maximally in the surveyed subjects-38 in no.(Table 7, Graph3).

No significant history of trauma was revealed by the study in subjects surveyed as case of "DVT" i.e. 32 subject had no such history.(Table 8, Graph4) .

Only 10%(i.e.4) of the studied subject revealed chest pain/dyspnea/minor exertion.(Table 9, Graph5).

In context of ability to ambulate, 37 participants (92.50%) had no problems in walking as disease progression is gradual in process.(Table 10, Graph6).

More than 50% "population-23 participants" were smokers showing some association with "DVT".(Table 11, Graph7).

Edema was seen in significantly higher no.ofparticipants'(39 i.e.97.50%). (Table10,F Graph8) while 100% of surveying subject reported swelling as symptom in the lower limb .(Table 13).

Calf tenderness as a sign was demonstrated in significant no. of subjects(38) in the research(Table 14; Graph9).

Almost equal numberof participants had redness in the lower-limb as symptoms i.e. 22subjects had redness while 18subjects did not revealing that this is variable.(Table 15; Graph10).

A significantly higher number of patients on examination revealed local rise of temperature which is 85% of the total or 34patients.(Table 16; Graph11).

Peripheral pulsation was palpable in 97.50% in the reviewed patients'.(Table 17)

Among the Wells Criteria, paralysis,paresis or recent immobilization of the lower extremities was revealed in 97.50%,H/O patients' bedridden >3days in 82.50%

was seen;& collateral superficial veins could be demonstrably seen in 100% of the surveillance.Entire leg swollen in just 2.50%,localized tenderness along the deep venous system;>3cm calf swelling in comparison to asymptomatic leg was just 12.50% showing minimal significance.Pitting edema was seen more in the affected leg in 6 patients(15%) as compared to others. Differential Diagnosis could not be thought for 33subjects (82.50%) (Table18; Graph12,13,14,15,16,17,18).

Out of 8 as total Score, 23participants had score as 4(57.50percent) with 0score in 3patients(7.50%) with maximum score in the surveillance came out to be 6 in one patient only(2.50%)(Table 19;Graph19.).

33i.e.82.50percent subjects revealed “DVT” by ColorDoppler(Table 20; Graph20).

33patients(82.50) were in the high risk(>3)section according to “Wells Score Criteria” while 3patients(7.50%)grouped in low risk(0)(Table 21; Graph21).

Wells Score Category as analysed was 37patients(92.50%) in intermediate&high risk group.(Table22).

“DVT”as Intermediate &High risk by Color Doppler was detected in 33participants’& 0% as Low risk. Without DVT 4 (57.14%) had intermediate and high risk and 3 (42.86%) had low risk(Table23).

Wells score category had sensitivity of 100percent in predicting DVT, Specificity was 42.86%, False positive ratewas 57.14%, False negative ratewas 0.00%, Positive predictive value was 89.19%, Negative predictive valuewas 100%, and the total diagnostic accuracy was 90%.(Table24)

DISCUSSION

In this study, Well's criteria was assessed as a predictive tool in confirmation of DVT.

Subjects randomized according to peer-group and gender. Observations were made based on duration of leg swelling, pain in the lower limb, history of trauma, presence of chest pain or dyspnea and ability to walk. Signs of calf tenderness, swelling, redness, local rise in temperature and peripheral pulsation were seen.

Around 2lac cases of "VTE" are observed annually. Among these, 30% mortality is seen in 30 days while one-fifth experience increased mortality due to pulmonary embolism; and around 30% are diagnosed with recurrent venous thromboembolism in 10 years. The DVT incidence in common community is 5/10,000 person - yrs.[2]

Inspite of adequate therapy, 1% to 8% patients that develop complications like pulmonary embolism will not survive,[2] whereas some others will develop issues like CTPH(4%)[2] and postphlebitic syndrome(40%)[2].

Diagnosing DVT clinically is not only a challenge but may imitate other disorders as well. This makes it dangerous to start empirical treatment with anticoagulants. Advanced imaging facilities like Doppler venous ultrasound may not be accessible in all hospitals. A delay in diagnosis leads to delay in treatment which further results in wastage of time and increase in the risk to patient's life.

Clinical assessment with Mose's and Homan's sign can give false positive results. Hence assessment of DVT based on these clinical signs alone may not be appropriate.

A clinical scoring system like Well's Score consists of many aspects in history taking and also detailed clinical signs that can help the physician arrive at a diagnosis. This can help in saving time and money which is otherwise lost in performing unnecessary investigations.

The revised index developed by Well's showed the strongest potential in estimation of probability of DVT in individual patients when used with additional diagnostic tests.[36] The pretest probability of detecting DVT using Well's score when combined alongwith non-invasive diagnoses reports was found to easier the diagnosis and cheaper.[29]

The Well's score is a reliable and robust method for pretest scoring irrespective of the assessor grade, as long as appropriate training has been carried out in terms of its use. A Well's score of >1 can authentically exclude incidence of "DVT" in injured making it an important pretest tool for risk stratification.[49]

For this purpose, a sum of around 40patients suspected of having "DVT"was assessed using Well's criteria.

The results showed that up to 34 of the 40 participants that had a significant score with Well's criteria were actually diagnosed with deep vein thrombosis. The remaining 6 patients with depressed "Well's score" also showed a nugatory diagnosis with doppler scan.

Out of the 37 with high Well's scores, 07 were females while 33 were males. However, out of these, four participants that had a Well's score of 3 and one participant with a Well's score of 2 also showed positive diagnosis of DVT.

Some studies also depicted the unreliability of the Well's criteria. The Well's score singly or conjunct with D-dimer testing will never accurately estimate the risk of "DVT" in prime concern subjects.[50]

Strengths: Well's criteria is a clinical tool that can be applied even in primary care centers with negligible radiological availability. Hence it can be an apt tool for diagnosis of poor patients in inaccessible areas. This can also ensure start of early prophylactic treatment.

Weaknesses: A higher number of patients could have provided a more reliable result and improved the statistical significance of the study. Also, Well's criteria is a predictive tool that requires additional diagnostic tests for confirmation of the diagnosis. Furthermore, beginning prophylactic treatment could increase the risk of adverse effects.

Thus, Well's criteria is a valuable and important pretest tool that can help in diagnosing a common and debilitating illness like DVT and ensure early treatment for the same.

CONCLUSION

In the research done on 40 patients to evaluate whether “WELLS CRITERIA” can be utilized as an important aid in the investigation of “DVT”, it was exhibited that it certainly helps the clinicians to arrive at disease & its process with its variables or parameters.This can benefit the patients in future to treat them earlier before it gets complicated and do not hamper their day-day activities improving their quality of life.

STRENGTH OF THE STUDY

Sensitivity of the study was seen 100% proving it is a reliable tool.

LIMITATION OF THE STUDY:

It represented only a portion of total “DVT”suffering population with limited number of participants and limited time period.

SUMMARY

Venous Thromboembolism (VTE), a disease that includes both Deep Vein Thrombosis ('DVT') and pulmonary embolism (PE), is the third most common vascular disease after myocardial infarction and ischemic stroke.

As DVT is common in postoperative patients and during period of hospitalization, it leads to significant raise in the expense to the patient due to prolonged period of stay in the hospital and also loss of resources and manpower.

The clinical diagnosis of DVT is not only challenging but may mimic other conditions as well, thereby making it risky to start empirical therapy with anticoagulants.

This study aimed to determine Wells Criteria as a reliable clinical tool in diagnosis of Deep Vein Thrombosis.

This one year cross sectional study was conducted in the Dept. of Gen.Surgery, KlesDr. P.K. and M.R.C, Belgaum. from January 2018 to December 2018.

A total of 40 patients with lower limb swelling and suspected to have deep vein thrombosis were clinically categorised as low, intermediate and high risk using wells prediction criteria and confirmed clinical diagnosis by colour doppler.

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ANNEXURE-I- CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled "TO DETERMINE WELLS CRITERIA AS A RELIABLE CLINICAL TOOL IN DIAGNOSIS OF THE DEEP VEIN THROMBOSIS'' A ONE YEAR CROSS SECTIONAL SINGLE CENTRIC HOSPITAL BASED STUDY conducted by Dr. _____, Post Graduate in M.S. General Surgery under the guidance of Dr._____ Associate Professor General Surgery Department Jawaharlal Nehru Medical College, Belagavi-10 under KLE university, Belagavi.

Respected Sir/Madam,

We request you to participate in our study as you are eligible for participating in the study. Your participation in the research is absolutely voluntary. Your decision to participate in the study or otherwise will not affect the relationship with KLE hospital. If you decide not to participate, you are free to withdraw at any time. During the study your operative outcome will be accessed by some questions which will be answered by your operating surgeon.

Risks and Benefits:

There is no increased risk involved in becoming a part of this study and the complications are those which are normally anticipated. This study will help to estimate the incidence of postoperative pain in comparison with the two procedures involved. The results derived at the end of study will benefit all similar patients admitted in this hospital.

Withdrawing/removal from the study

The participant has freedom to withdraw from the study whenever he/she wishes and with any prior notice. Even if you decline to participate, there will not be any change in the line of your management or the relationship with your doctor. You will be told about all the new information that affects your decision to participate in the study. The investigator may also exclude a participant from the study at anytime.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.

2. If required by law.

Institutional/sponsors policy:

If any unforeseen complications or injury occurs during the period of study the participant will be given treatment within the limitations of KLES Prabhakar Kore hospital general ward.

Financial Incentives for participation:

The participant neither gets any financial incentives during the period of study nor will be asked to pay for the purpose of this study.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

CONSENT STATEMENT

I the undersigned Mr./Mrs./Dr._____do hereby give consent for my participation in this researchstudy after being explained in-depth about the important elements of this study in my own vernacular language.

I give this consent voluntarily in my sound mind and good faith, knowing very well the risks involved and been given enough time to clear my doubts and other queries to participate as a 'subject' in this study. I do hereby also give consent for publication of this article in any media / journal and have no objections whatsoever.

Signature or left thumb print of participant or legally authorized representative

Participant's name: _____

Signature: _____

Witness/guardian name: _____

Signature_____

Investigator's name:

Signature_____

Guide's name:

Signature_____

Date: ___/___/_____Place: _____

ANNEXURE II. ETHICAL CLEARANCE

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http://www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 19 **Date: 22/11/2017**

To,

PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"TO DETERMINE WELLS CRITERIA AS A RELIABLE CLINICAL TOOL IN DIAGNOSIS OF DEEP VEIN THROMBOSIS A ONE YEAR CROSS SECTIONAL SINGLE CENTRIC HOSPITAL BASED STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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ANNEXURE III – PROFORMA

The proposed proforma/questionnaire to be used for data collection for the study tilted. "TO DETERMINE WELLS CRITERIA AS A RELIABLE CLINICAL TOOL IN DIAGNOSIS OF THE DEEP VEIN THROMBOSIS'' A ONE YEAR CROSS SECTIONAL SINGLE CENTRIC HOSPITAL BASED STUDY" is as follows:

Patient details:

In / Out Patient Department Number:

Date of admission:

Date of discharge:

Name:

Sex:

Age:

Address:

Occupation:

Chief Complaints

Swelling in the leg:

Yes / No Duration

Pain in the lower limb: Yes / No

Type of pain

Chest pain or dyspnea on minor exertion

Able to walk

General examination

Built and Nourishment:

Weight:

Pulse:

Blood pressure:

Respiratory rate:

Temperature:

Normal Abnormal finding

LOCAL EXAMINATION:

Wells clinical prediction criteria for Deep Venous Thrombosis

Clinical Feature Score

1) Active cancer (treatment ongoing or within the Previous 6 months or palliative)

2) Paralysis, paresis, or recent plaster immobilizationof the lower extremities

3) Recently bedridden for more than 3 days or major surgery within 4 weeks

4) Localized tenderness along the distribution of the deep venous system

5) Entire leg swollen

6) Calf swelling by more than 3 cm when compared to the asymptomatic leg(measured below tibial tuberosity)

7) Pitting edema (greater in the symptomatic leg)

8) Collateral superficial veins (nonvaricose)

9) Alternative diagnosis as likely orgreater than that of DVT

Total

Note: Risk category: low risk ≤0 points; intermediate risk=1 or 2 points; high risk ≥3points.

SYSTEMIC EXAMINATION

Cardiovascular system:

Respiratory:

Central nervous system:

Per abdomen:

INVESTIGATIONS

Colour Doppler lower limb:

ANNEXURE IV – KEY TO MASTER CHART

F	–	Female
M	–	Male
Y	–	Yes
N	–	No
P	–	Present
A	–	Absent

Serial number	In patient number	Date of admission	Date of discharge	Sex	Age (Years)	Chief complaints		H/O Trauma	Chest pain or dyspnoea or minot exertion	Ability to walk	Is the patient a smoker	Local examination						Wells Criteria										
						Duration of Swelling in leg (Days)	Pain in lower limb					Edema	Swelling	Calf tenderness	Redness	local rise of temperature	periperal pulsation	Active cancer (treatment ongoing or within the previous 6 months or palliative)	Paralysis, paresis, or recent plaster immobilization of the lower extremities	Recently bedridden for more than 3 days or major surgery within 4 weeks	Localized tenderness along the distribution of the deep venous system	Entire leg swollen	Calf swelling by more than 3 cm when compared to the asymptomatic leg	Pitting edema (greater in the symptomatic leg)	Collateral superficial veins	Alternative diagnosis as likely or greater than that of DVT	Total score(out of 8)	DVT(By Color doppler)
1	852532	14/1/2018	14/1/2018	F	23	3	Y	N	N	Y	N	P	P	P	A	A	P	0	0	1	1	1	0	0	0	0	3	Y
2	853894	22/1/2018	29/1/2018	F	53	3	Y	N	N	Y	N	P	P	P	A	A	P	0	0	0	1	1	0	0	0	-2	0	N
3	854277	23/1/2018	30/1/2018	F	39	12	Y	Y	N	Y	N	A	P	A	A	A	P	0	0	0	1	1	0	0	0	-2	0	N
4	854738	25/1/2018	26/1/2018	F	33	4	Y	N	N	Y	N	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
5	858088	14/2/2018	21/2/2018	M	52	11	Y	N	N	Y	Y	P	P	P	A	A	P	0	0	0	1	1	1	1	0	0	4	Y
6	858338	15/2/2018	24/2/2018	M	76	4	Y	N	N	N	Y	P	P	P	P	P	P	0	0	1	1	1	1	1	0	0	5	Y
7	863217	03-12-2018	17/3/2018	F	23	8	Y	N	N	N	N	P	P	P	P	P	P	0	0	1	1	1	1	1	0	0	5	Y
8	863572	14/3/2018	04-06-2018	M	29	8	Y	N	N	Y	Y	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
9	864357	19/3/2018	24/3/2018	M	41	4	Y	N	N	Y	Y	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
10	865223	04-07-2018	27/4/2018	M	50	7	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
11	872744	05-02-2018	14/05/2018	M	39	11	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
12	873385	05-05-2018	05-12-2018	M	59	2	Y	N	Y	Y	Y	P	P	A	P	P	P	0	0	0	0	1	1	1	0	-2	1	N
13	873695	05-07-2018	05-11-2018	M	77	3	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
14	874577	05-12-2018	28/05/2018	M	52	2	Y	N	N	Y	Y	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
15	879756	06-06-2018	13/6/2018	M	45	7	Y	N	N	Y	Y	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y

16	880732	06-08-2018	14/6/2018	M	41	5	Y	N	N	Y	N	P	P	P	P	P	P	0	0	0	1	1	1	0	0	-2	1	N
17	881893	18/6/2018	26/6/2018	M	50	9	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
18	882757	22/6/2018	07-03-2018	M	40	2	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
19	883501	26/6/2018	29/6/2018	M	65	2	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
20	884980	07-03-2018	07-10-2018	M	65	4	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	0	0	1	0	-2	0	N
21	885409	07-05-2018	13/7/2018	M	66	4	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
22	888819	23/7/2018	08-07-2018	M	28	11	Y	N	N	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
23	890670	08-01-2018	24/8/2018	M	51	10	Y	N	N	Y	Y	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
24	892265	08-08-2018	27/9/2018	M	57	9	N	Y	N	N	N	P	P	P	P	P	P	0	0	1	1	1	1	1	0	0	5	Y
25	892708	08-11-2018	30/8/2018	M	30	3	Y	N	N	Y	N	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
26	893538	16/8/2018	09-05-2018	M	20	2	Y	Y	N	Y	N	P	P	P	P	P	P	0	0	1	1	1	1	1	0	0	5	Y
27	893918	18/8/2018	24/8/2018	M	27	8	Y	Y	N	Y	Y	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
28	894711	22/8/2018	28/8/2018	M	16	9	Y	N	N	Y	N	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
29	897772	09-07-2018	19/9/2018	M	69	12	Y	N	Y	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	-2	2	N
30	898036	09-08-2018	09-12-2018	M	68	6	Y	Y	N	Y	N	P	P	P	P	P	P	0	0	0	1	1	1	0	0	-2	1	N
31	898513	09-11-2018	20/9/2018	M	66	4	Y	Y	N	Y	N	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
32	899169	15/9/2018	20/9/2018	M	52	4	Y	Y	N	Y	Y	P	P	P	A	P	P	0	1	1	1	1	1	1	0	0	6	Y
33	899288	16/9/2018	27/9/2018	F	70	3	Y	N	N	Y	Y	P	P	P	A	P	P	0	0	1	1	1	1	1	0	0	5	Y
34	899802	18/9/2018	23/9/2018	M	73	8	N	N	N	Y	Y	P	P	P	A	A	A	0	0	0	0	1	1	1	0	0	3	Y
35	900732	24/9/2018	25/9/2018	M	67	8	Y	N	Y	Y	Y	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
36	905430	15/10/2018	11-05-2018	M	18	4	Y	N	N	Y	N	P	P	P	P	P	P	0	0	0	1	1	1	1	0	0	4	Y
37	905468	16/10/2018	22/10/2018	M	39	3	Y	N	Y	Y	N	P	P	P	P	P	P	0	0	0	1	1	0	1	0	0	3	Y
38	907249	24/10/2018	29/10/2018	M	81	4	Y	N	N	Y	N	P	P	P	A	A	P	0	0	0	1	1	1	1	0	0	4	Y
39	910976	14/11/2018	21/11/2018	F	76	10	Y	N	N	Y	N	P	P	P	A	P	P	0	0	0	1	1	1	1	0	0	4	Y
40	913919	28/11/2018	28/12/2018	M	31	4	Y	Y	N	Y	N	P	P	P	A	P	P	0	0	0	1	1	1	0	0	0	3	Y