A CROSS SECTIONAL STUDY OF CHRONIC VENOUS INSUFFICIENCY AND QUALITY OF LIFE FOR PATIENTS PRESENTING TO IIUM TEACHING HOSPITALS IN PAHANG, MALAYSIA

BY

DINESHWARY A/P PERIASAMMY

A dissertation submitted in fulfilment of the requirement for the degree of Master of Surgery

Kulliyyah of Medicine
International Islamic University Malaysia

DECEMBER 2020

ABSTRACT

Chronic venous insufficiency (CVI) is one of the disease in the world which been frequently unrecognized and underestimated. It has been shown to have an adverse effect on the quality of life among its sufferers. Aim of this study is to describe demographic of CVI in a developing country and its effect on Quality of life (QoL). It is a cross sectional study of CVI cases presenting to vascular or surgical clinic of three IIUM teaching hospitals in Pahang between 1st February2018 to 28th February 2019. Consented patients with CVI aged 18 years and above without surgical intervention for chronic venous diseases were recruited in this study. Quality of life was assessed using a validated SF-36 questionnaire. A total of 110 patients were recruited with a slight male predominance (56%). The mean age was 57 (SD14). Ethnically, 66% were Malay, 26% were Chinese and 16% were Indian. The commonest symptom was pain (42%), followed by ulcer (34%). The majority presented with clinical staging of C2 (34%), followed by C5 (25%), C4 (18%), C3 (10%), C6 (9%) and C1 (4%). Reflux is the most common pathology (80%). Quality of life is significantly impaired both physical (Physical functioning, Role physical, Bodily pain & General health) and mental component (Vitality, Social functioning, Role emotion & Mental health) in patients with advanced clinical stage C4 to C6. The p value was significant for physical functioning, role physical, bodily pain, general health, vitality, role emotional and mental health components ($p \leq 0.001$). In conclusion, this study shows majority of our patients present at a later stage with complication and this have significantly affect their quality of life. We need to educate and raise awareness among our population, health care professionals and authorities. Treatment at early stages can reduced socioeconomic burden and improve quality of life.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master of Surgery.

.....
Ahmad Faidzal Othman
Supervisor

.....
Faisal Elagili
Co-Supervisor

.....
Mohd Norhisham Azmi Abdul Rahman
Co-Supervisor

.....
Hashima E Nasreen
Co-Supervisor

.....
David Ong Li Wei
Co-Supervisor

I certify that I have read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master of Surgery.

.....
Junaini Kasian
Examiner

This dissertation was submitted to the Department of Surgery and is accepted as a fulfilment of the requirement for the degree of Master of Surgery.

.....
Junaini Kasian
Head, Department of Surgery

This dissertation was submitted to the Kulliyyah of Medicine and is accepted as a fulfilment of the requirement for the degree of Master of Surgery.

.....
Azmi Md Nor
Dean, Kulliyyah of Medicine

DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

Dineshwary Periasammy

Signature: ……... Date: …….

INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA

DECLARATION OF COPYRIGHT AND AFFIRMATION OF FAIR USE OF UNPUBLISHED RESEARCH

A CROSS SECTIONAL STUDY OF CHRONIC VENOUS INSUFFICIENCY AND QUALITY OF LIFE FOR PATIENTS PRESENTING TO IIUM TEACHING HOSPITALS IN PAHANG, MALAYSIA

I declare that the copyright holder of this dissertation is Dineshwary Periasammy

No part of this unpublished research may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise without prior written permission of the copyright holder except as provided below

1. Any material contained in or derived from this unpublished research may only be used by others in their writing with due acknowledgement.

2. IIUM or its library will have the right to make and transmit copies (print or electronic) for institutional and academic purpose.

3. The IIUM library will have the right to make, store in a retrieval system and supply copies of this unpublished research if requested by other universities and research libraries.

By signing this form, I acknowledged that I have read and understand the IIUM Intellectual Property Right and Commercialization policy.

Affirmed by Dineshwary Periasammy

…… ……...

Signature Date

This thesis is dedicated to my parents, whose support has always been unwavering, whose patience, endless and whose love, unconditional.

ACKNOWLEDGEMENT

This dissertation was the culmination of two years of planning, research, data collection, analysis and writing. It would not have been possible to complete this dissertation without the help and support of many individuals

I would like to thank the International Islamic University Malaysia (IIUM) for giving me the opportunity to do this research. I would like to thank my supervisor Asst. Prof. Dr Ahmad Faidzal Othman and co supervisors (Asst. Prof. Dr Faisal, Asst. Prof. Dr Mohd Norhisham, Asst. Prof. Dr Hashima & Dr David Ong). I would like to thank Head of Department of Surgery of HTAA, IIUMC and HOSHAS for giving me the .opportunity to carry out this research at their clinics and wards I would like to thank Assoc Prof Dr Ahmad Faidzal and co supervisors for their supervision and support throughout this research. I would like to thank the Department of General Surgery IIUM, all my professors, consultants, specialists and fellow colleagues for the constant guidance and support throughout this project.

I would like to thank the wonderful staff of Surgical Clinic HTAA, IIUMC and HOSHAS for their support and help in conducting my research and ensuring it went smoothly. I would like to thank the Clinical Research Centre (CRC) for their help as well.

TABLE OF CONTENTS

Abstract ii
Approval page iii
Declaration v
Copyright vi
Acknowledgement viii
Table of Contents ix
List of Tables xi
List of Figures xii
List of abbreviation xiii

CHAPTER ONE: INTRODUCTION 1
1.1 Study Background 1
1.2 Research Questions 1
1.3 Objectives 2
1.3.1 General Objective 2
1.3.2 Specific Objectives 2

CHAPTER TWO: LITERATURE REVIEW 3
2.1 Chronic Venous Insufficiency – Demography, Epidemiology and Complications 3
2.2 Quality of Life in Chronic Venous Insufficieny 4

CHAPTER THREE: MATERIALS AND METHODS 6
3.1 Study Design 6
3.1.1 Study Type 6
3.1.2 Study Area 6
3.1.3 Study Period 6
3.2 Selection Criteria 6
3.2.1 Target Population 6
3.2.2 Study Population 6
3.2.3 Sampling 7
3.2.4 Inclusion Criteria 7
3.2.5 Exclusion Criteria 7
3.2.6 Sample Size 7
3.3 Data Collection 8
3.4 Flowchart 9
3.5 Variable Definitions 10
3.6 Data Analysis 12
3.7 Risk Assessment and Ethical Considerations 12

CHAPTER FOUR: RESULTS 14

CHAPTER FIVE: DISCUSSION 19
5.1 Overview 19

5.2 Results Overview 19
5.2.1 Demography 19
5.2.2 Ceap 22
5.2.3 Pathophysiology of Cvi 22
5.2.4 Quality of Life 23
5.3 Limitations 23
5.4 Recommendations and Suggestions 24

CHAPTER SIX: CONCLUSION 25

REFERENCES 26

APPENDIX I: DATA COLLECTION FORM 29
APPENDIX II: PATIENT INFORMATION SHEET (ENGLISH) 44
APPENDIX III: PATIENT INFORMATION SHEET (BAHASA MALAYSIA) 47
APPENDIX IV: INFORMED CONSENT FORM (ENGLISH) 50
APPENDIX V: INFORMED CONSENT FORM (BAHASA MALAYSIA) .. 52
APPENDIX VI: APPROVAL FROM KULLIYYAH RESEARCH COMMITTEE 54
APPENDIX VII: APPROVAL FROM IIUM RESEARCH ETHICS COMMI TTEE (IREC) 55
APPENDIX VIII: APPROVAL FROM MINISTRY OF HEALTH MEDICAL RESEARCH AND ETHICS COMMITTEE (MREC) 57

LIST OF TABLES

Table 4.1	Patient Demographics	15
Table 4.2	Patient Demographics (continuation)	15
Table 4.3	Pathophysiology of CVI	17
Table 4.4	Quality of life (QoL) items of SF-36 in different clinical presentation of CEAP classification	18

LIST OF FIGURES

Figure 3.1	Study flowchart	9
Figure 4.1	Distribution of Patients according to Gender	16
Figure 4.2	Distribution of Patients according to Ethnicity	16
Figure 4.3	Distribution of Patients according to Clinical CEAP Classification	17

LIST OF ABBREVIATION

CVI	Chronic venous insufficiency
QoL	Quality of life
BMI	Body mass index
SFJ	Saphenofemoral junction
SPJ	Saphenopopliteal junction
PF	Physical functioning
REP	Role physical
BP	Bodily pain
GH	General health
VT	Vitality
SF	Social Functioning
REE	Role emotional
MH	Mental health
PCS	Physical Component Score
MCS	Mental Component Score

CHAPTER ONE

INTRODUCTION

1.1 STUDY BACKGROUND

Chronic venous insufficiency (CVI) is one of the most common prevalent disease in the world which has been frequently unrecognized and underestimated. Chronic venous insufficiency is a progressive disease which includes changes resulting from dilatations of veins of lower limbs, incompetence of valves and venous hypertension (Jonathan D Beard et. all, 2014). Risk factors include advanced age, pregnancy, prolonged standing, smoker, obese, diabetic etc. The Clinical, Etiology, Anatomic, Pathophysiology (CEAP) classification was developed to provide uniformity in diagnosing and treating patient with CVI (Staffa R, 2002). CEAP classification reveal the severity of disease in patient with chronic venous insufficiency which eventually have significant impact on the quality of life of the patient. In our study, we identified patients with CVI and met the inclusion criteria were recruited. We collected the demographic details such as age, gender, body mass index (BMI), occupation, comorbidities and classified into CEAP stage of disease. We also compared the disease severity with their quality of life using validated SF-36 questionnaire.

1.2 RESEARCH QUESTIONS

i. What are the demographic patterns in patients with CVI?

ii. What is the impact of clinical presentation of CVI on the quality of life among patients presented to IIUM teaching hospitals?

iii. What are the complications arise in patients with CVI?

1.3 OBJECTIVES

1.3.1 General Objective

i. To assess the impact of clinical presentation of CVI on the quality of life among patients presented to IIUM Teaching Hospitals in Pahang.

1.3.2 Specific Objectives

i. To describe the pathophysiology of CVI in this population.

ii. To identify the complications of CVI in this population.

CHAPTER TWO

LITERATURE REVIEW

2.1 CHRONIC VENOUS INSUFFICIENCY – DEMOGRAPHY, EPIDEMIOLOGY AND COMPLICATIONS

Chronic Venous Insufficiency (CVI) is defines as the disease of the lower limb veins in which venous return is reduced over a number of years by reflux, obstruction or calf muscle pump failure. This leads to venous hypertension and complications such as edema, eczema, lipodermatosclerosis and ulcer formation (Jonathan D Beard et. all, 2014). The Clinical, Etiology, Anatomic, Pathophysiology (CEAP) classification was developed to provide uniformity in diagnosing and treating patient with chronic venous insufficiency (Robert T. Eberhardt et. all, 2005).

The main risk factors of CVI can be divided into modifiable and non-modifiable. This includes lifestyle, occupation, number of pregnancies, genetic influences and geographic factors. Edinburgh Vein Study is the largest epidemiological based chronic venous insufficiency study which was published in 1998. In this study, men had a higher prevalence of chronic venous insufficiency than women. This attributed to changes in lifestyle such as standing for a long duration, tight underwears, bathroom posture, prolonged sitting on a chair and low fiber diet. Therefore, Edinburgh Vein Study concluded that lifestyle changes might be contributing to an alteration in the incidence of venous disease (C J Evans et. all, 1999).

CVI is a common complication following DVT as a consequence of post thrombotic syndrome (PTS) which was acknowledged in Malaysian Clinical Practise Guideline (Abdul Rashid Abdul Rahman et. all, 2013).

2.2 QUALITY OF LIFE IN CHRONIC VENOUS INSUFFICIENY

WHO defines Quality of life (QoL) as an indivudual's understanding of their position in life in the context of the culture and values in which they live and in relation to their goals, expectations, standards and concerns (WHO QoL User Manual, 2012). It is a wide ranging concept affected in a complex way by an individual's physical health, psychological mindset, personal beliefs, social relationships and their relationship to pertinent features of their environment. QoL can be measured using a validated SF36 questionnaire based on 36 -items representing 8 health components (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health).

SF-36 represents a concise yet comprehensive 36-item questionnaire. It is developed in 1990s by a group of British researchers from the RAND cooperation and the questionnaire first included in medical outcome study (Sararaks et. all, 2005) SF -36 measures 8 scales - physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). It is further divided into two main components – physical component (physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH)) and mental component (vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). UK version of SF 36 questionnaire was translated into Malay (Bahasa Melayu) by a group of researchers from University Science Malaysia and validated between 1999 and 2000 (Sararaks et. all, 2005). SF 36 validated QoL questionnaire has been used in Quality of life in patients with chronic venous disease : San Diego pupolation study (Robert M.Kaplan et. all, 2003) and QoL in chronic venous insufficiency : Italian pilot study in Triveneto (G.M. Andreozzi et.all, 2005).

Italian pilot research in Triveneto reported that QoL is gradually worsening from CEAP class C1 to class C5-6 (G.M. Andreozzi et.all, 2005).The study also concluded that QoL is gradually impaired in CVI, involving mainly the physical component and the mental component with worsening of mental component only in advanced stages. Another study, QoL in patients with chronic venous disease : San Diego population study (Robert M.Kaplan et. all, 2003) concluded that the quality of life reduced with disease severity especially in C5 & C6.

CHAPTER THREE

MATERIALS AND METHODS

3.1 STUDY DESIGN

3.1.1 Study Type

This was a multi-centre, cross sectional study conducted among patients with chronic venous insufficiency who presented to IIUM teaching hospitals.

3.1.2 Study Area

This research was conducted in Hospital Tengku Ampuan Afzan (HTAA), Kuantan, Pahang, Hospital Sultan Ahmad Shah, Temerloh (HOSHAS) , Pahang and International Islamic University Medical Centre (IIUMC), Kuantan, Pahang

3.1.3 Study Period

The study period was from February 2018 to February 2019.

3.2 SELECTION CRITERIA

3.2.1 Target Population

Patients with chronic venous insufficiency in Pahang.

3.2.2 Study Population

Chronic venous insufficiency patients who presented IIUM Teaching Hospitals

(Outpatients at surgical / vascular clinics and inpatients at surgical wards)

3.2.3 Sampling

Purposive sampling was employed. There was no randomization. All subjects fulfilling the inclusion criteria were counselled for recruitment into the study.

3.2.4 Inclusion Criteria

i. Patients with chronic venous insufficiency as defined presented to the forementioned hospitals

ii. Patients who are aged 18 years old and above

3.2.5 Exclusion Criteria

i. Patient who does not agree to involve in the study.

ii. Recurrent chronic venous insufficiency patients who underwent surgical intervention (post-surgery)

3.2.6 Sample Size

In this study, we have achieved 80% statistical power and confidence level of 95% with +/-5% sampling error, the sample size was obtained by applying the following formula:

$$n = Z^2 \frac{p(1-p)}{e^2}$$

- n is the number of samples required
- Z^2 is the abscissa of the normal curve that cuts off an area at the tails (*desired Confidence level*, e.g.95% or 1.96)
- e is the desired level of precision / margin of error +/- 5% to 10%
- p is the estimated proportion of an attribute that is present in the population 0.5 (reference for p was 50% based on literature review [5],[18])

$$n = \frac{1.96^2 \times 0.5 (1-0.5)}{0.1^2}$$

$$n = \frac{3.8416 \times 0.5 (1-0.5)}{0.1 \times 0.1}$$

$$= 96.04 \rightarrow 110$$

Reference for quality of life on literature review was about 100. (G.M. Andreozzi et. all, 2005, B. Kanchanabat et.all, 2010, Regina M .F.Moura et. all, 2010, MM Shahin-Ul-Islam et. all, 2008)

3.3 DATA COLLECTION

This study evaluates the impact of clinical presentation of chronic venous insufficiency (CVI) on quality of life among patients presented to vascular / surgical clinics of IIUM Teaching Hospitals in Pahang. Demographic data (age, sex, ethnicity etc), presence of comorbidities (hypertension, diabetes mellitus, cardiovascular disease, hyperlipidaemia) were identified based on subject's history. Subjects who met the inclusion criteria were recruited and consent obtained. Subjects were interviewed, physical examination and ultrasound performed during the visit. Doppler ultrasound performed using linear probe and B mode with patient lying in supine with reverse Tredelenburg's or standing position. Subjects interviewed and examined by myself while ultrasound is performed by myself and my supervisor. Information documented in a purposely constructed profoma (refer to appendix). Profoma includes patient demographic details such as age, gender, occupation, BMI, etiology, complications, anatomy, pathophysiology and clinical staging of disease. Etiologic classification divided into congenital, primary, secondary or unidentified cause. Anatomy is divided into superficial, deep, perforator or unidentified location. Pathophysiology are reflux,

obstruction, thrombosis or unidentified cause. CEAP is summarized into 6 categories (1-6). C 0 with no evidence of venous disease, C1 with telangiectasia, C 2 with varicose veins, C 3 with oedema, C 4 with skin pigmentation or lipodermatosclerosis, C 5 with healed ulcer and C 6 with active ulcer. Subjects were given a set of SF 36 Quality of life validated questionnaire (refer appendix) to answer after consent signed.

3.4 FLOWCHART

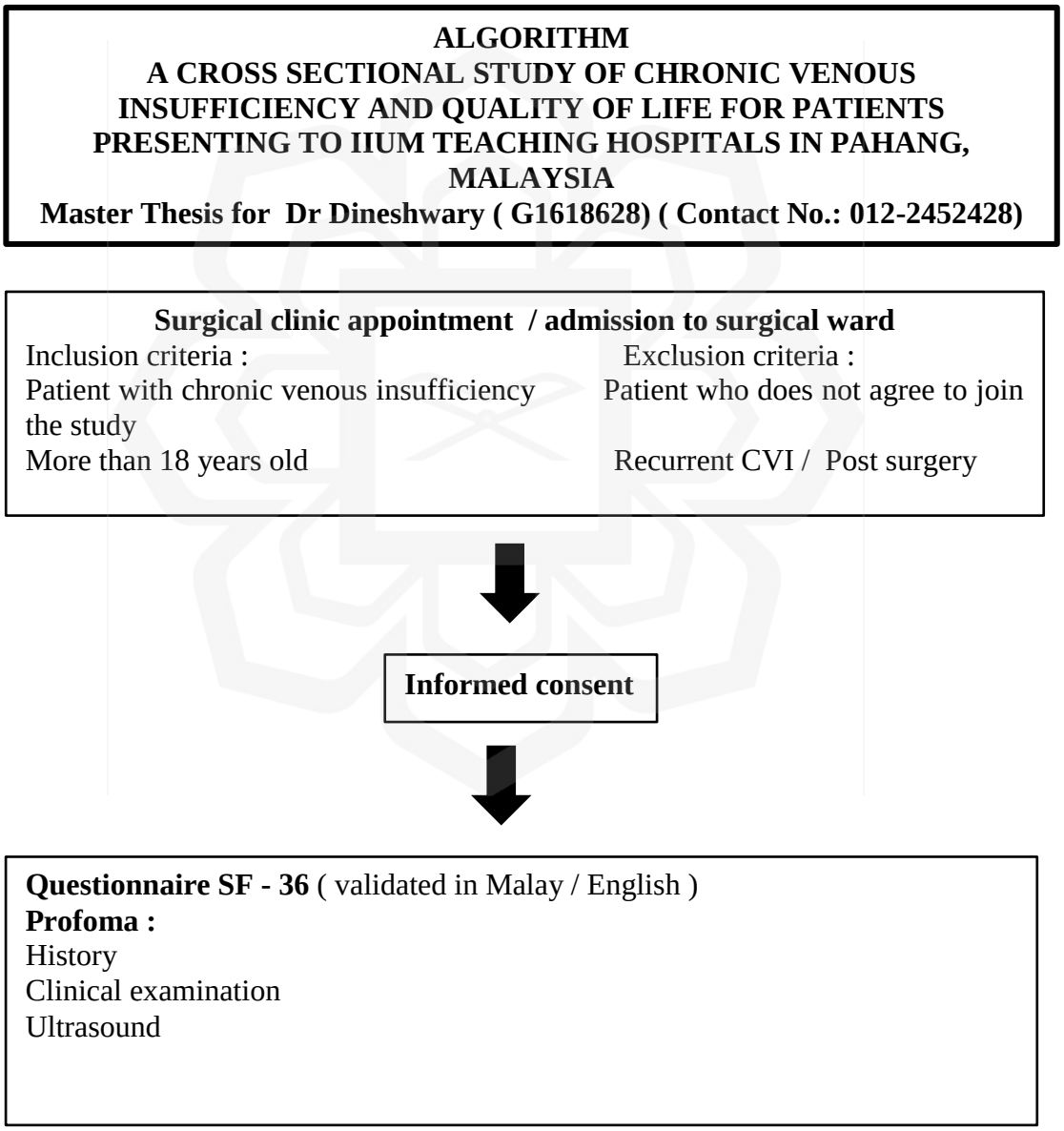

Figure 3.1 Study flowchart

3.5 VARIABLE DEFINITIONS

Chronic venous insufficiency (CVI) is a progressive disease of lower limb veins which results from dilatations of veins due to valvular imcompetence and venous hypertension

CEAP Classification:

C - Clinical Presentation

E - Etiology

A - Anatomy

P - Pathophysiology

i) **Telangiectasia** - abnormal dilatation of superficial venules beneath skin which is less than 1mm in diameter (spider veins, hyphen webs and thread veins)

ii) **Reticular veins** - is dilated bluish subdermal veins usually between 1mm – 3mm in diameter (blue veins, subdermal varices and venulectasias)

iii) **Varicose vein** - is subcutaneous dilated veins greater than or equal to 3mm in diameter as measured in the upright position (varix, varices and varicosities)

iv) **Corona phlebectatica** - is a fan shaped pattern of numerous intradermal veins on the medial or lateral aspects of the ankle and foot (malleolar flare and ankle flare)

v) **Oedema** - is a perceptible increase in volume of fluid in the skin and subcutaneous tissue characteristically indenting with pressure. Usually located in the ankle but also can extend to the leg and foot.

vi) **Pigmentation** - is a brownish darkening of the skin resulting from extravasated blood, which usually occurs in the ankle region but may extend to the leg and foot. A sign of increasing venous pressure due to CVI.

vii) **Eczema** - is an erythematous dermatitis which may progress to blistering, weeping, or scaly eruption of the skin of the leg. Commonly

located near varicose veins but can be localised anywhere on the leg and reflects uncontrolled CVI.

viii) **Lipodermatosclerosis** is localised chronic inflammation and fibrosis of the skin and subcutaneous tissue of the lower leg and suggests severe CVI.

ix) **Atrophie blanche** is a localised whitish and atrophic skin area surrounded by dilated capillaries and sometimes hyperpigmentation. It is a sign of severe CVI and not to be confused with healed ulcer scars.

x) **Venous ulcer** is a full thicknesses defect of the skin most frequently seen in the ankle region that fails to heal spontaneously and is sustained by CVI

CLINICAL classification:

C0 - no visible or palpable signs of venous disease.

C1 - telegiectasia or reticular veins

C2 - varicose veins>3mm

C3 - oedema

C4 - pigmentation or eczema & Lipodermatosclerosis or atrophie blanche

C5 - healed venous ulcer

C6 - active ulcer

ETIOLOGIC classification:

Congenital/primary - existing at or before birth (condition developed in-utero)

Secondary - post thrombus

Idiopathic - no venous cause identified

ANATOMICAL classification:

Superficial veins - telangiectasies , long saphenous vein above knee, long saphenous vein below knee, small saphenous vein and non - saphenous veins

Perforators - veins which perforate the the deep fascia of muscle to communicate with superficial thigh and leg.