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REVOLUTIONIZING VARICOSE VEIN TREATMENT: AN OVERVIEW OF CURRENT MODALITIES

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***Abstract* :** Varicose veins are one of the manifestations of chronic venous insufficiency (CVI), the features of which include venous reflux and dysfunction of the valves, accompanied by pain, edema, and thrombophlebitis. Minimally invasive procedures have also become a mainstay of traditional methods in surgery like the vein stripping procedure, which has been largely utilised in preference due to its better efficacy and quicker healing. The present review is a discussion of the recent developments in the treatment of varicose vein including minimally invasive surgery and regenerative therapies in the management of venous diseases. The most common form of treatment is endovenous thermal ablation (EVLA, RFA) where thermal energy is used to successfully close veins with minimal recovery. Cyanoacrylate adhesive closure is a non-thermal, non-tumescent type of a medical glue. The Micro-foam sclerotherapy produces fibrosis to treat the incompetent vein. CHIVA is used to maintain the venous activity by re-directing the blood flow, using strategic ligation. HIFU is a non-invasive approach based on ultrasound energy that is used to ablate veins. TIPP enhances vein removal using transillumination and suction to minimize traumas on the procedure. These new methods increase the effectiveness, safety and results of treatment of varicose veins. The changes which occurred in the treatment of varicose veins- starting with traditional surgeries, to the minimally invasive and regenerative procedures have transformed the field of practice. Although novel therapies have a great potential, additional large-scale clinical trials and long-term studies are necessary to confirm the effectiveness and safety of these therapies. The developments of AI, nanotechnology, and molecular therapeutics in the future can offer improvements to the treatment plans and make them more optimal, which can maximize the outcomes of the patient.

Keywords: Varicose veins, chronic venous insufficiency (CVI), minimally invasive surgery, non-thermal ablation, tumescent and non-tumescent procedures, vein occlusion procedures.

INTRODUCTION

Varicose veins are commonly believed to be jutting veins on the lower and sometimes the upper legs at the standing position. “Varicose vein in the dictionary of Cambridge defined as a swollen and painful vein, particularly in the legs(1). Simply, there are one-way valves in the veins that enable blood to flow to the heart; when such valves fail due to any reasons, blood reflux occurs, which cause varicose veins(2).

figure 1: varicose veins

It has been found that incidence of varicose veins varies widely with incidence in the world varying between 2-73 percent. They are more common in Western and industrialized countries(3).In a study that was carried out in northern India varicose veins were identified as being common in 46.7% of the women and 27.8% of the males(4). Varicose veins are a significant health concern in India and the prevalence of the same is a major concern among a significant proportion of the population.

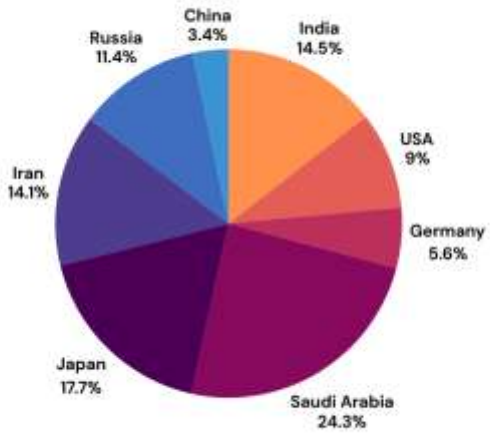

figure 2: varicose veins prevalence.

Etiology: It appears that the etiology of varicose veins is venous disease leading to valvular backflow. Even though the exact pathophysiology remains controversial, it involves the weakening of vascular walls, incompetent valves, an increase in intravenous pressure, and a hereditary predisposition. Valvular dysfunction is usually believed to be caused by the loss of vein wall elasticity and hence the inability of the valve leaflets to fit. Malfunctioning or useless valves allow blood to push to the wrong way, in the reverse manner, superficial to deep and distal to proximal. The bigger veins can become longer and curved due to the force of the greater stress on the corresponding venous system. The main axial superficial veins, which could be affected by the varicose veins in the legs could be the great and small saphenous veins and their tributaries that are superficial.

Risk Factors:The risk factors of varicose veins include family history of venous disease, old age, incessantly increased intra-abdominal pressure by obesity, pregnancy, and tumor, prolonged standing, secondary venous revascularization of valves damaged by deep vein thrombosis, and arteriovenous shunts(5).

CEAP Classification: The classification of stages of the condition is performed with the help of the CEAP (Clinical Etiology-Anatomy-Pathophysiology). In stage C1, the disease manifestation is the spider vein and reticular veins. Stage C2 is characterized by simple varicose veins. The disease has more severe forms, which are called chronic venous insufficiency. Stage C3 has oedema with no skin changes. In later stages, there are complications with serious skin lesions trophic changes or lipodermatosclerosis (C4), healed (C5) and active ulcerations (C6). Consequently, it may be fatal or lead to the cause of the afflicted limb and it can even be life threatening. We shall also review various types of minimally invasive treatment modalities, their history, clear descriptions of the mechanism of action, as well as the list of their respective indications and limitations. The current review highlights the increasing use of minimally invasive procedures and its possible effects on patient care(6).

BASIC TREATMENTS:

Table 1: Basic Treatment for Varicose Veins(7)**.**

TREATMENT	PRINCIPLE	LIMITATIONS
1)Sclerotherapy	This outpatient procedure is invasive. Injecting into different veins is done with a needle. Sclerosing solution is injected into the varicose vein using a small or medium-sized needle. A few weeks later, the vein collapses and disappears.	Several sessions of treatment High rates of recurrence
2)Phlebectomy	Another name for it is micro-phlebectomy. The procedure is minimally invasive. Varicose veins that are located just beneath the skin's surface are removed with a tiny scalpel and needle.	Invasiveness and a longer recuperation period Danger of nerve damage Bruising and the development of hematomas time-consuming Increased rate of recurrence
3)Compression	This technique involves applying pressure to the varicose veins. It can lessen edema or discomfort. Compression therapy uses a number of devices, including boots, bandages, and stockings.	Ineffectiveness as a first line of treatment limited advantages beyond immediate use Noncompliance of the patient
4)Hydrotherapy	The term "hydrotherapy" is a combination of the words "hydro" and "therapy." Water is referred to as hydro. Water is therefore used as a treatment in this therapy. In order to relax veins, hydrotherapy is used. Warm bathing is a helpful method.	Limited scientific evidence

Historically, conservative management was taken as a treatment option, comprising of compression therapy, lifestyle change and low risk minimally invasive surgery such as sclerotherapy and phlebectomy. Nevertheless, the approaches have weaknesses such as a high rate of recurrence, invasiveness, and long-term recovery. As medical technology has improved, contemporary treatment methods have transformed to provide more effective and least invasive treatment modality that guarantees quick healing and better patient outcomes.

This review discusses the replacement between traditional treatment modalities and the new modalities, including cyanoacrylate embolization (VenaSeal™), high-intensity focused ultrasound (HIFU), endovenous laser ablation (EVLA), ultrasound-guided foam sclerotherapy (UGFS), transilluminated powered phlebectomy (TIPP), and CHIVA (ambulatory conservative hemodynamic correction of venous insufficiency). These new processes apply thermal, chemical, or mechanical forces on the veins that have been affected to seal or debride the affected veins with little discomfort and downtime.

ADVANCED TREATMENT:-

1) Ablation of cyanoacrylate embolization.

VenaSeal ™ is also a proprietary cyanoacrylate glue that is an n-butyl cyanoacrylate that has some special properties including high viscosity and fast polymerization when blood is exposed to it. Such properties help to prevent embolization. Moreover, VenaSeal™ cyanoacrylate glue has been designed to be flexible that it can be flexed and torsed after it is hardened(8).

This procedure involves injecting Cynoacrylate into the damaged vein with a catheter. On exposure to the blood, the cyanoacrylate displays a cascade reaction resulting in the adhesive bonding and polymerization. In this therapy, the damaged vein is closed using an external physical pressure(9).

Thus, the aim of the study was to determine the effectiveness and safety of the VenaSeal Closure System as a treatment alternative to patients with refluxing varicose veins with long-term results of 94 per cent. Due to its technical simplicity, fast rate of operation, high rate of venous occlusion and absence of tumescent anesthesia or prolonged compression after the procedure, cyanoacrylate glue is applied to varicose veins (10).

figure 3: ablation of cyanoacrylate embolization.

Case Study

The patient was diagnosed in June 2020, and his age was 54. The anamnesis, clinical, and ultrasound diagnostic revealed many varicose veins. The large saphenous vein and right small saphenous vein were affected. We recommend the use of VenaSeal to all three truncal veins simultaneously and later the microfoam therapy of the lateral branches of varicose veins on both legs. The insurance of the patient was estimated(11).

2) High Intensity Focused Ultrasound (HIFU).

High-intensity focused ultrasound (HIFU) therapy is an emerging area of focus that has become popular in recent times as a non-invasive intervention of lower limb varicose veins by using ultrasound. HIFU is an efficient technique of non-invasive destruction of deep target tissues. The therapeutic concept of its use lies in focusing energy to a certain focus by the use of a concave HIFU probe. This leads to a multiplicity of effects e.g. cavitation, mechanical, and thermal effects which result in specific tissue necrosis and vascular fibrosis. To ablate varicose veins, researchers have been able to apply HIFU in clinical practice on a small number of patients and in animals. Ultrasound imaging guides the delivery of therapy in clinical trials; this is to ensure that the therapy is delivered to the vein of interest with high precision. The system includes a 12 MHz mid-high frequency single-element imaging probe, a 4.5 MHz focusing therapeutic probe as well as an accurate scanning and positioning structure. The ability to offer high frame rate imaging that will be capable of managing the detailed and winding vein morphology to offer precise treatment, as well as, high speed scanning and positioning are among the primary benefits of this type of system(12).

figure 4: high intensity focused ultrasound (hifu)

HIFU is based on the real-time image, which serves to create heat at a given location. The Sovein (HIFU) equipment measures the skin of the veins and alters the energy required in order to treat the varicose veins(13). Performance monitoring is done by imaging the tissues at D0, D3, D7, and D21 using a special Doppler-mode ultrasound scanner (SmartUS, Telemed, Lituania). Nevertheless, HIFU-based treatments do not require multiple stab incisions, insertion of catheters, or the creation of skin scarring; no discolouration or pigmentation of the skin is required when lasers are used as well (14).

3) Endovenous Laser Ablation Therapy

Endovenous laser ablation (EVLA) is a well-known and popular minimally invasive intervention that can be successfully applied to treat leg varicosities (15). A thermal ablation of the treated vein is accomplished by applying a laser which is a form of electromagnetic radiation (near infrared light). The EVLA method of venous closure through heat induction of collagen shrinking and fibrotic vein lumen sealing are the two mechanisms through which laser technology has been used to treat varicose vectors. To kill a vein with laser, the vein wall needs to absorb sufficient energy to generate sufficient heat to damage all the layers in the veins. Lack of adequate energy absorption will lead to recanalisation of the vein. Conversely, excess heat produced will be dispersed to the surrounding tissues causing unwanted damage in the case of too much energy absorption.

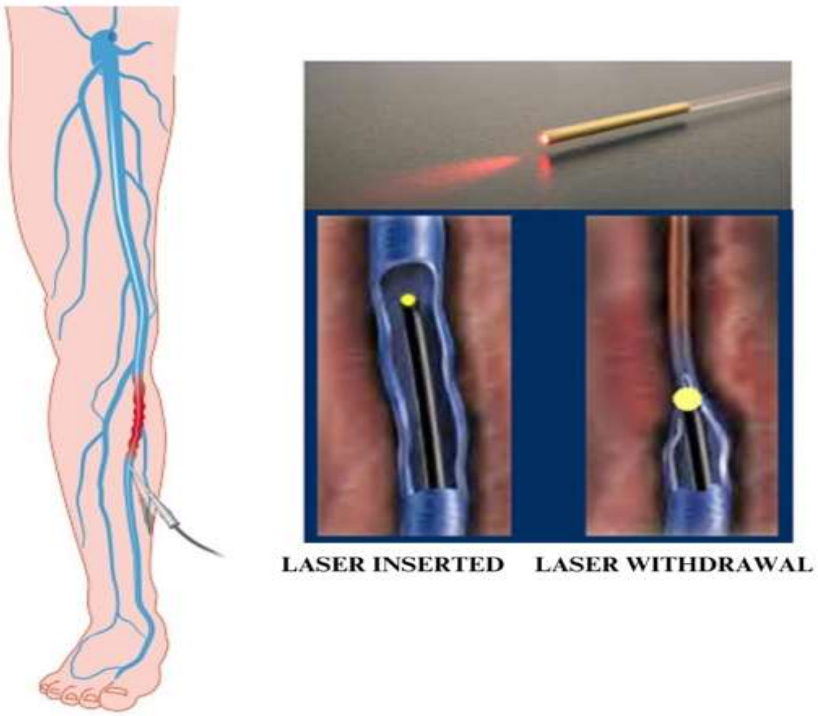

Figure 5: Endovenous Laser Ablation Therapy

The tunica intima of the treated vein is lost at the acute phase as per the experimental research. The vein becomes fibrotic in a month due to thickening of the vein wall, inflammatory alterations and the presence of fibroblasts. EVLA(16) is important in reducing the formation of thrombus. Endovenous laser ablation can remove reflux hence lowering morbidity, hastening recovery and yielding better cosmetic results and patient satisfaction(17).

4)Ultrasound guided foam Sclerotherapy (UGFS).

The sclerosant therapy is known as chemical ablation, where the sclerosant is used to ablate the vein wall, resulting in fibrosis and closing of the lumen. Endovenous sclerosants are divided into three major categories, i.e.: osmotic (hypertonic saline), chemical irritant (chromated glycerine), and detergent (sodium tetradecyl sulphate polidocanol). As a rule, larger veins require more sclerosant concentration. The advantage of using this technique is that it causes the sclerosant to become more echogenic and more voluminous and potent. Foam sclerosant performs better as compared to liquid sclerosant when acting on the truncal veins. This therapy is advantageous to large varicose veins since the foam is able to cover more of the surface area as well as remain longer in the vein(18).

figure 6: ultrasound guided foam sclerotherapy (ugfs)

5) Transilluminate Powered Phlebectomy System.

TIPP involves three technologies, all of which help define the operative plane with hydrodissection, provides local anesthesia, and helps in hemostasis: 1) tumescent anesthesia, which identifies the varicosities visibly; 2) powered endoscopic tissue dissector, which removes the varicosities fast and effectively(21)

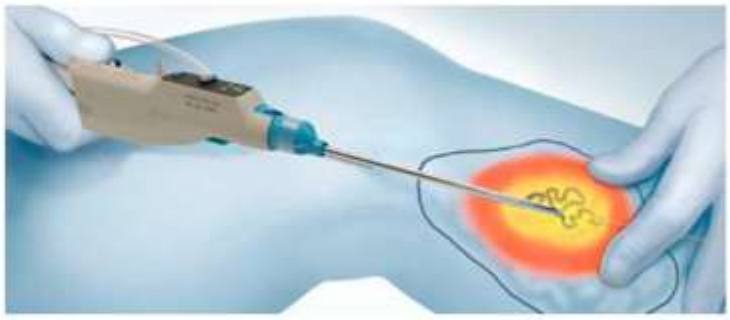

figure 7: transilluminate powered phlebectomy system

Phlebectomy device powered is supplied with tumescent anesthesia transilluminator and infuser. Once a small (23mm) incision has been made to insert the transilluminator cannula, tumescent anesthesia is given into the subcutaneous space adjacent to the target varicosities. Then, a second minor incision is done to put the powered resector cannula into the subcutaneous plane adjacent to the target vein, slightly higher than the transilluminator cannula. Tumescent anesthesia is Re-infused to prevent the formation of hematoma after varicosity resection, which is the same process as directed liposuction. This system is used together with transilluminator and tumescent anesthesia (500 mg lidocaine, 1 mg epinephrine, and 12.5 mEq sodium bicarbonate added to 1 litre of 0.9% normal saline) (22).

Transilluminated powered phlebectomy (TIPP) has the benefit that it uses fewer and larger incisions than the traditional surgery, making the procedure more cost-effective in terms of time and effective on large or recurrent varicose veins. TIPP is also applied in some circumstances where the other forms of treatment are not practicable since it has been reported to cause a lot of pain and discomfort to most of the patients. It can be considered in case of patients with many varicosities, repeated operations, severe thrombophlebitis, obesity or bariatric surgery(23-25).

6) CHIVA

Ambulatory conservative hemodynamic correction of venous insufficiency procedure (or Cure conservatrice et hémodynamique de linsuffisance veineuse en ambulatoire in French) is a minimally invasive procedure that is based on venous hemodynamics, but intentionally preserves the superficial venous system(26).

CHIVA works under two principles, which are unlike the traditional approaches. First, it intercepts the high pressure venous reflux, which leads to the development of varicose veins by blocking the stalled sites of reflux with high ligation. Second, the reserved varicose vein helps the skin venous drainage to occur and ensure the varicose vein recurrence is prevented by ensuring that the varicose veins with perforator and drainage capacity is not fully resected(27).

A CHIVA duplex scan is taken in order to map out the great saphenous vein and collaterals prior to surgery. B-mode ultrasound is applied to see the target vein when the patient and duplex probe are ready. A long needle is then placed (out-in and in-out) under ultrasound guidance after the administration of local anesthesia. It leaves the skin 0.5 cm to the lateral direction on both sides of the collateral and moves behind the vein. A thread is pulled close to the skin creating a tight wire known as the vein. Confirmation of the location of the vein after palpation is done through duplex ultrasound. After making a small incision above the vein (3–4 mm), the vein is then followed until its junction with the saphenos vein. To minimize the

surgical trauma, it is done by making larger incisions only where necessary. Non-absorbable sutures are employed in the case of flush ligation. This is followed by the removal of the wire and the skin is sealed. It is a less invasive technique that improves the patient outcomes by reducing tissue damage.

With respect to the destructive techniques, CHIVA has considerably minimized surgical trauma and remodeling. Due to the nature of the patient, the thigh incisions that are used in CHIVA can at times be big. Also, there could be the prevention of a long-term venous remodeling, which occurs after the elimination of the saphenous(28).

FUTURE PROSPECT:

The future management of varicose veins is parsimoniously subject to new developments with the introduction of new technologies, individualized treatment models, and improved patient care models. Robotic-assisted procedures and artificial intelligence (AI)-based diagnostics may become more precise to minimize the risks and recurrence rates of the procedure. More effective and safer vein closure with few side effects is under investigation using biodegradable adhesives as well as next-generation sclerosants.

More traction is likely to go over to non-thermal methods like HIFU and cyanoacrylate embolization, which do not require anesthesia and are more accessible to treatment. The growing importance of telemedicine and remote patient monitoring may improve the post-procedure follow-ups, and make them more compliant and long-term. Moreover, nanotechnology, bioengineered scaffolds, and regenerative therapies, including endothelial progenitor cell-based vascular repair and targeted gene therapies are redefining the treatment world.

The future of the treatment of varicose veins is becoming more patient-friendly, effective, and safer with the continuous research and development and further changes making it more effective, which will, in turn, enhance the quality of care and decrease the incidence of chronic venous diseases.

CONCLUSION :

The current developments in the management of varicose veins have greatly enhanced the treatment of patients as invasive surgeries are supplanted with minimal invasive surgeries which guarantee faster recovery and less complications. Although the earlier practices such as compression therapy and sclerotherapy continue to be applied, other more recent practices like have proven to be more effective and beneficial in the long run. With the help of novel processes, these treatments target diseased veins with accuracy, reducing the unpleasant experience of patients and the occurrence rates. With these methods still under development through research, the management of varicose veins is likely to be even more effective, more convenient and easily available to the patients and eventually enhances the quality of life of the survivors.

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