"ENDOSCOPIC VERSUS OPEN SUBFASCIAL LIGATION IN THE TREATMENT OF PERFORATOR INCOMPETENCE OF VARICOSE VEIN IN TERMS OF POST OPERATIVE PAIN AND COSMETIC OUTCOME – ONE YEAR OBSERVATIONAL STUDY"

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Endorsement

This is to certify that the dissertation entitled **"ENDOSCOPIC VERSUS OPEN SUBFASCIAL LIGATION IN THE TREATMENT OF PERFORATOR INCOMPETENCE OF VARICOSE VEIN IN TERMS OF POST OPERATIVE PAIN AND COSMETIC OUTCOME – ONE YEAR OBSERVATIONAL STUDY"** is a bonafide research work done by **REG NO. BH0119006.**

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LIST OF ABBREVIATIONS

A-V	–	Arterio-venous
CVD	–	Chronic venous disease
CVI	–	chronic venous insufficiency
DVT	–	Deep vein thrombosis
GSV	–	Great Saphenous Vein
JNMC	–	Jawaharlal Nehru Medical College
KAHER	–	KLE Academy of Higher Education and Research
KAHER	–	KLE Academy of Higher Eduaction and Research
KLES	–	Karnataka Lingayat Education Society
LSV	–	Long saphenous vein
MIS	–	Minimally Invasive Surgery
MOCA	–	Mechanochemical Ablation
OPD	–	Out Patient Department
OSAS	–	Observer Scar Assessment Scale
POD	–	Post Operative Day
POSAS	–	The Patient and Observer Scar Assessment Scale
PSAS	–	Patient Scar Assessment Scale
RFA	–	radio-frequency ablation
SD	–	Standard Deviation
SEPS	–	Subfascial endoscopic perforator surgery
SFJ	–	Saphenofemoral junction
SPJ	–	Saphenopopliteal junction
USG	–	Ultrasonography
VAS	–	Visual Analogue Score
VAS	–	Visual Analogue Scale

ABSTRACT

TITLE: "ENDOSCOPIC VERSUS OPEN SUBFASCIAL LIGATION IN THE TREATMENT OF PERFORATOR INCOMPETENCE OF VARICOSE VEIN IN TERMS OF POST OPERATIVE PAIN AND COSMETIC OUTCOME – ONE YEAR OBSERVATIONAL STUDY"

INTRODUCTION: Varicose veins are defined as dilated palpable subcutaneous veins, generally larger than 4mm in the upright position. Severity of the disease may vary from telangiectatic veins to venous ulceration. Subfascial endoscopic perforator surgery (SEPS) is a new, minimally invasive technique performed in patients with advanced chronic venous insufficiency, enables surgeons to address perforator vein incompetence less invasively, with small upper calf incisions remote from severely diseased skin in the distal leg, with less surgical complications compared to open subfascial perforator ligation.

AIM: To compare the post operative pain in patients undergoing surgery for varicose veins secondary to perforator incompetence of lower limb by Subfascial endoscopic versus open subfascial ligation using visual analogue scale and cosmetic outcome on basis of the Patient and Observer Scar Assessment Scale.

MATERIALS AND METHODS: Patients admitted under Department of General Surgery who had undergone subfacial endoscopic perforator vein surgery and open ligation with stripping of above knee long saphenous vein at KAHER, on IPD basis with diagnosis of lower limb venous insufficiency from January 2020 to December 2020.

RESULTS: We studied on post operative pain and cosmetic out come between two groups. the general demographic patterns were age distribution was maximum between 50-59 years with a mean of 43 years and incompetent SFJ was about 93.6% and almost all had perforator incompetence. Coming to outcome variables there were significant in p values on 1^{st}, 3^{rd} ,7^{th} POD in terms of post operative pain using visual analogue scale (VAS) and significant p value in terms of cosmetic outcome using patient and observer scar assessment scale (POSAS).

CONCLUSION: In the research done on 30 patients, the study showed the superiority of SEPS over open ligation in terms of lesser post operative pain, better cosmetic outcomes and shorter hospital stay.

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INTRODUCTION

Varicose veins and venous ulcer were known to be a problem as early as the fourth century BC[3].

Varicose veins and chronic venous insufficiency (CVI) are a major cause of morbidity and decreased quality of life. Varicose veins are dilated, tortuous, subcutaneous veins more than three mm in diameter measured in the upright position with demonstrable reflux.[3]

The main pathology is perforator incompetence, SFJ and SPJ incompetence which on long standing leads to lipodermatosclerosis and develops into varicose ulcer [4,5].

There is strong evidence supporting increased incidence of venous disease with age, due to increased pressure on weakened vessel wall and weakened calf muscles. The occurrence of skin changes ranges from 3% to 13%. CVI is a very frequent explanation for venous leg ulcers, these ulcers are slow to heal with high recurrence rate. Venous ulcer is the final stage of CVI [4].

Chronic venous insufficiency (CVI) affects around 10–20% of the Western population and 5% of Indians. Some reports suggest that isolated superficial venous reflux may be the chief cause of venous ulcers in over 50% of the patients with CVI. Prevalence of CVI additionally vary, from <1% to 17% in men and < 1% to 40% in women. Varicose vein occurs more commonly in obese females ranging from 1% to 73% [6].

The association between venous disease and the ulcer on the lower limb was made by Hippocrates. He was also the first to propose compressive bandaging as a treatment [3].

Currently over 5,00,000 people suffer from venous stasis ulcers. The occurrence of dynamic and healed ulcers is around 1% to 2.7%. Active venous ulcers affect around 0.3% of the adult population in the developed nations. The scarcity of powerful remedies and additionally the recurrent nature results in heavy burden in the health care system[8].

Several techniques exist to deal with varicose veins and lower extremity skin ulcers which have no proper topical, medical, or surgical remedy.

Traditional open surgical technique involves high ligation and stripping. Newer techniques include foam sclerotherapy, endovenous ablation of varicose veins either by radio-frequency ablation (RFA) or laser ablation, MOCA therapy (Mechanochemical Ablation), endovenous glue injection and SEPS [8].

The procedures as described by Linton, Cockett and Dodd were often successful in treating venous ulceration, but also had major disadvantages, such as a high percentage of wound problems.

Subfascial endoscopic perforator surgery (SEPS) enables surgeons to address perforator vein incompetence less invasively, with small upper calf incisions remote from severely diseased skin in the distal leg. Though all the above procedures have been performed widely but the treatment of choice for varicose vein still remains a debate[11].

The commonly performed surgical procedures for varicose veins are Endovenous laser ablation, open flush ligation of perforators with stripping and SEPS [11].

SEPS is performed in many centers as a component of a comprehensive treatment program for venous insufficiency.

Only few studies were done and it was found that similar ulcer healing, lower recurrence rates and lower surgical complication rates with SEPS, but the study was too small to enable definitive conclusions about the efficacy of SEPS. The rest of the studies incorporating SEPS, have had an observational study design, often without comparison treatment groups, so the usefulness of SEPS in patients with venous disease remains uncertain. With new advances as we are going for minimal invasive surgeries, still open subfascial ligation of perforators remain the most common form of treatment but not SEPS [31,32,33].

The purpose of the study is to compare the outcomes and complications of open subfascial perforator ligation surgery versus endoscopic perforator surgery (SEPS) for treatment of varicose veins in terms of post-operative recovery by studying factors such as stay duration, postoperative pain, hematoma formation, wound site infection, post-Operative edema, ulcer healing individually.

OBJECTIVE

Primary objective:

To compare the post operative pain in patients undergoing surgery for varicose veins secondary to perforator incompetence of lower limb by Subfascial endoscopic versus open subfascial ligation using visual analogue scale.

Secondary objective:

To compare cosmetic outcome on basis of the Patient and Observer Scar Assessment Scale.

REVIEW OF LITERATURE

HISTORY OF VARICOSE VEINS

Evolution is a wonderful thing, but one of the aspect that human could have lived happily without is Varicose veins. The ability of the human to stand and walk on his two legs gifted with unsightly and unhealthy consequence. Varicose veins are dilated, tortuous superficial veins of lower extremities of the body. Main cause of varicose veins is incompetent superficial/ deep venous system/ perforators resulting in reflux of blood and increase in venous pressure leading to ulceration [1].

The earliest records of varicose veins is in the papyrus of Ebers, written in 1550 BC, where the author described them as " tortuous and solid, with many knots, as if blown up by air". Its first illustration appears in a votive tablet at the base of Acropolis in 400 BC [(6)]. It was around this time Hippocrates, 'Father of Medicine' noticed the association between varicose veins and leg ulcers which lead to introduction of vein punctures, cautery (using a hot or caustic agents) and compression bandages as a treatment options. Numerous treatment options for varicose veins were developed over next two centuries [8].

Surgical option for treating varicosity was made possible by Egyptian around 270 BC. But it is understood that removal of varicose veins was too much for notorious Roman warlord from their saying that "I see the cure is not worth the pain".

It was around 600 AD, Greek surgeon realized that great saphenous vein could be ligated or removed. In 1485, a landmark was developed when Leonardo da Vinci produced accurate drawings of lower limb, depicting how venous system works. Two centuries later, first documented attempt at sclerotherapy took place by injecting acid and creating thrombus[4]. By 1900s treatment option included saphenous vein ligation, vein perforation to treat ulcer and application of special agents to close varicose veins.

Since 1960s, treatment option includes the use of guide wires, catheters, angioplasty and stents. Most recent and sophisticated are duplex ultrasound scanning, radiofrequency ablation, foam sclerotherapy and diode laser [5]

General Anatomy

Although much thinner walled than arteries, veins are also composed of intimal, medial, and adventitial layers. In comparison with arteries, veins have a weaker muscular layer and less elastic tissue.[5] The adventitia is the thickest layer of the veins wall, containing proportionately more collagen and rendering veins stiffer than the arteries. The high capacitance of the venous system is critical to the function of the calf "muscle pump" (described later) and is largely due to the elliptical cross section of the lower extremity veins, which allows volume to increase without an increase in circumference or pressure.[4]

The superficial, deep, and most perforating veins contain bicuspid valves formed from folds of endothelium supported by a thin layer of connective tissue. Valves are most numerous in the distal leg and decrease toward the hip. In the lower extremities, the valves function to divide the hydrostatic column of blood into segments and to ensure flow from superficial to deep and from caudal to cephalad. As described by van Bemmelen et al,[6,7] the lower extremity valve cusps remain open during rest in the supine position. Valve closure is a passive event initiated by reversal of the resting antegrade transvalvular pressure gradient. As the pressure gradient is reversed, there is a short period of retrograde flow, or reflux, until the gradient becomes sufficient to cause valve closure. Thus, valve closure requires first the cessation of antegrade flow, followed by a brief interval of retrograde flow (< 0.5 seconds in the upright position) of sufficient velocity to coapt the cusps completely. In

other words, reflux lasting less than 0.5 seconds is a normal and expected finding. In the upright position, retrograde flow persisting > 0.5 seconds is usually defined as pathologic reflux.

The veins of the lower extremity are classified according to their relationship to the muscular fascia and are located in either the superficial or deep compartment. The venous system of the lower extremities includes the deep veins, which lie beneath the muscular fascia and drain the lower extremity muscles; the superficial veins, which are above the deep fascia and drain the cutaneous microcirculation; and the perforating veins that penetrate the muscular fascia and connect the superficial and deep veins. Communicating veins connect veins within the same system (i.e., deep to deep, superficial to superficial).

SURGICAL ANATOMY

A thorough knowledge of the anatomy of the leg veins is essential both for understanding the basic pathology and for adequate surgical treatment.

The venous system:

For practical purpose the veins may be divided into 4 main systems.

a) The superficial system.

b) The perforator system.

c) The deep system.

d) The communicating veins

a) The Superficial System:

The superficial system of the leg consists of two major veins and their tributaries, namely the long and short saphenous veins**.** They lie superficial to deep fascia**.**

Long saphenous vein:(LSV)

LSV commences from the inner part of the dorsal venous arch of the foot by the confluence of the medial marginal veins and the internal malleolar vein. It passes in front of the medial malleolus straight up to the posteromedial aspect of the knee joint, and then up to the fossa ovalis or saphenous opening (4cm below and lateral to public tubercle) where it enters the femoral vein. The saphenous nerve is closely associated with the long saphenous vein.

Tributaries and Communicating veins:

The long saphenous vein receives several branches along the course.

At the Ankle:

1) The intermediate superficial branch from the foot.
2) Connection with upper 3 ankle perforators.
3) Free anastomosis between a tributary of short saphenous vein.

Around Knee:

1) The posterior arch vein.
2) Anterior vein of the leg.
3) Leonardo's vein[4] a perforating vein which joins it to posterior tibial vein.

The posterior – arch vein:

It is medio-dorsal contribution to the LSV in the lower leg. This collects blood from a complex of veins overlying the postero-medial aspect of the calf and its main drainage is into the deep system via multiple veins perforating the deep fascia. This particular vein is extremely important since it is connected with the deep system by at least two important ankle perforating veins. It should be observed that stripping of the LSV from the ankle does not interrupt.

In the Thigh:

1) Postero medial vein.
2) Antero-Lateral vein.
3) Perforator in middle & lower 3rd junction joins the LSV with a tributary of femoral vein.
4) **Giacomini Vein[4]** – Branch of short saphenous vein which joins LSV through the posteromedial branch.

Terminal Tributaries:

1) Superficial external pudendal vein.
2) Deep external pudendal vein (may cause labial varicosities)
3) Superficial epigastric joins the counterpart across midline.
4) Superficial circumflex iliac vein.

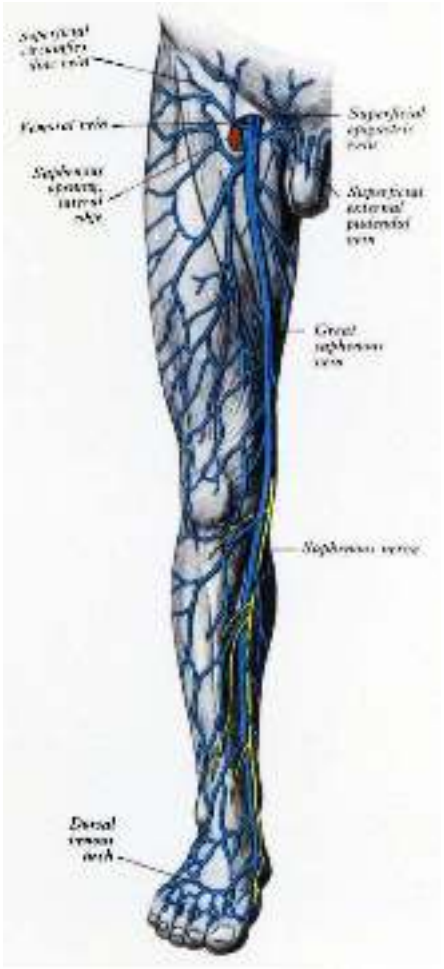


Fig 1: Long saphenous vein tributaries

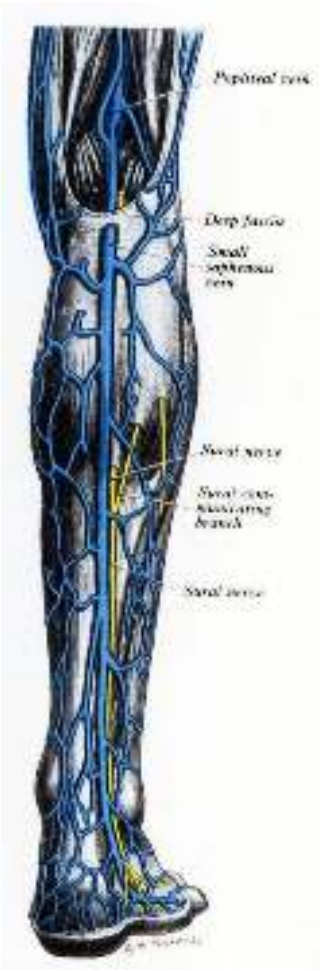


Fig 2: Short saphenous vein& its tributaries

Short Sapheous Vein:

The short saphenous vein originates as the continuation of the lateral end of the dorsal venous arch. It collects blood from the lateral part of the foot and passes upwards between the Tendo-Achilles and the lateral malleolus. It runs on the outer edge of the Tendo - Achilles, shift to the midline of the posterior part of calf to reach the Popliteal fossa. Here it dips sharply to pierce the deep fascia about 1.25cm below the transverse crease of the knee.

The short saphenous vein normally terminates in the popliteal vein. The sapheno-popliteal junction is usually located near the knee 3cm above the fold, but can be quiet variable in position.

The sural nerve is closely related to short saphenous vein.

a) The perforator system

These veins connect superficial system with deep system and are valved, such that blood flows from the superficial to deep system and are classified as**:**

1.Indirect

2.Direct

1.**Indirect :** Connect superficial veins to muscular veins and then to deep veins

2.**Direct :** Connects directly from superficial to deep veins and constant perforators are as shown in fig.3

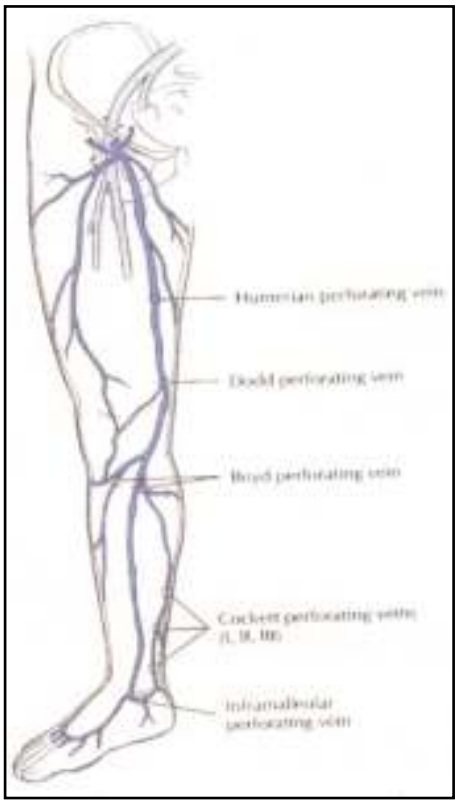


Fig 3: Sites of important perforators

b) The Deep Venous System :

The deep veins of the lower limb are

i) Anterior tibial vein

ii) Posterior tibial vein

iii) Peroneal vein

iv) Popliteal vein

v) Superficial femoral vein

vi) Common femoral vein.

Anterior tibial vein, posterior tibial vein and peroneal vein join to form the popliteal vein. The popliteal vein continues as superficial femoral vein in the adductor canal. The superficial femoral vein joins with the profunda femoris vein to become common femoral vein.

Venous Valves: The Venous valves are bicuspid valves allowing the flow of blood from distal to proximal end. The greater number of valves in the lower limb is due to their need to bear the hydrostatic pressure.

The valves are folds in the intima of the vein and appear likes semi lunar pockets on the internal surface of the wall and are directed with their free edges inthe direction of the blood flow. The valves are usually bicuspid occasionally being tricuspid.

APPLIED PHYSIOLOGY:

The presence of delicate but extremely strong bicuspid valves in the superficial and deep veins, allow blood flow only towards the heart. An expanded sinus at the site of each valve allows the valves to open widely without making contact with the venous wall. Thus when venous flow begins to reverse rapid valvular closure is permitted. The deep vein contains more valves than the superficial veins. Valves are present in venules as small as 0.15 mm in diameter. In all areas of the leg, valve cusps are intended to direct flow centrally and to prevent reflux of venous blood. Although the valves in perforating veins usually permit blood to flow only from the superficial to deep venous system, valves in the foot, in contrast, allow flow from the deep to superficial system.

Following factors help in venous return

1) Negative pressure in the thorax.
2) The calf muscle pump.
3) Vis-a- tergo.
4) Competent valves.

At rest, pressure is a superficial vein is equal to the height of the column of blood extending there from the heart. Every time one moves the legs, one tightens the muscles and compresses the veins either in the muscles or adjacent to them and this squeezes the blood out of the veins. The valves in the veins are so arranged that the direction of blood flow can only be towards the heart. Consequently every time a person moves the legs or even tenses the muscles, a certain amount of blood is propelled towards the heart and the pressure in the veins is lowered. This pumping

system is known as the “venous pump” or “muscle pump” and it is efficient enough that under ordinary circumstances, the venous pressure in the feet of a walking adult remains close to or less than 25 mm Hg. The efficiency of the muscle pump depends on the competency of the lower limb valves.

In upright position, the physical properties of the venous wall, venous valves function and the calf muscle pump action prevents the accumulation of blood in the lower limbs. By the action of the foot, calf, and thigh muscle pumps, deep veins are responsible for around 90% of the venous return in the lower limbs, which in turn dependent on the deep fascia of the leg, which constrains the muscles during contraction and generates high pressure within the muscular compartments[20]. Among the three pumps, the calf pump has the largest capacitance and generates the highest pressures.[18,21] The ejection fraction of the calf muscle pump is ~65%, whereas it is only 15% for the thigh pump. With contraction of the calf, posterior compartment pressure increases to 250 mm Hg,[21] blood in the veins is emptied, and resting venous pressure is decreased as the retrograde flow is prevented by valves. Pressure in the posterior tibial vein accordingly reduces from 80 to 100 to less than 30 mm Hg. A decrease in deep venous pressure during the relaxation phase after contraction favours flow from the superficial to the deep system through the perforating veins.

Pathological retrograde flow or reflux happens when the valves are not present or rendered incompetent either due to degenerative processes (primary venous disease) or by DVT (secondary venous disease). Under these circumstances, retrograde flow during calf muscle relaxation prevents the usual reduction in pressure and rapid venous refilling occurs from the retrograde flow of blood as well as slow capillary inflow. High venous pressure may also be transmitted from the deep veins to the superficial veins through incompetent perforators. The calf muscle pump function

may also be impaired in patients with chronic venous disease, an observation that is at least partially related to a reduced ankle range of motion.[22]

The severe clinical manifestations of chronic venous insufficiency are primarily due to ambulatory venous hypertension or failure to lower venous pressure adequately with exercise. The severity of chronic venous disease is closely related to the magnitude of venous hypertension as measured through a 21-gauge dorsal foot vein needle after 10 tiptoe manoeuvres. Ulceration usually does not occur at ambulatory venous pressures less than 30 mm Hg, but the incidence is 100% at pressures greater than 90 mm Hg.[23] However, the determinants of ambulatory venous pressure are complex and include venous reflux as well as obstruction and calf muscle pump dysfunction.[24,25] For any degree of reflux, the ambulatory venous pressure is worsened by associated venous obstruction. Similarly, abnormal calf muscle pump function is associated with a higher incidence of ulceration and non-invasive indices of venous pressure.[22] Although the relationship with disease severity has not been consistent,[26,27,28] the calf muscle pump ejection fraction is lowest in limbs with active ulceration (35%), followed by limbs with healed ulcers (49%) and those without ulceration but with duplex evidence of reflux (53%).[29] This observation may be related to the progressive decrease in ankle range of motion with increasing severity of disease.[22]

If a human being stands perfectly still, the venous pump does not work, and venous pressures in the lower part of the leg will rise to the full hydrostatic value of 90mmHg in about 30 seconds. The pressure in the capillaries also increases greatly causing fluid leak from the circulatory system into the tissue spaces. As a result the legs swell and the blood volume diminishes, indeed 10 to 20 % of blood volume can be lost from the circulatory system within the first 15 minutes of standing still.

MECHANISM OF VENOUS VALVE CLOSURE AND ROLE OF THE VALVE IN CIRCULATION: A NEW CONCEPT

Valve cycle: The time between two consecutive closure of the valves. Divided into 4 phases.

1) Opening Phase (0.27+0.05sec)
2) Equilibrium Phase (0.65+0.08sec)
3) Closing Phase (0.41+0.07sec)
4) Closed Phase (0.45+0.05sec)

During the opening phase the cusps move from the closed position toward the sinus wall. After reaching a certain point, the valves cease opening and enter the equilibrium phase. During this phase the leading edges remain suspended in the flowing stream and undergo self-excited oscillations with amplitude of 0.01 to 0.16cm. During closing the leaflets move synchronously towards the centre of the vein. In the subsequent closed phase the cusps remain closed.

During the equilibrium phase, flow separation occurs at the leading edge of the cusp with reattachment at the wall of sinus. At this point, flow splits into two streams at each valve cusp. Part of flow is directed in to the sinus pocket behind valve cusp, forming a vortex along the valve cusp, before re-emerging in the main stream in the vein. When the valve is maximally open, the two cusps create a narrowing of the lumen about 35% smaller than the vein distal to the valve. In this narrowed area flow accelerates, forming a proximally directed jet.

Thus in addition to prevention of retrograde flow, the valve acts as a venous flow modulator. The vertical stream behind the valve cusps participates in the

operation of the valve, and prevents stasis in the side of the valve pocket. The central jet possibly facilitates out flow.

PATHOLOGY OF VARICOSE VEINS

Varicose veins are the response to a dynamic process of strong reversed flow. It typically consists of a retrograde circuit having 4 components.

1) A source of outflow from deep to superficial veins at high level.
2) A pathway of incompetence running down the limb.
3) Re-entry points where superficial down flow joins the deep veins.
4) A return pathway provided by the deep veins and the Musculo-venous pumping mechanisms.

In a retrograde circuit based on an incompetent long or short saphenous vein, the upper end provides the source, the main stem and in competent branches form the pathway of incompetence and one or more perforating veins are the re-entry points The deep veins receiving this down flow may be principal conduits, such as tibial veins or the venous sinuses (pumping chambers) within any muscle group in the leg, or the veins of the foot.

The cause of reversed flow may be primary or secondary to multiple factors. The exact aetiology is yet to be established as the cause lies in the defective wall or valve. Accordingly, two theories have been put for thin the causation of primary varicose veins.

A. Weak vein wall theory.
B. Faulty valve theory.

Both the factors may contribute in different proportions to result in the large spectrum of disease.

Venous pump mechanism, which leads to venous hypertension is the seat cause of problems associated with varicosities.

Other factors:

1) Erect posture
2) Hereditary factors
3) Hormonal factors
4) Height & weight
5) Race
6) Occupation
7) Gender
8) Violent muscular effort.

The secondary factors mentioned above are contributory and not causative by themselves.

Effect on tissues:

Skin changes: Eczema, pigmentation, lipodermatosclerosis, ulceration. **Muscle changes:** Flabby weak muscles are often due to fatty degeneration due to defective circulation and improper nutrition.

Veins: Phlebitis and thrombophlebitis may occur in the veins. This can lead to

occlusion of the vein and relief from symptoms. Calcification occurs in these veins quite frequently. Peri phlebitis may extend to the neighbouring arteries and cause periarteritis.

Bone: Malnutrition, chronic irritation and infection may give rise to periostitis and osteomyelitis with thickening of bone.

Hypothesis of Venous Hypertension:

Fibrin cuff Hypothesis: It was accepted for many years that venoushypertension result in extravasation of proteins like fibrin, collagen IV and fibronectin which formed a peri vascular cuff. It was originally thought that the fibrincuff acted as a barrier to diffusion preventing nutrient exchange between the capillaries and tissues resulting in ulcer formation. Research and theoretical calculations have shown that the reisno-physical barrier to the diffusion of nutrients to the tissues in this condition.

White cell trapping hypothesis: It has been shown that venous hypertension causes leucocyte sequestration in the microcirculation of the leg and inappropriate activation of leucocytes instigates the series of events which give rise to the changes associated with venous hypertension. That is Edema, lipodermatosclerosis, pigmentation (due to hemosiderin deposition) and ulceration.

Types of varicose veins:

1) Primary varicose veins.
2) Secondary varicose veins.
   A) Obstructed / incompetent deep venous system.
   B) Following destruction of the valves of the ankle perforators and /or the

short saphenous system as sequelae to deep venous thrombosis.

C) Following pressure on the iliac segment due to pelvic and intraabdominal mass and pregnancy.

D) Secondary to A-V fistula.

3) Congenital varicose vein: Klippel -Trenaunay syndrome a congenital lateral venous anomaly, due to persistence of primitive sciatic venous system.

Parkes-Weber syndrome Arterio venous communications with limb lengthening. The deep venous system of the leg is often hypoplastic or absent in these syndromes such that malformations acts as the primary venous out flow from the leg. The treatment of this condition is primarily medical with compression hosiery.

CEAP AND VENOUS ANATOMY

The CEAP classification system, developed under the auspices of the American Venous Forum, provides a mechanism for the uniform diagnosis of venous disease and comparison of populations of patients. The four components of the CEAP classification are a description of the clinical disease class (C) based upon objective signs, the etiology (E), the anatomic (A) distribution of reflux and obstruction, and the underlying pathophysiology (P), whether related to reflux or obstruction.

CEAP	DESCRIPTION
1.CLINICAL CLASSIFICATION	
C0	No visible or palpable signs of venous Disease
C1	Telangiectasias or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation and/or eczema
C4b	Lipodermatosclerosis and/or atrophie blanche
C5	Healed venous ulcer
C6	Active venous ulcer
Cs	Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
Ca	Asymptomatic
2.ETIOLOGICAL CLASSIFICATION	
Ec	Congenital
Ep	Primary
Es	Secondary (post-thrombotic)
En	No venous etiology identified
3.ANATOMICAL CLASSIFICATION	
As	Superficial veins
Ap	Perforator veins
Ad	Deep veins
An	No venous location identified

4.PATHOPHYSIOLOGICAL CLASSIFICATION	
Pr	Reflux
Po	Obstruction
Pr,o	Reflux and obstruction
Pn	No venous pathology identified

Table 1: CEAP classification

THE DUPLEX ULTRASOUND EXAMINATION - Venous duplex ultrasound plays a vital role in the management. Report should contain information on patency of deep venous system, location of normal and refluxing axial veins, and presence of duplicate or accessory refluxing vein segment.

The following data needs to be established: [17]

(1) Saphenous junction incompetency, their locations and diameters.

(2) The reflux status of saphenous veins of the thighs and legs and their diameters.

(3) The number, location, diameter and function of incompetent perforating veins.

(4) Other veins that show reflux.

(5) The state of the deep venous system competence of valves and evidence of previous phlebothrombosis.

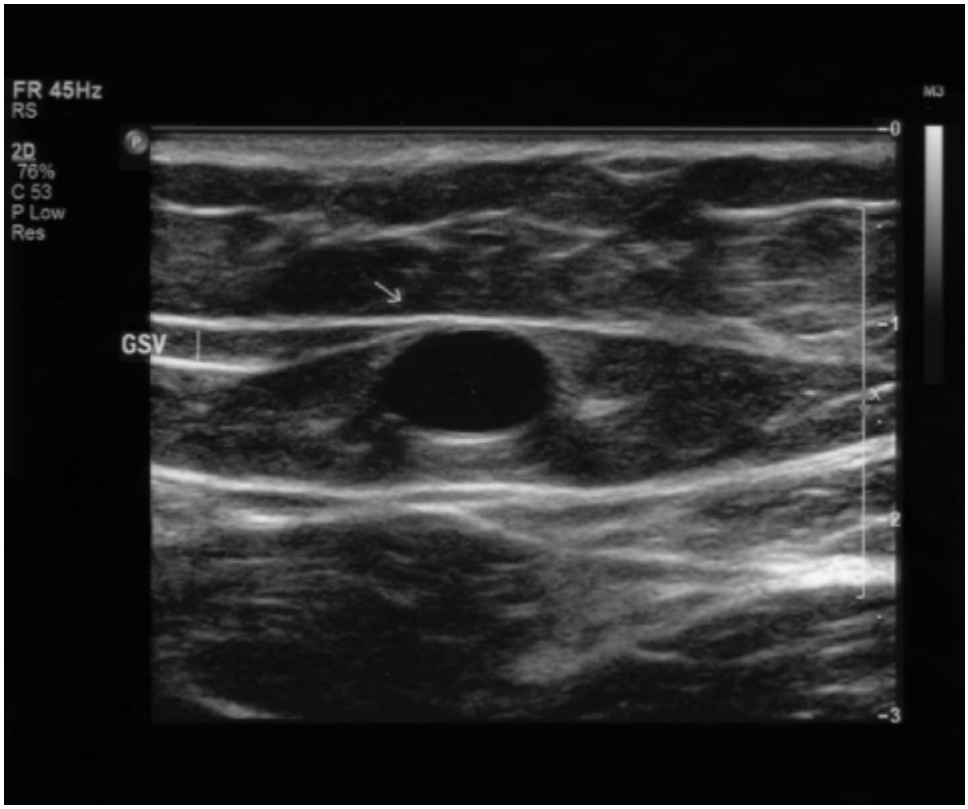


Fig 4 : Ultrasound image of GSV

Transverse ultrasound image of the great saphenous vein. The great saphenous vein lies in a sub-compartment bordered superficially by the saphenous fascia and deeply by the muscular fascia.

Common etiological factors for varicose veins include Prolonged standing, Pregnancy, Pelvic obstruction, Chronic straining, Obesity, Heredity.

Venous ulcer is defined as loss of epidermis with a part of dermis, commonly caused by CVI (45-60%), Arterial insufficiency (10-20%),Diabetes (15-25),Vasculitis, Haemorrhagic diseases, Infections, Trauma, Skin conditions-pyoderma gangrenosum, necrobiosis lipoidica ,Malignancies, Genetic- Klinefelter's syndrome.[27]

Common in obese females and incidence increases with advancing age and occupation demanding prolonged standing.

In a study done by Terence Kiat Beng Teo , they concluded that it affects 4 % of the population aged more than sixty five years, with a female-to-male ratio of 3:1, with an average age of 62.9 years [44].

Another study conducted by Robert J. Min et al, had included 423 patients in the study showed a mean age of 42 years [29].

The Bonn Vein which enrolled 3072 participants (1722 female and 1350 male), age ranging from 18 to 79, located signs of CVD in 49.1% of males and in 62.1% of females[27].

Superficial vein incompetence is because of weakened valves. Deep venous system is affected due to past DVT, inflammatory changes, scarring of valves and decreased calibre of vessels. The resting pressure within the vein is based on impedence to outflow, capillary inflow, valve function and muscle pump function [(34)]. The clinical complications are Bleeding, Eczema, dermatitis, Lipodermatosclerosis, Venous ulcer Deep vein thrombosis, Thrombophlebitis, Calcification of vein, Periostitis, Talipes equino varus .

S Shivakumar et al [31] studied 40 cases comparing SEPS with open ligation and reported SEPS being superior to open ligation in terms of shorter hospital stay, decreased post op pain and multiple perforator ligation.

Johannes E.M.M Sybrandyet al [32]compared SEPS with open ligation with long term follow up showing SEPS procedure having significant less morbidity.

Mark J. Kulbaskiet al [33] compared SEPS with open ligation showing less morbidity in SEPS procedure and can be performed as day care procedure.

Florian Roka et al[34] showed that in patients with venous leg ulcer, SEPS in addition to superficial reflux ablation promotes ulcer healing and results in a low

midterm ulcer recurrence rate due to meticulous elimination of pathologic venous flow.

M. G. Vashist et al[35] showed Subfascial endoscopic perforator vein surgery is a safe and effective method for treating incompetent perforating veins. The number of perforators ligated in SEPS was more as compared to the open subfascial ligation group. Possibly some perforators may be missed on Doppler localization and ligation, which may be a cause of future recurrence in varicose veins in the open ligation group. Early relief of symptoms in terms of ulcer healing is better in the SEPS group. Other major advantage of SEPS was fewer incidences of wound complications which were considerably high in the open ligation group because of incision over already compromised skin[5]. Hence, SEPS should be mode of surgery for the management of incompetent perforators to reduce long-term recurrences and faster wound healing

MATERIALS AND METHODS

SOURCE - Patients admitted under Department of General Surgery who had undergone subfascial endoscopic perforator vein surgery and open ligation with stripping of long saphenous vein at KAHER, on IPD basis with diagnosis of lower limb venous insufficiency from January 2020 to December 2020

STUDY POPULATION- Patients getting admitted for lower limb venous insufficiency under department of General Surgery at KAHER.

STUDY DESIGN - Comparative observational study

STUDY SETTING - KAHER, Belagavi.

STUDY PERIOD - January 2020 – December 2020.

STUDY DURATION - 1 year

SAMPLE SIZE - 30

SAMPLE SIZE FORMULA-

The minimum sample size formula based on prevalence rate is

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

Where P - percentage of prevalence

d - Percentage likely difference in the prevalence.

zα is associated with the level of significance.

For 5% level of the significance zα = 1.96.

Ref: [2]

With P = 73% and d = 25% of P = 18.35%, the sample size is 23

To make the study more confirmative, the sample size will be raised to 30.

SELECTION CRITERIA

All patients who fulfilled the inclusion criteria were included in the study.

INCLUSION CRITERIA

Patients presenting to OPD and admitted in KAHER Hospital, Belgaum and those who give written and informed consent for participation

- Any gender
- Age more than 18 years of age
- CEAP classification C3-C6
- Ankle–brachial index of more than 0.8 in affected limb
- Primary superficial venous reflux.

EXCLUSION CRITERIA-

- Deep vein thrombosis
- Secondary varicose veins
- Pelvic tumours
- Previous surgical history or recurrence
- Peripheral arterial disease
- AV malformation
- Lymphedema
- Suspected / proven malignancy
- Hypercoagulable state
- Pregnancy
- Uncontrolled diabetes mellitus
- Ischemic heart disease
- Patients who refused to provide consent

ALLOCATION OF STUDY POPULATION:

Based on the selection criteria, those who fulfilled them were included in the study. They were allocated into group A or group B based on the surgical management they were undergoing.

Group A population underwent stripping of long saphenous vein up to above knee with SEPS of the below knee incompetent perforators.

Group B population underwent stripping of long saphenous vein up to above knee with open ligation of below knee incompetent perforators.

Random selection of patients was done to avoid and minimise the bias in the study. Alternate patients were selected for SEPS.

ETHICAL CLEARANCE - The Ethical Clearance was obtained from the Institutional Ethics Committee, KAHER, Belagavi prior to the commencement.

INFORMED CONSENT - Those patients who fulfilled selection criteria were briefed about the nature of study, procedure and follow up pattern.

METHOD OF COLLECTION OF DATA- Patients satisfying the choice standards have been interviewed and the demographic facts inclusive of age and sex, chief complaints have been noted. The patients underwent clinical and systemic examination and the findings were recorded on a pre-designed and pre-tested proforma.

The subjects have been enrolled in the study after written and informed consent. A detailed history was taken and all subjects were subjected for

1. Preoperative Doppler evaluation
2. CEAP classification.

Patients were followed from the date of admission to the date of discharge. Initial thorough clinical examination was performed and routine preoperative

investigations and evaluations were done. Specific investigations suggesting venous insufficiency like colour Doppler were performed.

Prior to the day of surgery patients were prepared and the incompetent perforators were marked with permanent skin markers under ultrasound guidance.

Patient undergoing surgery was taken either under general anaesthesia or spinal anaesthesia.

SURGICAL PROCEDURE:

Fig 5: Image showing marked incompetent perforator site

TRENDELENBURG PROCEDURE[42]

Under spinal anaesthesia in supine position, 2.5cm laterally and below the pubic tubercle skin incision is made exposing the membranous layer of superficial fascia to adequately expose the SFJ. By blunt dissection long saphenous vein is found and traced up to T shaped termination with femoral vein. Saphenous is drawn forward to facilitate the division of its branches (superficial inferior epigastric, superficial circumflex iliac, superficial external pudendal, anterolateral and posteromedial thigh veins close to SFJ) When saphenous vein is isolated completely, the stump is ligated

flush with common femoral vein. Venotomy is done above the ligature through which the tip of the stripper is passed. Stripper's end is identified below knee and olive of diameter around 8mm or more depending upon the vein, is attached to the upper end of the stripper. With firm traction on the wire vein is stripped off. Immediately after stripping, limb is raised above and compression is given. Wound is closed in layers and skin is closed with ethilon.

Fig 6: Position of limb for SEPS

SEPS procedure[31]

SEPS will be done by two port method. The knee was flexed at 90° with the hip flexed and abducted. A 10mm endoscopic port will be placed on the medial side of the calf, 7-10cm distal to tibial tuberosity, under direct vision by incising the fascia. A subfascial plane will be created and carbon dioxide insufflation was used to widen the space and facilitate access after port placement.[1]

The distal 5- or 10-mm port will be placed postero-medially and slightly inferior to the first port under direct visualization with the camera.

Fig 7: Port placement in SEPS procedure

Fig 8: Dissection in SEPS procedure

Throughout the procedure pressure will be maintained at 16-20 mm. Blunt and sharp dissection to be done. Large perforators will be clipped and small perforators will be coagulated with electrocautery. Entire subfascial compartment will be explored to

look for more perforators. Subfascial compartments will be deflated manually and port site skin closed with ethilon. The limb will be wrapped in an elastic crepe bandage and elevated. No tourniquet or special balloon dissector were not used.

OPEN LIGATION PROCEDURE[42]

Preoperatively incompetent perforators were marked with permanent skin markers under USG guidance. Incision is taken on the marked site and meticulous blunt and sharp dissection is done and perforators were identified by the T shaped division. Perforators were ligated in the subfascial plane. Haemostasis was achieved and skin was closed with ethilon.

Fig 9: Open perforator ligation

Fig 10: Stripped long saphenous vein from thigh

Fig 11: specimen of venectomy

In this study, initially it was started with dissection of LSV and stripper is passed and placed in situ. Following which either open subfascial ligation or SEPS was performed. Stripping was the step in the procedure following which elastic bandage with crepe and elevation was given.

OUTCOME VARIABLES

Postoperative pain assessment using VAS and face pain rating scale on post op day 1, 3,7,11 was done.

Scar was assessed on post operative day 11 and 30 using patient observer scar assessment scale. Study also observed parameters such as

1) Intra operative duration

2) Post operative infection and complications such as hematoma

3) Post operative day of ambulation.

4) Post operative stay period

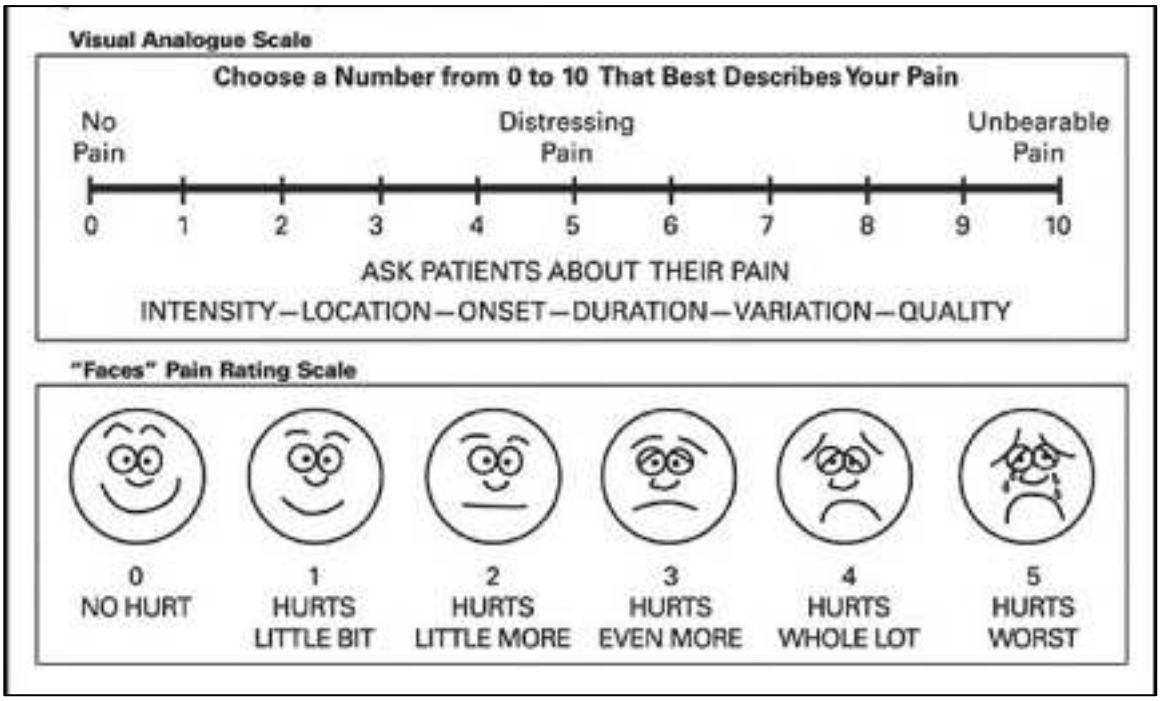


Fig 12: visual analogue scale

The cosmetic outcomes are assessed using patient observer scar assessment scale on Day 11 and Day 30.

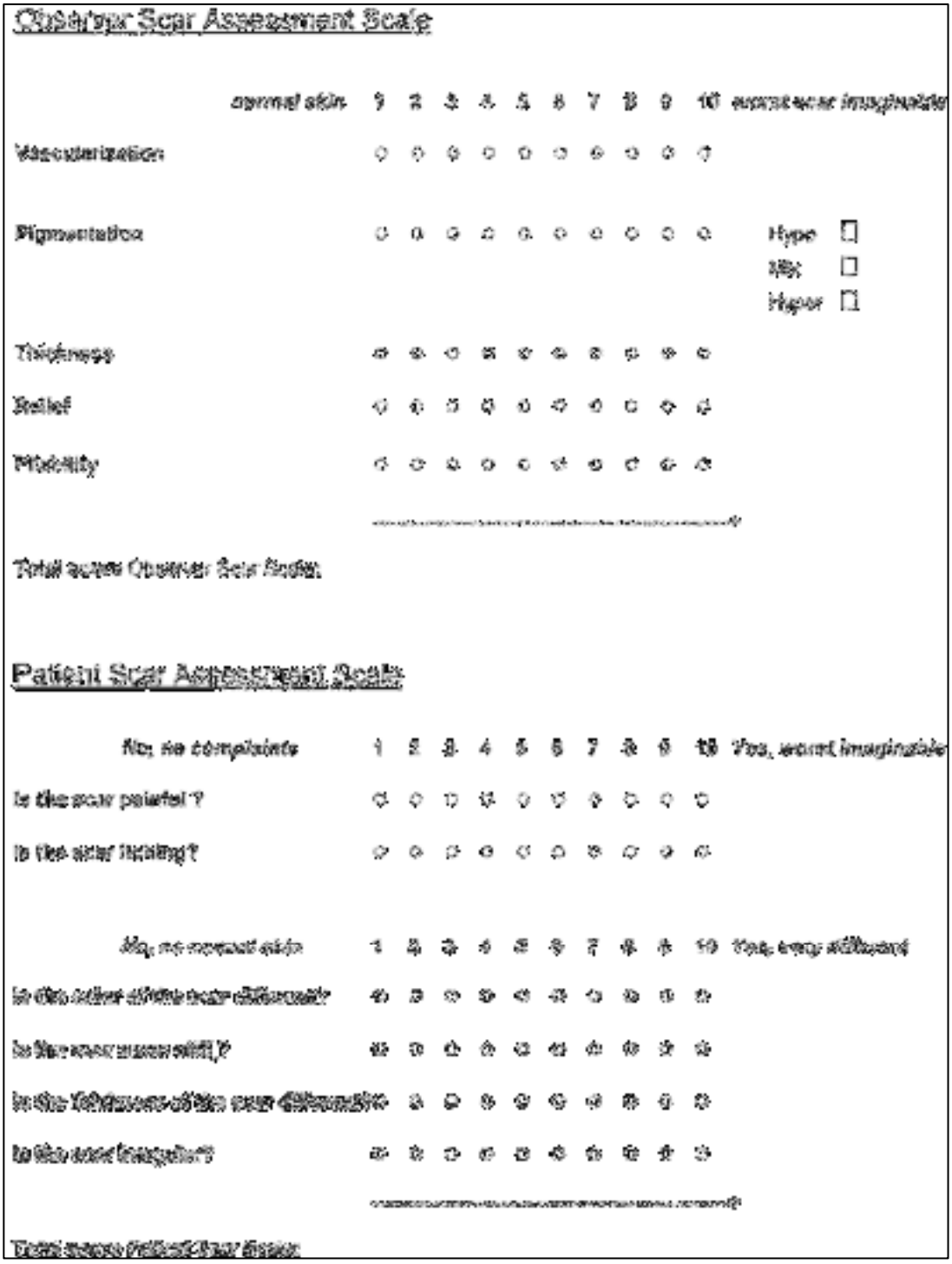


Fig 13: patient and observer scar assessment scale

RESULTS

This observational study consisted of 30 patients, admitted under Department of Surgery with varicose vein at KLES PRABHAKAR KORE HOSPITAL AND MRC, BELGAUM from JANUARY 2020- DECEMBER 2020. They underwent open ligation and subfascial endoscopic perforator vein ligation

In this study we studied on post operative pain and cosmetic out come between two groups using visual analogue scale and face pain rating scale and cosmetic outcome using patient and observer scar assessment scale.

All quantitative variables were checked for normal distribution within each category.

The quantitative parameters, was assessed by unpaired student t-test in both groups and "P value of <0.05 were considered significant".

DESCRIPTIVE ANALYSIS OF AGE IN STUDY GROUP

In our study population mean age was 43.3yrs. Minimum age was 21 years and maximum was 61 years with standard deviation 10.77yrs

AGE	GROUP A	GROUP B	NUMBER
20 - 29	3	1	4
30 - 39	7	2	9
40 - 49	1	3	4
50 - 59	4	8	12
60 - 69	0	1	1
TOTAL	15	15	30

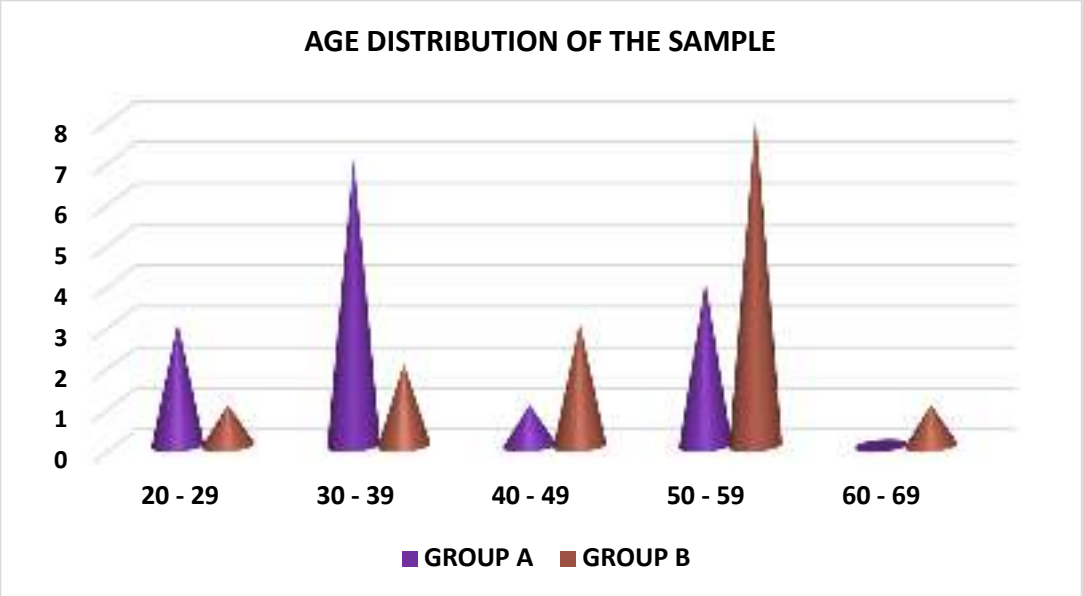
Table 2: Comparison of age distribution between two groups

AGE	MEAN	S.D.	MIN	MAX
AGE	43.33	10.77	21	61

Table 3: Mean and standard deviation of age distribution between two groups

AGE	NUMBER	%
20 - 29	4	13.33
30 - 39	9	30.00
40 - 49	4	13.33
50 - 59	12	40.00
60 - 69	1	3.33
TOTAL	30	100.00

Table 4: Percentage of patients belonging to that particular age group



Graph 1: Age distribution between the two groups

DESCRIPTIVE ANALYSIS OF GENDER IN STUDY GROUP

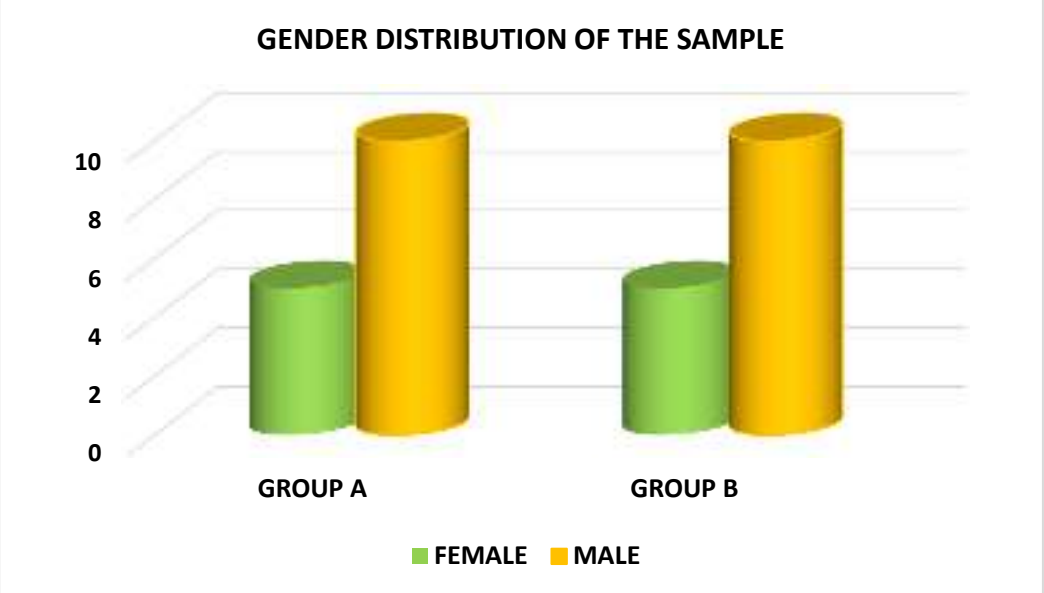
Among the study population, 20 (66.6%) were male participants and remaining 10 (33.3%) participants were female. In both group A and group B, male and female were equally distributed.

GENDER	GROUP A	GROUP B	TOTAL
FEMALE	5	5	10
MALE	10	10	20
TOTAL	15	15	30

Table 5: Comparison of sex distribution between two groups

GENDER	GENDER	GENDER
FEMALE	10	33.33
MALE	20	66.67
TOTAL	30	100.00

Table 6: Percentage of patients with respect to sex



Graph 2: Sex Distribution between the two groups

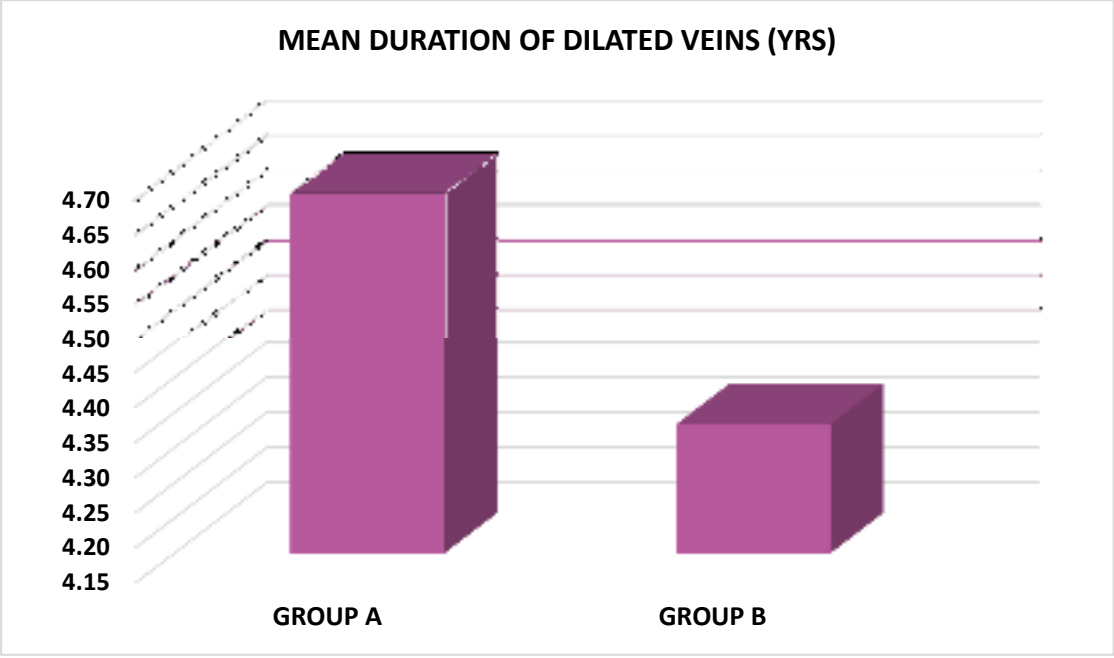
In both group, male and female were equally distributed.

DESCRIPTIVE ANALYSIS OF DURATION OF VARICOSE VEIN

In our study the mean duration of history of dilated torturous vein was 4.67yrs in group A and 4.33yrs in group B. (p-value – 0.6804 which was statically non significant)

Table 7: Percentage of patients having history of long standing ulcer

	GROUP A				GROUP B				
	MEAN	S.D.	MIN	MAX	MEAN	S.D.	MIN	MAX	p VALUE
DURATION OF DILATED VEINS (YRS)	4.67	2.47	2	9	4.33	1.88	2	7	0.6804



Graph 3: Mean duration of dilated veins between the two groups

DESCRIPTIVE ANALYSIS OF HISTORY OF LONG STANDING LOWER LIMB ULCER

In our study only 8 (26%) out of 30 patients had history of long standing ulcer, of them 5 were placed in group A and 3 were placed in group B

H/O LONG STANDING LOWER LIMB ULCER	NUMBER	%
YES	8	26.67
NO	22	73.33
TOTAL	30	100.00

Table 8: Comparison of patients having history of long standing ulcer

H/O LONG STANDING LOWER LIMB ULCER	GROUP A	GROUP B	TOTAL
YES	5	3	8
NO	10	12	22
TOTAL	15	15	30

Table 9: Comparison of patients having history of long standing ulcers between the two groups

DESCRIPTIVE ANALYSIS OF SFJ INCOMPETENT IN STUDY GROUP

In our study 28 patients (93.6%) had saphenofemoral junction incompetence and only 2 patients had competent saphenofemoral junction competence, those 2 patient belong to group A.

All patients had perforator incompetence.

SFJ COMPETENCY	NUMBER	%
COMPETENT	2	6.67
INCOMPETENT	28	93.33
TOTAL	30	100.00

Table 10: Comparison of SFJ competence between all selected patients

SFJ COMPETENCY	GROUP A	GROUP B	TOTAL
COMPETENT	2	0	2
INCOMPETENT	13	15	28
TOTAL	15	15	30

Table 11: Comparison of SFJ incompetence between the two groups

DESCRIPTIVE ANALYSIS OF LATERALITY IN STUDY GROUP

In our study population 14 patients (48%) had history bilateral lower limb varicose vein and 16(52%) had single limb involvement.

Out of 14 patients with bilateral varicose vein, they had undergone surgery for only single limb with maximum complaints.

H/O DILATED VEIN TO (SIDE)	GROUP A	GROUP B	TOTAL
B/L	7	7	14
LEFT	5	1	6
RIGHT	3	7	10
TOTAL	15	15	30

Table 12: Distribution of laterality of varicose veins between the two groups

H/O DILATED VEIN TO (SIDE)	NUMBER	%
B/L	14	46.67
LEFT	6	20.00
RIGHT	10	33.33
TOTAL	30	100.00

Table 13: Distribution of laterality of varicose veins within the study group

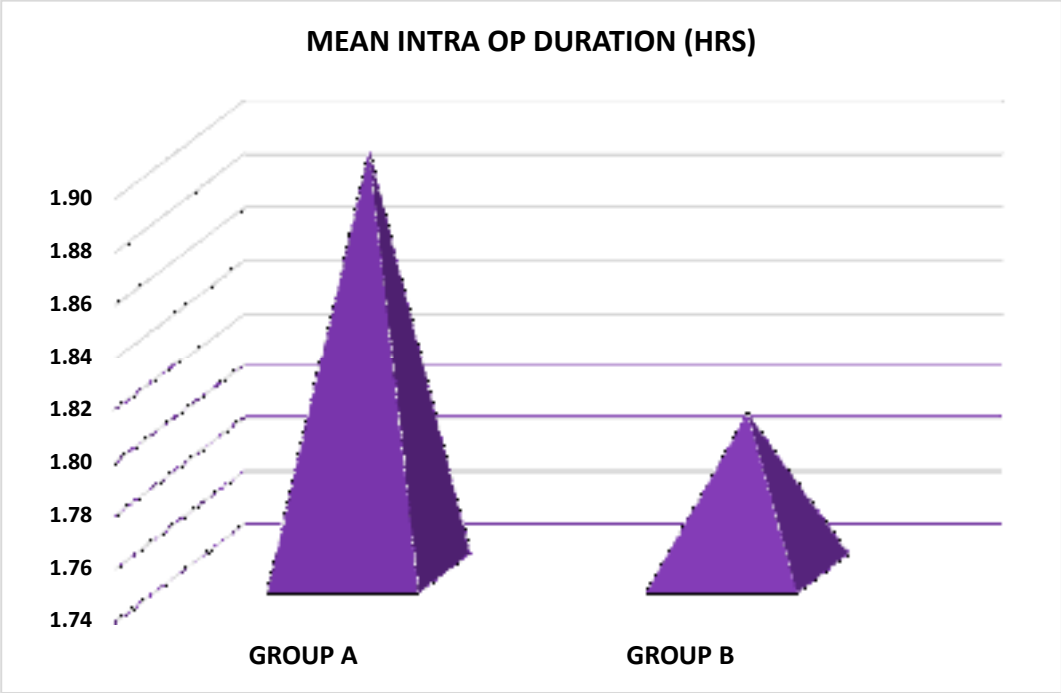
DESCRIPTIVE ANALYSIS OF INTRA OPERATIVE DURATION

In both group the intra operative duration was assessed, the mean duration in group A was 1.90 hrs, and in group B 1.80 hrs.

There was no significance in p value (p value – 0.4378)

	GROUP A				GROUP B					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
INTRA OP DURATION (HRS)	1.90	0.42	1.25	2.5	1.80	0.26	1.5	2.25	0.4378	NS

Table 14: Comparison of intra operative duration between the two groups



Graph 4: Mean of intra operative duration between the two groups

DESCRIPTIVE ANALYSIS OF POST OPERATIVE DAY OF AMBULATION

In both group, post operative day of ambulation was studied, in group A 10 patients (66.6%) were ambulated in post operative day 2nd while in group B 9 patients were ambulated on post operative day 4th i.e. 9 patients (60%) .

POST OP DAY OF AMBULATION	GROUP A	GROUP B	TOTAL
2	10	0	10
3	4	5	9
4	1	9	10
5	0	1	1
TOTAL	15	15	30

Table 15: Comparison of post op day of ambulation between the two groups

DESCRIPTIVE ANALYSIS OF POST OPERATIVE HOSPITAL STAY

Among both groups the post operative stay in the hospital was assessed, i.e., post operative day of discharge

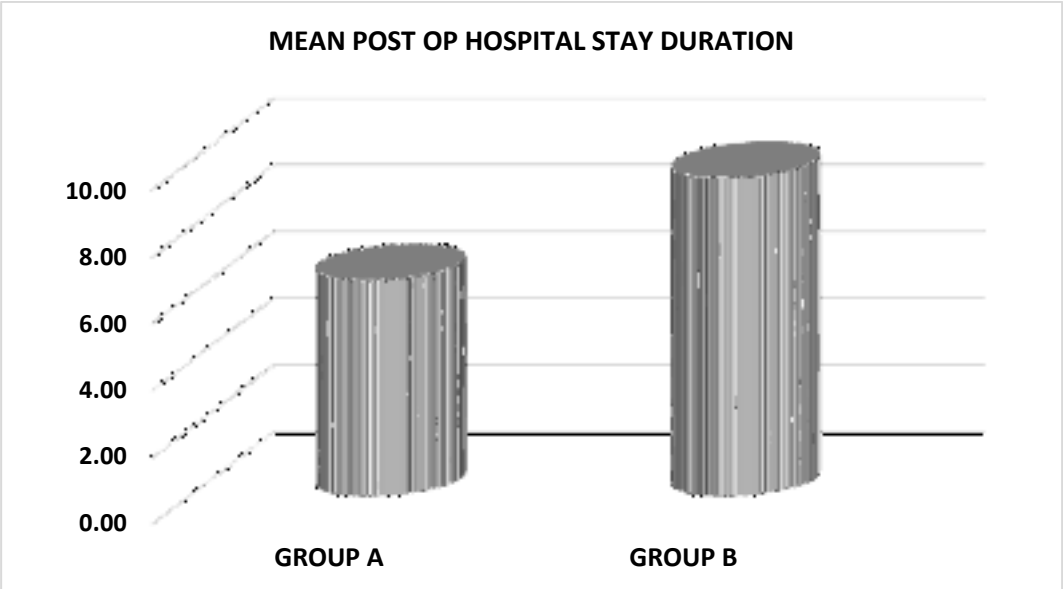
In group A the mean post operative day of discharge was 6.47 with S.D. of 1.73 with range of 4 days to 10 days hospital stay.

In group B the mean post operative day of discharge was 9.53 with S.D. of 1.41 with range of 7 days to 12 days maximum hospital stay.

The p value between both the group in terms of post operative hospital stay duration was significant (p value – 0.0001)

	GROUP A				GROUP B				
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**
POST OP HOSPITAL STAY DURATION	6.47	1.73	4	10	9.53	1.41	7	12	< 0.0001

Table 16: Comparison of post-operative hospital stay period between the two groups



Graph 5: Mean of post-operative stay duration of the two groups

DESCRIPTIVE ANALYSIS OF POST OPERATIVE PAIN ASSESSMENT USING VISUAL ANALOG SCALE AND FACE PAIN RATING SCALE

In our study, we assessed the pain in post operative day 1st, 3rd, 7thand day 11th using VAS and Face pain rating scale

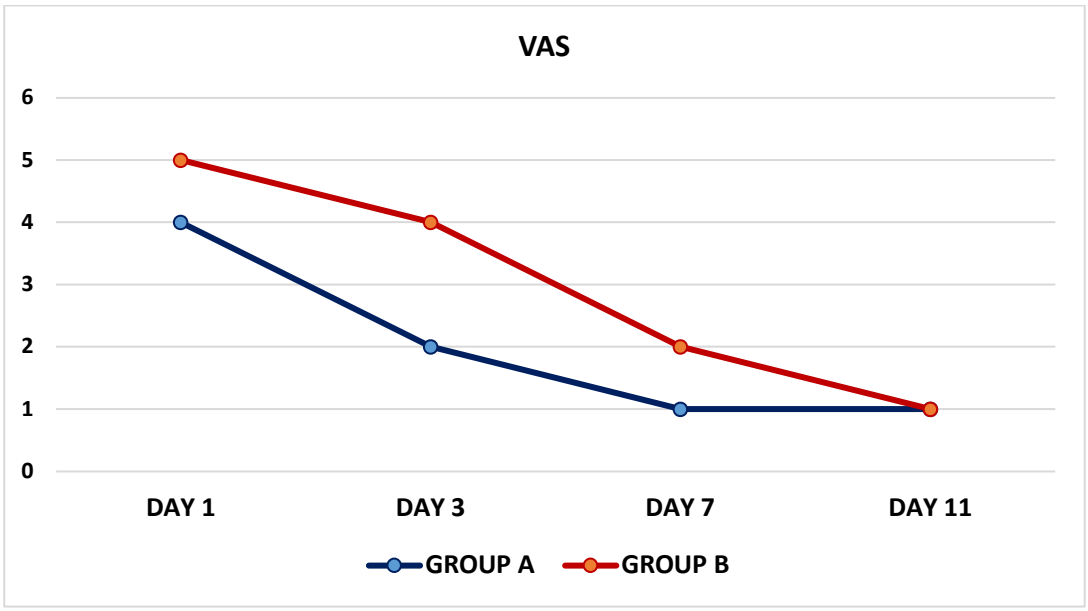
For a discrete variable p value is calculated using MANN-WHITNEY TEST

		MEDIAN			
		GROUP A	**GROUP B**	**p VALUE**	**INFERENCE**
Day 1	**VAS**	4	5	0.0017	VS
	FACES PRS	2	3	0.0001	HS
Day 3	**VAS**	2	4	0.0104	S
	FACES PRS	1	2	0.0006	HS
Day 7	**VAS**	1	2	0.0181	S
	FACES PRS	0	1	0.0005	HS
Day 11	**VAS**	1	1	0.6534	NS
	FACES PRS	0	0	0.0887	NS

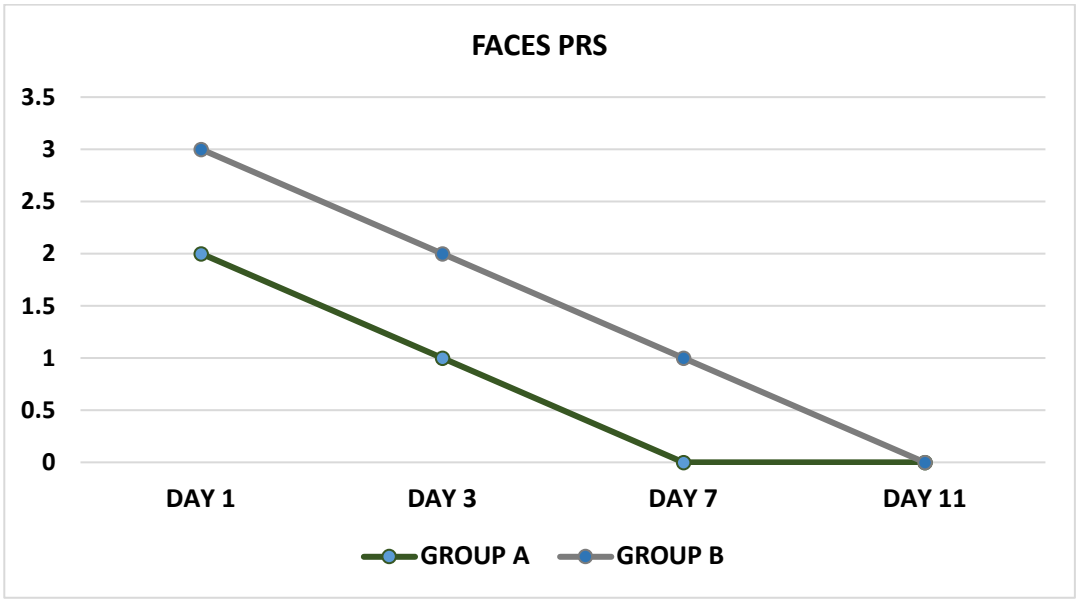
Table 17: Comparison of pain assessment between the two groups

There was a significance in p value in post operative date 1st, 3rd, and 7th between both groups.

There was no significance in p-value in post operative day 11th.



Graph 6: The graph showing difference in both group A and group B using VSA.



Graph 7: The graph shows difference in both group A and group B using Face pain rating scale.

DESCRIPTIVE ANALYSIS OF COSMESIS IN BOTH GROUPS

The cosmetic outcome was assessed using patient scar assessment scale and observer scar assessment scale on post operative day 11 and day 30.

	GROUP A				GROUP B				
DAY 11	**MEAN**	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**
OSAS	12.07	1.87	10	17	16.80	2.98	9	21	< 0.0001

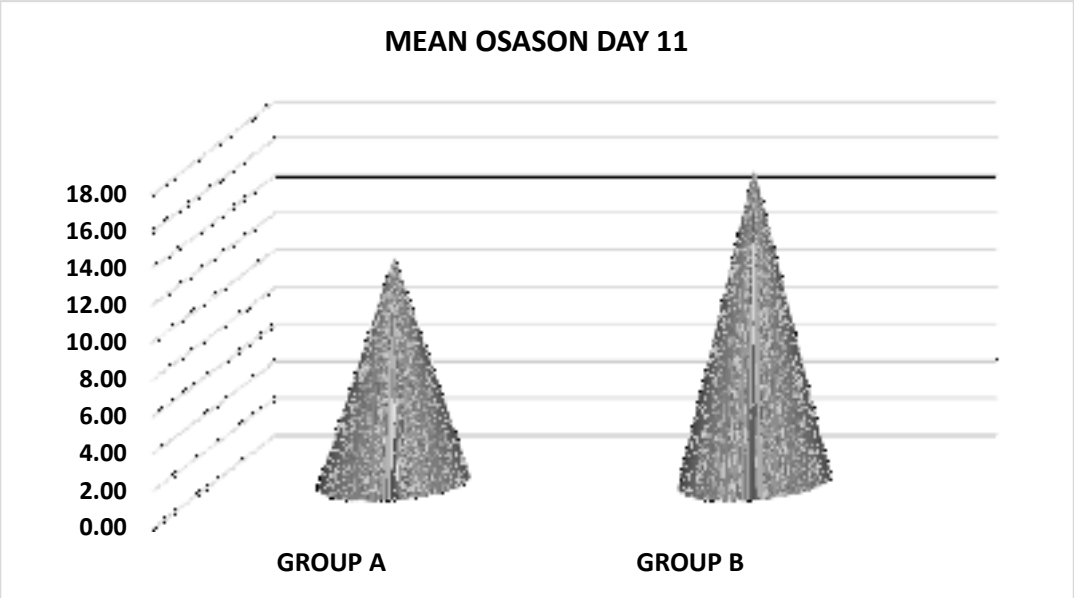
	GROUP A				GROUP B				
DAY 11	**MEAN**	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**
PSAS	13.80	2.70	8	19	16.20	4.72	8	24	< 0.0001

	GROUP A				GROUP B				
DAY 30	**MEAN**	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**
OSAS	8.33	2.06	6	14	10.27	2.28	6	14	< 0.0001

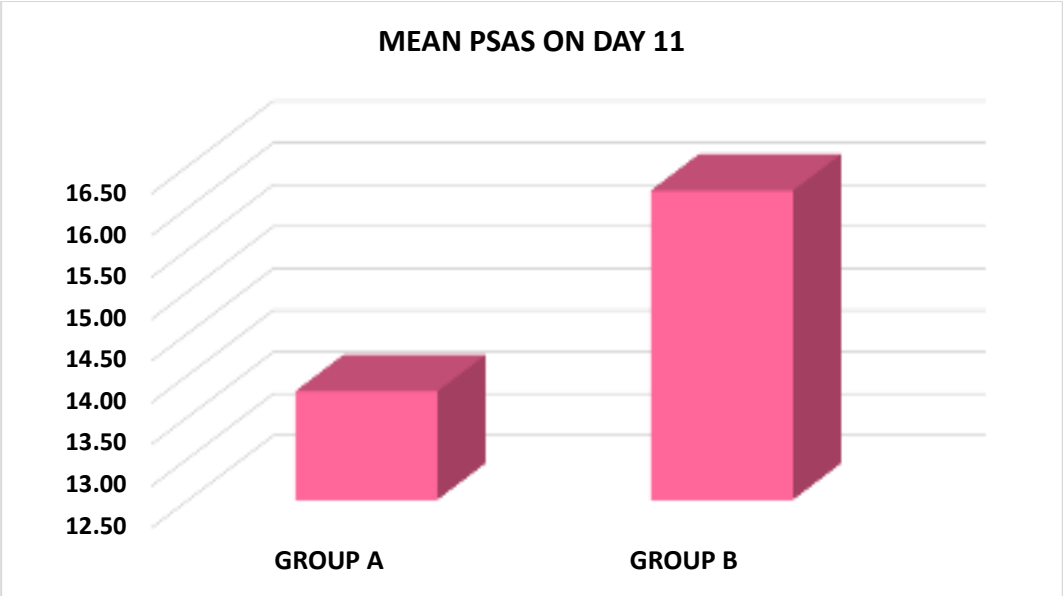
	GROUP A				GROUP B				
DAY 30	**MEAN**	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**
PSAS	8.53	1.88	6	13	10.60	3.09	6	16	< 0.0001

Table 18: Assessment of cosmetic outcome between the two groups

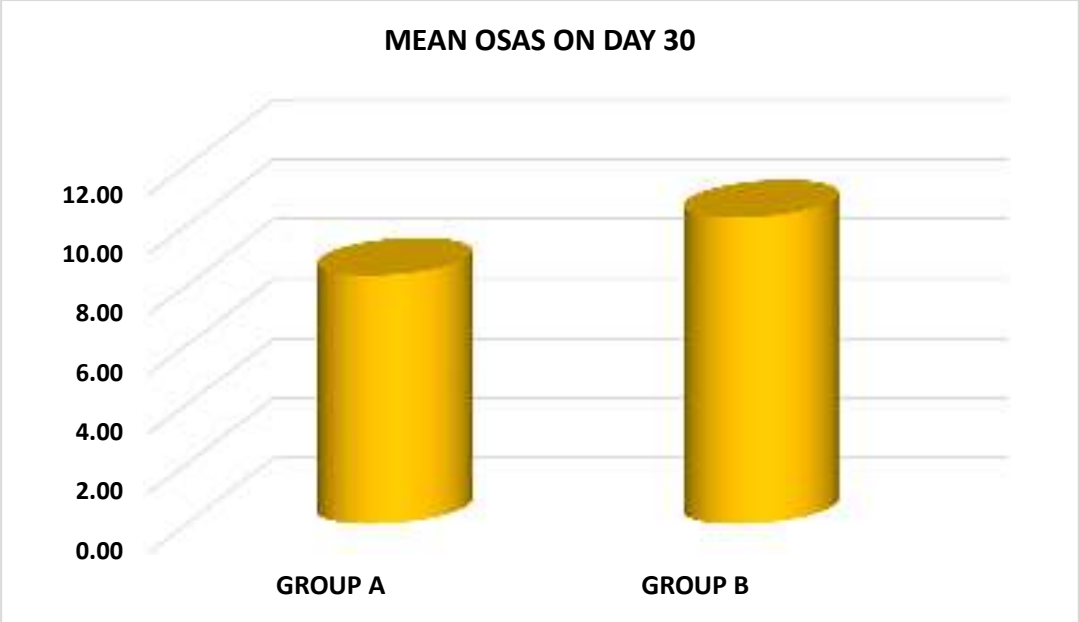
There was significance in the p value (0.0001) with group A and B in comparison of scar outcome on day 11th POD and 30th POD using Patient and Observer Scar Assessment Scale.



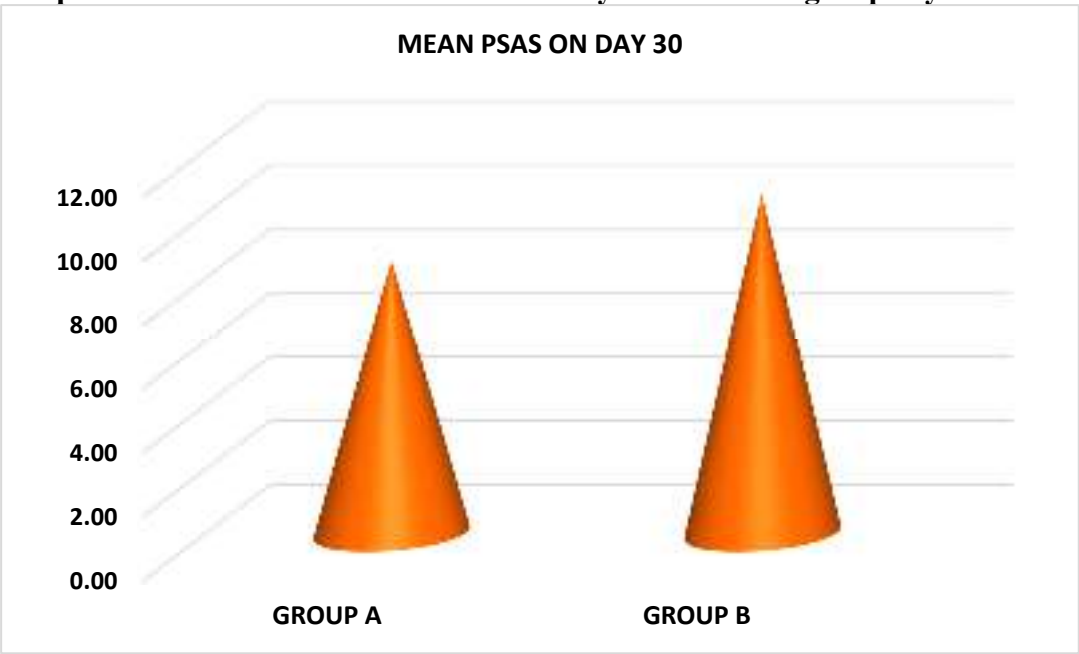
Graph 8: Mean of cosmetic outcome on day 11 of the two groups by OSAS



Graph 9: Mean of cosmetic outcome on day 11 of the two groups by PSAS



Graph 10: Mean of cosmetic outcome on day 30 of the two groups by OSAS



Graph 11: Mean of cosmetic outcome on day 30 of the two groups by PSAS

DISCUSSION

BASELINE SOCIODEMOGRAPHIC VARIABLES

In this study 30 subjects were included. All subjects had preoperative Doppler evaluation and underwent either open ligation of below knee perforator or endoscopic subfascial ligation of perforators according to their assigned group and along with, they also underwent stripping of great saphenous vein up till knee level.

Following parameters were assessed

1) Post operative pain on day 1st, 3rd, 7th and day 11th using VAS and face pain rating scale.
2) Secondary objective was the scar outcome of both groups on day 11th and 30th post operative day.

In group A (endoscopic subfascial perforator vein surgery), out of 15 patients 5 (33.3%) were female and 10 (66.67%) male patients with mean age between 30 to 39 years. Among them, history of dilated vein was for about 2 years to 9 years with mean duration of 4.67 years. Out of them only 2 patients had competent SFJ and those 2 patients underwent only below knee endoscopic perforator ligation, were as all other 13 patients in group A, had undergone both perforator ligation along with stripping of long saphenous vein from thigh. Among them only 5 (33.3%) patients had history of long standing lower limb ulcer.

In group B (open ligation group), out of 15 patients 5 (33.3%) were female and 10 (66.67%) male patients which was similar to group A with mean age between 50 to 59 years. Among them, history of dilated vein was for about 2 years to 7 years with mean duration of 4.33years which is slightly lower compared to other group, yet was not statically significant. Out of 15 patients all had incompetent SFJ and all

underwent stripping of long saphenous vein from thigh with open ligation of perforators below knee.

Comparing the post operative pain in both groups, on particular interval i.e. day 1st, 3rd, 7th, 11th post operative day using the VAS and face pain rating scale, there was a significance in p value between both groups on all days (p-value with VAS – POD 1st -0.0017, POD 3rd – 0.0104, POD 7th – 0.0181) (p-value with FACE pain rating scale POD 1st -0.0001, POD 3rd – 0.0006, POD 7th – 0.0005) expect POD 11th which was similar and statically non significant (p-value – with VAS and Face pain rating scale on POD 11th -0.6534 and -0.0886)

From our results in terms of post operative pain there was significantly less pain in endoscopic subfascial perforator ligation group when compared to open ligation group in initial post operative period.

In our study we also assessed the day of discharge from the day of surgery (i.e. post operatively – stay in hospital), and there was statically significance in SEPS group. SEPS group had comparatively shorter duration of stay post operatively (mean stay duration in SEPS group 6.47 and in open group 9.53 days with p-value 0.0001)

In terms of post operative day of ambulation of patient, in our study the SEPS group maximum patients (10 patients i.e. – 66.7%) were ambulated on POD 2 were as in open group maximum patients (9 patients i.e. – 60%) were ambulated on 4th POD.

In our study the mean intra operative duration was 1.90 min and 1.80min in SEPS group and open group respectively. In open group there was comparatively shorter intra operation duration. There was no significance in p value (p value – 0.4378)

Comparing the cosmetic outcome, it terms of surgical scar among both groups on particular interval i.e. on POD 11th and 30th using Patient and Observer scar

assessment scale there was a statistical significance between two groups. (p-value - 0.0001)

Fig 15: Post operative scar outcome

S.Shivakumar., Gopi Tupakar et al.[31] studied 40 patients in 2 groups of 20 each and interpreted the post operative out come. The mean study population age was 44.3 +/- 15.8 SD, which was more similar to our study (i.e. 43.3 +/- 10.5). the post operative stay duration was also comparable, the mean stay duration in their study was 5.2 and 7.3 in SEPS group and Open group where as in our study it was 6.47 +/- 1.73 SD and 9.53 +/-1.4 SD. And it was statistically significant in both groups. They also compared the post operative pain with VAS and found statistical significance over open group to SEPS group which was similar to our study.

B.Kianifard., J.Holdstock., C.Allen et al in 2004 studied about 66 patient with varicose vein who had undergone GSV ligation with stripping along with open perforator ligation and SEPS, found no difference in pain, quality in life, and morbidity. Yet they found a significant presence of incompetent perforating vein in no SEPS group compared with SEPS group at the end of one year follow up by duplex scan. They also concluded that SEPS do not add significant morbidity yet reduce the number of incompetent perforating vein in follow up[22].

Johannes E.M.Sybrandy., Wijnand B Van Gent., et al[32] studied 39 patients in two groups, SEPS and Open subfascial ligation (Lipton group) in 2011 and concluded that with mean follow up period of 50.6 month the ulcer recurrence rate in Lipton group was 22% were as in SEPS group, recurrence rate was 12%. They also concluded that the presence of deep vein incompetence dose not influence the ulcer healing but lead to formation of new incompetent perforator.

Mark JKulbaski., Felmont Eaves., John C Ofenloch et al[36] studied 20 patients who had undergone SEPS and concluded that SEPS as a safe procedure for incompetent perforator. They used two 10mm port in medial side of leg, and had a mean operating time 1.5 hours. Had a result of ulcer healing in 19 patients and with one patient there was a recurrence in venous ulcer.

Vashist MG., Malik V., et al[35] in 2012 studied 100 patients in two groups SEPS and open ligation, both group they did stripping of GSV and used 2 port without balloon dissector or tourniquet for SEPS group and ligated 178 and 136 perforators in SEPS and open group. They concluded that the ulcer healing rate in SEPS group was 33% faster compared to open ligation group. And by the end of 3 month follow up almost all patients had complete ulcer healing. There was a higher incidence of surgical site infection in open ligation group 16% which was 8% in SEPS group.

Peter gloviczki., et al[25] studied SEPS and concluded the SEPS is superior to open ligation in incompetent perforating veins. They also commented that the ulcer recurrence rate at 2 year follow up was 10-15% were as it was 22% with open ligation.

S.Shivakumar., Gopi Tupakar et al[31]. assessed ulcer healing rate post operatively, complete resolution of ulcer, ulcer recurrence during the follow up and quoted as in favour of SEPS group. In our study these factors were not assessed.

CONCLUSION

In this research done on 30 patients to evaluate the post operative pain and cosmetic outcome between SEPS and open ligation group. The study showed the superiority of SEPS over open ligation in terms of lesser post operative pain, better cosmetic outcomes and shorter hospital stay. There was also significant reduction in post operative hospital stay and post operative day of ambulation in SEPS group. No complications were encountered with SEPS whereas 1 patient with open ligation had developed hematoma postoperatively.

SUMMARY

Varicose veins are defined as dilated palpable subcutaneous veins, generally larger than 4mm in the upright position. Severity of the disease may vary from telangiectatic veins to venous ulceration.

Subfascial endoscopic perforator surgery (SEPS) is a new, minimally invasive technique performed in patients with advanced chronic venous insufficiency, enables surgeons to address perforator vein incompetence less invasively, with small upper calf incisions remote from severely diseased skin in the distal leg, with less surgical complications compared to open subfascial perforator ligation

The commonly performed surgical procedures for varicose veins are Endovenous laser ablation, open flush ligation of perforators with stripping and SEPS.

In our study, we assessed the post operative outcome between two group i.e., SEPS group and open ligation group in terms of post operative pain, cosmetic out come and also other factors like intra operative duration, no. of perforators ligated, post-operative day of ambulation, post-operative hospital stay. The study population was 30 with15 in each group and was conducted at KAHER, on IPD basis with diagnosis of lower limb venous insufficiency from January 2020 to December 2020.

The general demographic patterns are age distribution was maximum between 50-59 years with a mean of 43 years and incompetent SFJ was about 93.6% and almost all had perforator incompetence. Coming to outcome variables there were significant in p value on 1^{st}, 3^{rd} and 7^{th} POD in terms of post operative pain using visual analogue scale (VAS) and significant p value in terms of cosmetic outcome on 11^{th} and 30^{th} post-operative day using patient and observer scar assessment scale(POSAS).

The study showed the superiority of SEPS over open ligation in terms of lesser post operative pain better, cosmetic outcomes and shorter hospital stay.

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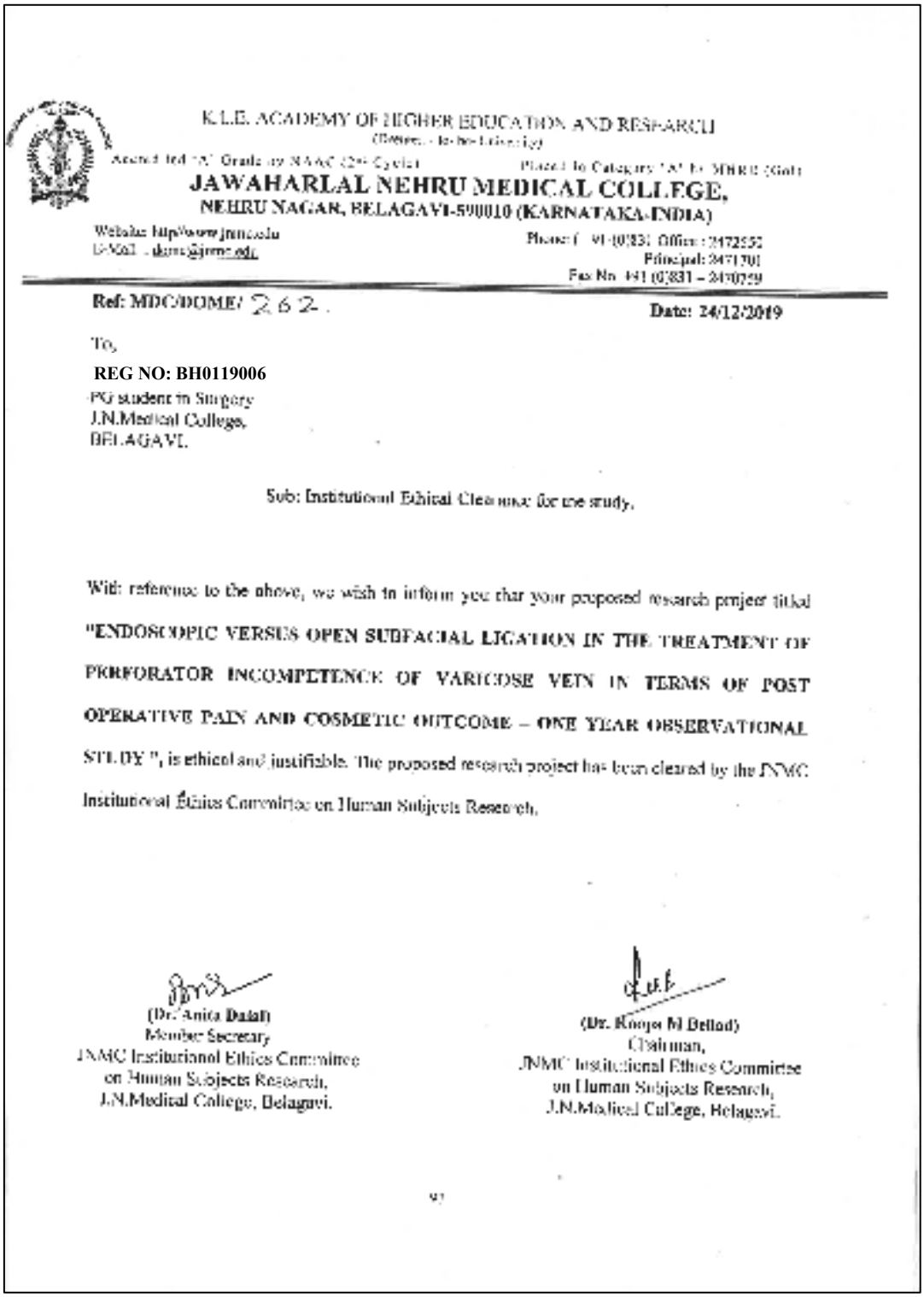
ANNEXURE I. ETHICAL CLEARANCE.



K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed-to-be-University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (Govt)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http\\www.jnmc.edu
E-Mail : dean@jnmc.edu
Phone: (91-0831) Office: 2472552
Principal: 2471701
Fax No. (91-0831) – 2470259

Ref: MDC/DOME/ 262. **Date: 24/12/2019**

To,

REG NO: BH0119006
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 **"ENDOSCOPIC VERSUS OPEN SUBFACIAL LIGATION IN THE TREATMENT OF PERFORATOR INCOMPETENCE OF VARICOSE VEIN IN TERMS OF POST OPERATIVE PAIN AND COSMETIC OUTCOME – ONE YEAR OBSERVATIONAL STUDY "**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

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

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

ANNEXURE II - INFORMED CONSENT

Study title: **"ENDOSCOPIC VERSUS OPEN SUBFASCIAL LIGATION IN THE TREATMENT OF PERFORATOR INCOMPETENCE OF VARICOSE VEIN IN TERMS OF POST OPERATIVE PAIN AND COSMETIC OUTCOME – ONE YEAR OBSERVATIONAL STUDY"**

Subject's name: _____

(i) I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. ☐

(ii) I understood that my participation in the study is voluntary and that I am free to withdraw at anytime, without giving any reason, without my medical care or legal rights being affected. ☐

(iii) I understood that doctor of the clinical trial, others working on the doctor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understood that my identity will not be revealed in any information released to third parties or published. ☐

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). ☐

(v) I agree to take part in the above study. ☐

Subject name: _____

Signature (or thumb impression) of the subject: _____

Date (dd-mm-yyyy): ☐☐ - ☐☐ ☐☐☐☐

Name of the person obtaining informed consent: _____

Signature of the person obtaining informed consent: _____

Name of the patient: _____

Name of the Legally Acceptable Representative: _____

Relationship to the patient: _____

Signature of the Legally Acceptable Representative: _____

Date (dd-mm-yyyy) : ☐☐-☐☐-☐☐☐☐

SCREENING PROFORMA

"ENDOSCOPIC VERSUS OPEN SUBFASCIAL LIGATION IN THE TREATMENT OF PERFORATOR INCOMPETENCE OF VARICOSE VEIN IN TERMS OF POST OPERATIVE PAIN AND COSMETIC OUTCOME– A RANDOMISED CONTROLLED TRIAL"

1. Proforma no: ☐☐
2. Patient's IP no: ☐☐☐☐☐☐
3. Patient name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
4. Age (in years): ☐☐
5. Gender: 1). Male 2). Female ☐
6. History:
   - i. Dilated tortuous veins: duration ☐☐
   - ii. Ulcer 1. Yes 2.No ☐
7. History of previous surgery for Varicose Vein 1.Yes 2.No ☐
8. H/o DVT 1. Yes 2.No ☐
9. Number of incompetent perforators in Colour Doppler ☐☐
10. Applicant is willing to give consent 1.Yes 2.No ☐
11. Final result: 1. Ineligible ☐
    2. Eligible and refused
    3. Eligible and participating

ANNEXURE III

PROFORMA

"ENDOSCOPIC VERSUS OPEN SUBFASCIAL LIGATION IN THE TREATMENT OF PERFORATOR INCOMPETENCE OF VARICOSE VEIN IN TERMS OF POST OPERATIVE PAIN AND COSMETIC OUTCOME– A RANDOMISED CONTROLLED TRIAL"

1. proforma no: ☐☐
2. Patient's IP No: ☐☐☐☐☐☐
3. Name : ☐☐☐☐☐☐☐☐☐☐☐
 ☐☐☐☐☐☐☐☐☐☐☐
4. Age : ☐☐
5. Gender 1) Male 2) Female ☐
6. Address: _____
 _____
 _____
7. Occupation : _____
8. Education: _____
9. Date of admission: ☐☐ ☐☐ ☐☐
10. Date of discharge: ☐☐ ☐☐ ☐☐
11. Chief complaints: _____
 _____
12. History of presenting complaints: _____

13. Past history: _____

14. Specific history:

1) History of previous surgery for Varicose Vein: 1.Yes 2.No ☐
2) H/o DVT 1. Yes 2.No ☐

15. General physical examination:

- Built and nourishment: _____
- Pallor/ icterus/ cyanosis /clubbing / oedema / lymphadenopathy
- Vitals PR: ___ / min, BP: / mmHg, RR:__/ min, Febrile/Afebrile

16. .Examination of b/l lower limb: _____

_____

_____

_____

17. Colour Doppler finding: _____

18. Clinical diagnosis: _____

19. Date of intervention ☐☐ ☐☐ ☐☐

20. Patient placed in: 1) Group A 2) Group B ☐

21. Type of Anaesthesia: ☐

1) Spinal
2) Spinal with Epidural
3) General Anaesthesia

22. Intraoperative duration : ☐☐

23. Intraoperative complication: 1) No ☐

2) Yes

If Yes, _____

24. Postoperative day of ambulation: ☐

25. Post operative hospital stay : No of days ☐

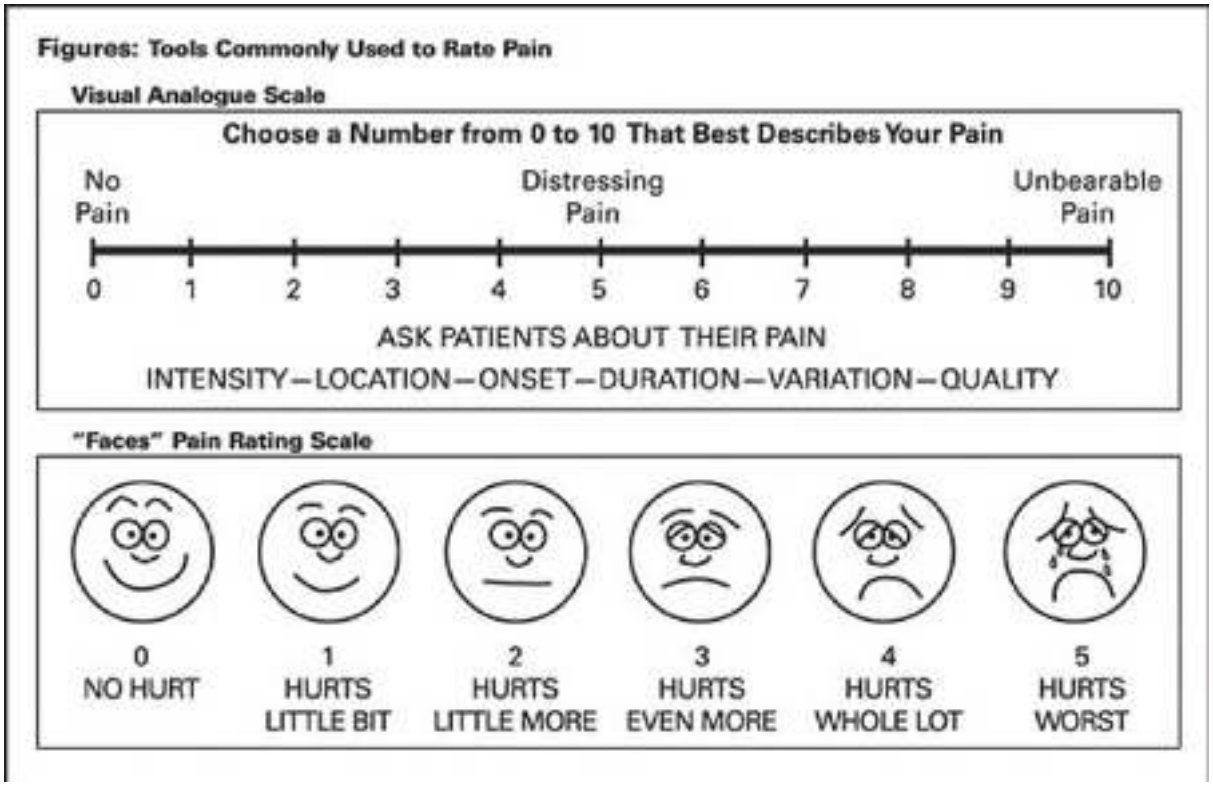
26. Post operative wound infection: 1. Yes ☐

2. No

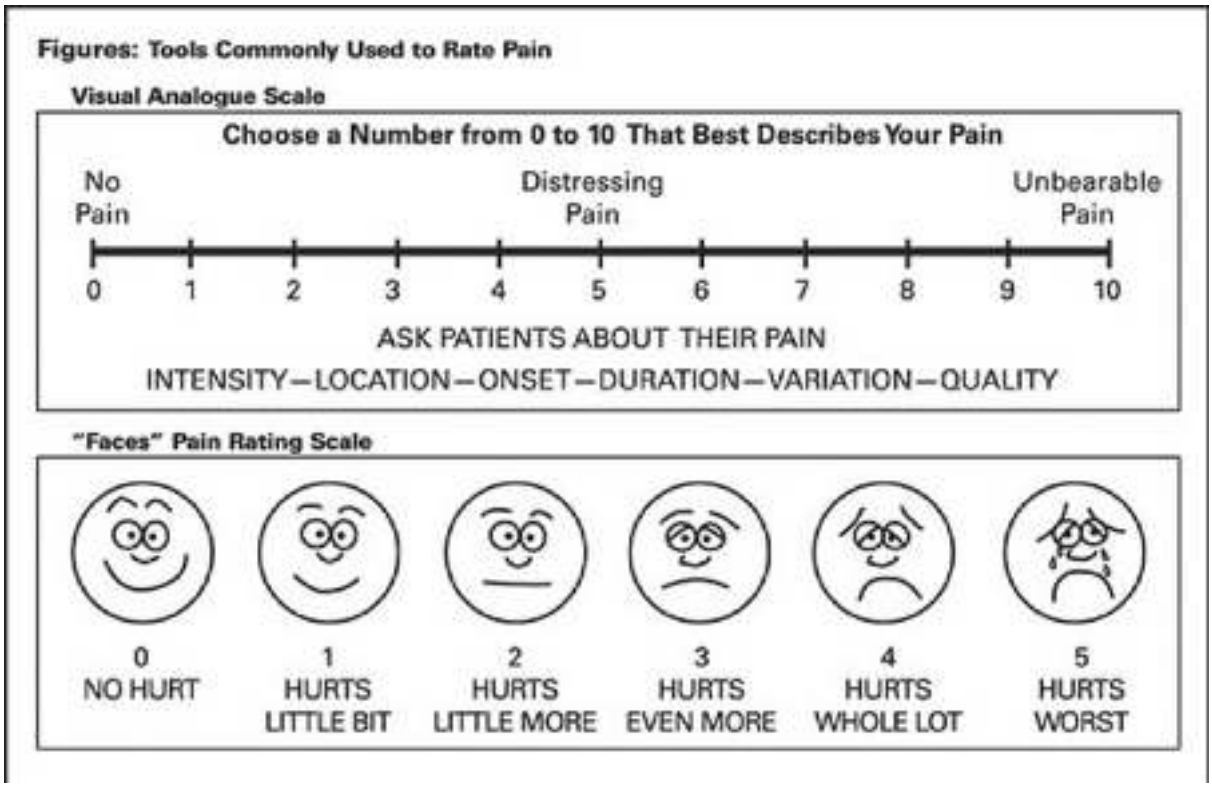
ANALYSIS

1. Post operative pain by using visual analogue scale:

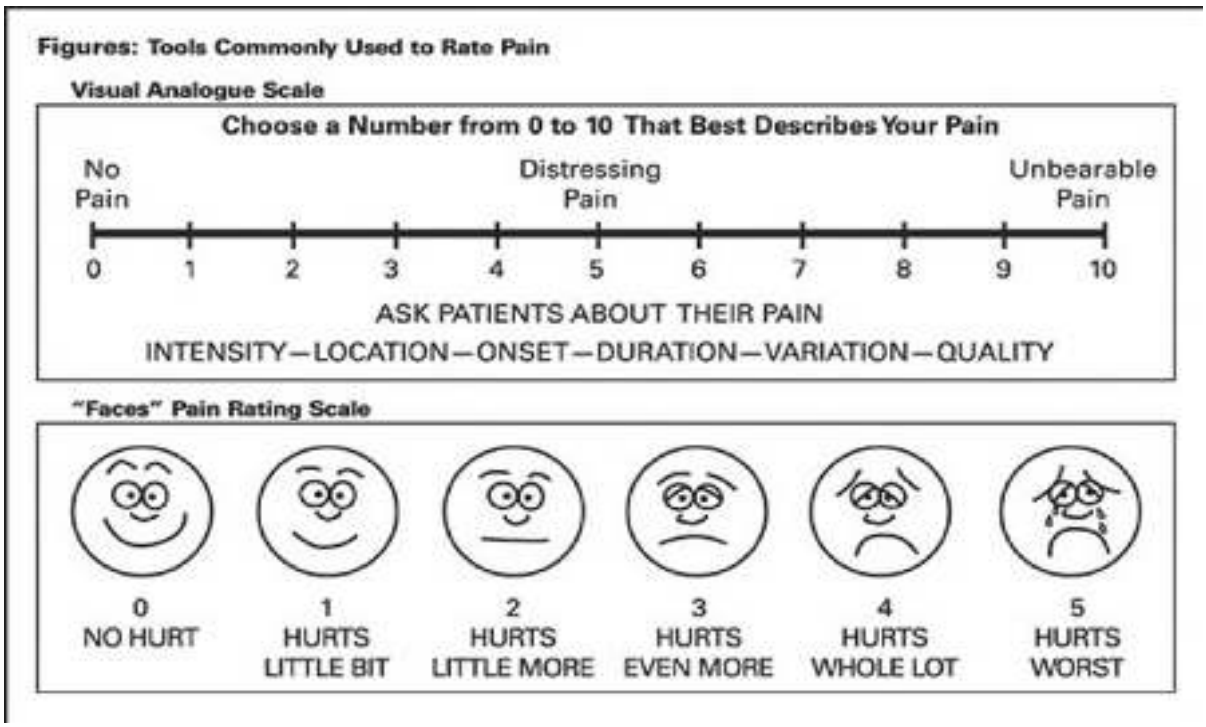
Day 1:



Day 3:


Figures: Tools Commonly Used to Rate Pain
Visual Analogue Scale
Choose a Number from 0 to 10 That Best Describes Your Pain
No Pain
Distressing Pain
Unbearable Pain
0 1 2 3 4 5 6 7 8 9 10
ASK PATIENTS ABOUT THEIR PAIN
INTENSITY—LOCATION—ONSET—DURATION—VARIATION—QUALITY
"Faces" Pain Rating Scale
0 NO HURT
1 HURTS LITTLE BIT
2 HURTS LITTLE MORE
3 HURTS EVEN MORE
4 HURTS WHOLE LOT
5 HURTS WORST

Day 7:

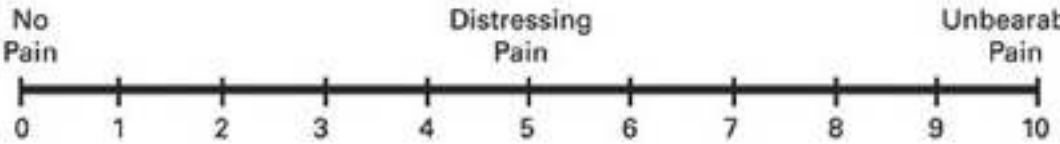

Figures: Tools Commonly Used to Rate Pain
Visual Analogue Scale
Choose a Number from 0 to 10 That Best Describes Your Pain
No Pain
Distressing Pain
Unbearable Pain
0 1 2 3 4 5 6 7 8 9 10
ASK PATIENTS ABOUT THEIR PAIN
INTENSITY—LOCATION—ONSET—DURATION—VARIATION—QUALITY
"Faces" Pain Rating Scale
0 NO HURT
1 HURTS LITTLE BIT
2 HURTS LITTLE MORE
3 HURTS EVEN MORE
4 HURTS WHOLE LOT
5 HURTS WORST

Day 11:

Figures: Tools Commonly Used to Rate Pain

Visual Analogue Scale

Choose a Number from 0 to 10 That Best Describes Your Pain



ASK PATIENTS ABOUT THEIR PAIN

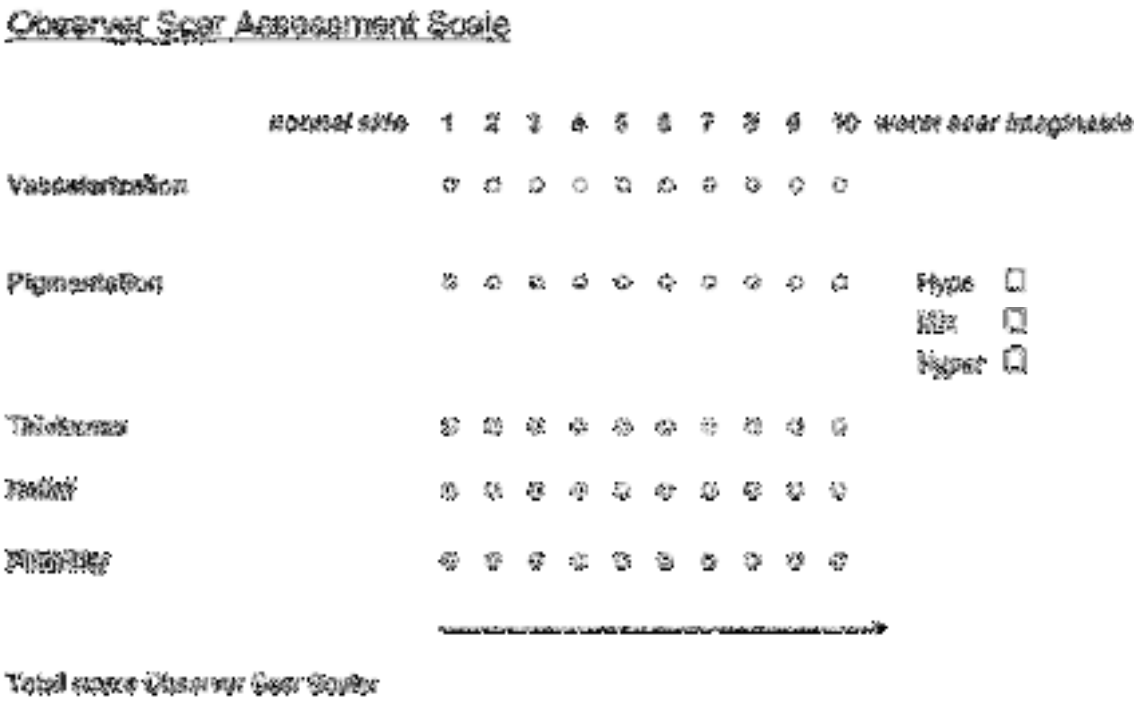
INTENSITY—LOCATION—ONSET—DURATION—VARIATION—QUALITY

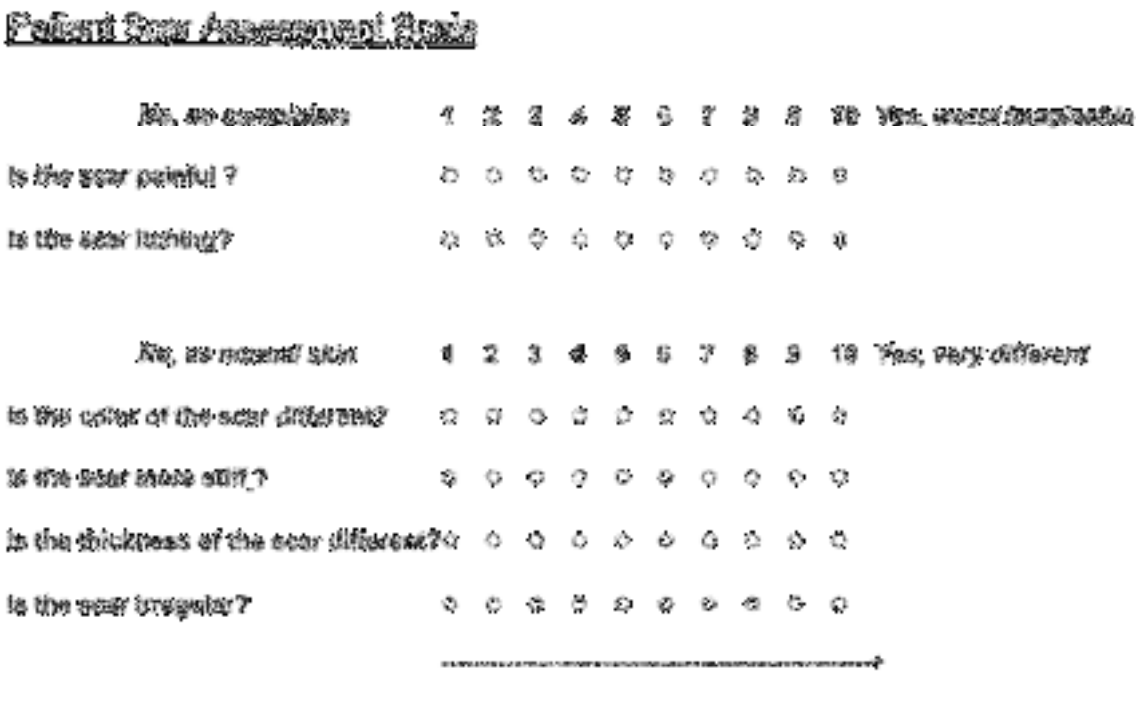
"Faces" Pain Rating Scale

0	1	2	3	4	5
NO HURT	HURTS LITTLE BIT	HURTS LITTLE MORE	HURTS EVEN MORE	HURTS WHOLE LOT	HURTS WORST

2. COSMOSIS BY PATIENT AND OBSERVER SCAR ASSESSMENT SCALE:

Day 11:





Day 30:

Observer Scar Assessment Scale

	normal skin	1	2	3	4	5	6	7	8	9	10	*worst scar imaginable*
Vascularization												
Pigmentation												Hypo ☐ Mix ☐ Hyper ☐
Thickness												
Relief												
Pliability												

Total score Observer Scar Scale:

Patient Scar Assessment Scale

	No, as normal skin	1	2	3	4	5	6	7	8	9	10	*Yes, worst imaginable*
Is the scar painful?												
Is the scar itching?												

	No, as normal skin	1	2	3	4	5	6	7	8	9	10	*Yes, very different*
Is the color of the scar different?												
Is the scar more stiff?												
Is the thickness of the scar different?												
Is the scar irregular?												

Total score Patient Scar Scale:

COSMETIC OUTCOME

Patient 1

Patient 2

Patient 3

Patient 4

Patient 5

Patient 6

COLOUR DOPPLER IMAGES

Sapheno femoral incompetence

Sapheno femoral **incompetence** (**Colourduplex**)

Saphenopopliteal junction

CLINICAL IMAGES - LOWER LIMB VARICOSE VIENS

Class 2 –Varicose veins, pigmentation

Class 4 – Eczema, Lipodermatosclerosis.

Class5 – Healed ulcer (SSV incompetence)

Class 6 –Active ulcer

S. No	Date	IP No	Age	Gender	Occupation	Consent	H/O dilated vein to (side)	duration of dilated veins	H/O long standing lower limb ulcer	duration	co-morbodity	H/O previous surgery for varicose vein	H/O DVT	SFJ competency	below knee incompitent perforator	Group	anaesthesia	intra op duration	no of perforator ligated	intra op complication	post op dayof ambulation	post op hospital stay duration	post op wound infection	analysis							analysis of Cosmosis			
																								analysis of pain											
																								Day 1		Day 3		Day 7		Day 11		Day 11		Day 30	
																								VAS	Faces PRS	VAS	Faces PRS	VAS	Faces PRS	VAS	Faces PRS	OSAS	PSAS	OSAS	PSAS
1	10-09-2020	1022114	54	FEMALE	HOUSE WIFE	YES	B/L	8YRS	NO	NIL	HTN, T2DM	NO	INCOMPETENT	PRESENT		A	GA	1HR 45MIN	2	NIL	2	4	NIL	04-Jan	1	2	1	0	1	1	0	17	16	7	6
2	12-07-2020	1022447	34	FEMALE	HOUSE WIFE	YES	RIGHT	4 YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		A	GA	2HR15MIN	2	NIL	2	10	NIL	5	2	3	1	1	0	1	0	12	14	7	8
3	06-02-2020	996010	50	MALE	FARMER	YES	B/L	4YRS	YES	5 MONTHS	HTN, T2DM	NO	INCPMPETENT	PRESENT		A	GA	1HR45MIN	3	NIL	2	5	NIL	4	2	3	1	2	1	1	0	10	10	6	8
4	13-01-2020	995165	29	FEMALE	TEACHER	YES	B/L	2YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		A	GA	1HR15MIN	2	NIL	3	6	NIL	4	2	2	1	2	0	1	0	13	14	8	8
5	04-02-2020	993908	55	MALE	FARMER	YES	LEFT	3YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	1HR30YRS	3	NIL	3	7	NIL	6	2	3	1	2	1	1	0	13	10	7	8
6	12-01-2020	993529	21	MALE	SHOP KEEPER	YES	B/L	2YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	1HR45MIN	3	NIL	4	9	NIL	6	3	4	2	2	1	1	0	18	21	11	13
7	29-01-2020	998361	53	FEMALE	HOUSE WIFE	YES	RIGHT	2YRS	NO	NIL	T2DM	NO	INCPMPETENT	PRESENT		B	SA	1HR45MIN	4	NIL	4	9	NIL	5	3	4	2	3	1	2	1	17	16	11	9
8	21-02-2020	1002300	58	MALE	FARMER	YES	B/L	7YRS	YES	1YR	NIL	NO	INCPMPETENT	PRESENT		B	SA	1HR45MIN	2	NIL	3	8	NIL	4	2	3	1	2	1	0	0	15	11	8	9
9	31-07-2020	1019095	34	MALE	FARMER	YES	LEFT	2YRS	NO	NIL	NIL	NO	COMPETENT	PRESENT		A	GA	1HR30MIN	3	NIL	2	5	NIL	4	2	4	1	3	1	2	1	11	19	9	13
10	15-07-2020	1018751	34	MALE	TEACHER	YES	LEFT	3YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		A	GA	1HR30MIN	3	NIL	2	4	NIL	4	1	5	1	4	1	3	0	10	13	14	9
11	31-07-2020	1019319	45	MALE	FARMER	YES	RIGHT	5YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	1HR40MIN	3	NIL	4	8	PRESENT	3	2	5	3	3	2	3	2	21	19	14	15
12	29-07-2020	1019095	36	MALE	FARMER	YES	RIGHT	6YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	2HR15MIN	2	NIL	4	9	NIL	5	3	4	2	3	1	1	0	18	21	13	16
13	04-08-2020	1020065	51	FEMALE	HOUSE WIFE	YES	B/L	8YRS	YES	4 TO 5 YRS	NIL	NO	INCPMPETENT	PRESENT		A	GA	2HR30MIN	4	NIL	3	9	NIL	4	2	4	1	2	1	1	0	15	17	11	8
14	02-02-2021	1040238	37	MALE	FARMER	YES	LEFT	6YRS	YES	6MONTHS	NIL	NO	INCPMPETENT	PRESENT		A	GA	2HR	4	NIL	2	7	NIL	3	2	2	1	1	1	1	1	11	12	8	6
15	16-08_2020	1019906	27	MALE	SELF EMPLOYIED	YES	RIGHT	3YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		A	GA	2HR30MIN	3	NIL	2	8	NIL	4	2	2	2	1	1	1	0	12	14	7	9
16	01-08-2020	1019852	49	MALE	SHOP KEEPER	YES	B/L	8YRS	YES	4 TO 5 YRS	T2DM	NO	INCPMPETENT	PRESENT		A	GA	1HR30MIN	4	NIL	3	6	NIL	4	2	3	1	4	0	2	1	11	14	10	12
17	05-11-2020	1027248	54	FEMALE	HOUSE WIFE	YES	B/L	6YRS	NO	NIL	T2DM	NO	INCPMPETENT	PRESENT		B	SA	1HR30MIN	3	NIL	4	11	NIL	5	3	4	2	4	2	2	1	19	24	12	14
18	06-03-2020	1018954	28	MALE	FARMER	YES	LEFT	3YRS	NO	NIL	NIL	NO	COMPETENT	PRESENT		A	GA	2HR	4	NIL	2	6	NIL	4	2	2	1	1	0	1	0	11	12	8	8
19	04-02-2020	993908	30	MALE	TEACHER	YES	RIGHT	4YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		A	GA	1HR45MIN	3	NIL	4	6	NIL	4	2	2	1	1	0	1	0	12	14	7	9
20	31-01-2020	998632	50	MALE	FARMER	YES	B/L	9YRS	YES	3 TO 4 YRS	NIL	NO	INCPMPETENT	PRESENT		A	GA	2HR30MIN	3	NIL	2	8	NIL	5	2	3	1	1	0	1	0	12	14	7	9
21	15-01-2020	995439	33	FEMALE	HOUSE WIFE	YES	B/L	2YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		A	GA	1HR30MIN	3	NIL	3	7	NIL	4	2	2	1	2	0	1	0	13	16	7	8
22	12-02-2020	996489	51	FEMALE	HOUSE WIFE	YES	B/L	5YRS	NO	NIL	T2DM	NO	INCPMPETENT	PRESENT		B	SA	1HR30MIN	2	NIL	4	11	NIL	6	3	4	2	2	1	1	1	9	8	6	6
23	15-11-2020	1030119	53	FEMALE	HOUSE WIFE	YES	B/L	5YRS	NO	NIL	HTN, T2DM	NO	INCPMPETENT	PRESENT		B	SA	2HR	3	NIL	5	12	NIL	5	3	4	2	2	1	1	0	18	15	9	11
24	26-09-2020	1037976	61	MALE	FARMER	YES	RIGHT	3YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	1HR45MIN	3	NIL	4	9	NIL	4	2	3	1	2	1	1	0	17	11	9	8
25	03-08-202	1001381	46	MALE	FARMER	YES	RIGHT	2YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	1HR50MIN	4	NIL	3	9	NIL	5	3	2	1	2	1	1	1	14	17	9	8
26	26-10-2020	1041634	39	MALE	FARMER	YES	LEFT	4YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		A	GA	2HR15MIN	3	NIL	2	6	NIL	3	2	2	1	1	0	1	0	11	8	9	7
27	09-07-2020	1015174	51	MALE	TEACHER	YES	B/L	6YRS	YES	2YRS	T2DM	NO	INCPMPETENT	PRESENT		B	SA	2HR	4	NIL	3	9	NIL	5	3	3	2	2	1	1	1	19	16	11	14
28	30-08-2020	1030559	38	FEMALE	HOUSE WIFE	YES	B/L	7YRS	YES	4YRS	HTN, T2DM	NO	INCPMPETENT	PRESENT		B	SA	2HR15MIN	3	NIL	4	11	NIL	6	3	4	2	3	2	2	1	19	22	13	11
29	19-11-2020	1047163	52	MALE	FARMER	YES	RIGHT	4YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	1HR30MIN	2	NIL	4	11	NIL	5	3	3	1	2	1	1	0	18	17	10	9
30	01-12-2020	1048492	47	MALE	FARMER	YES	RIGHT	2YRS	NO	NIL	NIL	NO	INCPMPETENT	PRESENT		B	SA	2HR	2	NIL	3	10	NIL	4	2	3	2	2	1	1	0	17	15	11	8