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Case Report

Endovenous Cyanoacrylate Glue Using VenaSeal Closure System for the Treatment of Varicose vein associated with Large Venous Leg Ulcer- Excellent Outcome: A Case Report

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Abstract

Varicose vein and Venous ulcer are the stages of Chronic venous insufficiency (CVI) is a form of Venous disease that occurs when veins in legs are damaged that causes blood to pool in leg veins, leading to high pressure in those veins. Varicose veins are swollen blood vessels that appear just under skin's surface in lower body due to weakening of walls of vein and improper working of valves leading to blood backs up in vein. On the other hand, Venous ulcers are a sign of varicose vein disease progression. Venous leg ulcers indicate the most advanced form of chronic venous insufficiency. Duplex study is the gold standard for the diagnosis. The treatment of varicose vein and venous leg ulcers vary from stripping, high ligation of saphenous vein, endovenous ablation (Thermal & Non- thermal ablation) technique. VenaSeal closure system is a non-thermal endovenous ablation technique is safe and more effective in the treatment of varicose vein with venous leg ulcer.

Keywords

Cyanoacrylate glue, VenaSeal closure system, Great Saphenous vein (GSV), Venous ulcer, Chronic Venous Insufficiency.

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Introduction

Varicose veins are a medical condition in which superficial veins become swollen, enlarged, and twisted that usually occur on the legs and feet due to incompetent saphenous vein. Venous reflux is a significant cause. Other related factors are pregnancy, obesity, menopause, aging, prolonged standing and abdominal straining. Venous ulcers, also known as open sores, are a serious sign of varicose vein disease progression. Varicose vein and Venous ulcer are the stages of Chronic venous insufficiency (CVI) is a form of Venous disease but Venous leg ulcer is the advanced form of chronic venous insufficiency. Venous ulcers most commonly appear in the inner side of the leg or ankle. Venous ulcers caused due to inappropriate functioning of the venous valves [1]. Any trauma that damages or ruptures venous valves which may lead to the prevention of back flow of blood that raises the pressure within the veins, which causes hypertension, which in turn causes ulcers [2]. Varicose veins are very common, affecting about 30% of people at some time in their lives. They become more common with age. Women develop varicose veins about twice as often as men [3] [4]. The symptoms and signs that are frequently connected to chronic venous disease are also brought on by an increase in venous pressure [5] Duplex ultrasound study of the affected lower limb is the gold standard of investigation to detect the presence of reflux or incompetence of saphenous vein of the affected limb to determine the planning of further treatment. Surgical stripping was the preferred method of treating varicose veins and chronic superficial venous disease until the discovery of endovenous thermal ablation or endovenous radiofrequency ablation and laser ablation technique in the late 1990s [6]. Endovenous radiofrequency ablation and Laser ablation techniques are used to treat the refluxing superficial saphenous veins. Recently, a new technique 'The VenaSeal Closure System' (Medtronic, Minneapolis, Minnesota, USA) has been approved for the treatment of chronic superficial venous incompetence. Studies have demonstrated that When treating CVI, early endovenous intervention with vein closure results in a much faster healing period and a lower risk of ulcer recurrence [7-9]. This is a non-thermal, non-tumescent endovenous ablation system in which n-butyl-2-cyanoacrylate (NBCA), a medical tissue adhesive is used. This system was approved by the U. S Food and Drug administration for closure of lower extremity superficial truncal veins in February 2015 [10]. In Korea, November 2016 saw the approval of the cyanoacrylate closure system 1 for the management of incompetent saphenous veins. Here we report a case of Varicose vein associated with large venous ulcer in the rt. leg treated with endovenous cyanoacrylate glue using VenaSeal Closure System with excellent outcome.

Case Report

A 44-year-old man, lived in abroad visited with me at outpatient department of our hospital with the complaints of multiple tortuous swelling on the medial aspect of the lower and middle part of rt. thigh and upper part of rt. leg for about 3-4 yrs. with blackish discoloration of skin [Figure 1].



Figure 1: Varicose vein on the medial aspect of the lower and middle part of rt. thigh and upper part of rt. leg.

and a large non-healing venous ulcer on the medial aspect of lower part of right leg which was about 8.5 cm for about four to five months. He had also complained of feeling of heaviness of rt. lower limb associated with itching sensation around the ulcer with discharge of pus from the ulcerated area. He had also a history of diabetes mellitus and dyslipidemia. He was a long-standing worker. He was also a chain smoker [Figure 2].



Figure 2: A 5 months old Venous ulcer just above the medial malleolus of rt. leg at initial presentation.

Duplex ultrasound of rt. lower limb venous system was performed -showed reflux at rt. Saphenofemoral junction with an incompetent Great saphenous vein. The Great saphenous vein was straight in course from below the saphenofemoral junction to the upper two third of rt. leg with 6.0 mm in diameter up to lower part of thigh and rest of the part had 4.5 mm in diameter. Other superficial and deep venous system was normal. No thrombus was found... Then discussed with the patient about his diagnosis and treatment plan which was include care of the wound and VenaSeal closure treatment of varicose vein and leg ulcer. Initially under local anesthesia, bedside wound debridement was done at outpatient department was done, wound swab was sent for culture and sensitivity test. and compression therapy was started with advised daily dressing of the wound. Antibiotic was started according to culture and sensitivity test. After one week of dressing of the wound, the patient was admitted to the hospital under cardiovascular surgery department for his further management.

The day after admission, patient underwent endovascular ablation of great saphenous vein (GSV) with the VenaSeal closure system under local anesthesia. The patient is placed in a supine position. After disinfecting the area to be treated, a sterile drape is placed over it. At first the puncture site of great saphenous vein was identified with ultrasound below the knee at upper part of ulcerated area and infiltrated with local anesthesia [Figure 3].



Figure 3: Puncture site of great saphenous vein under the Doppler ultrasound guidance.

Access the GSV under the Doppler ultrasound guidance and inserted a 7-Fr introducer sheath and pass a dilator into the sheath. Then pass a 7-Fr dilator over the guidewire and flushed with saline and the syringe is locked to the dilator until the 5-Fr catheter is ready to be inserted. The delivery catheter is primed with cyanoacrylate glue

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and advanced the catheter to the saphenofemoral junction and catheter tip was positioned 5 cm distal to the saphenofemoral junction (SFJ) [Figure 4].



Figure 4: Advancement of the catheter to the saphenofemoral junction.

The proximal part of great saphenous vein was compressed by using an ultrasound probe to apply pressure 2 cm proximal to the tip of the delivery catheter to prevent entering of glue into deep venous system [Figure 5].

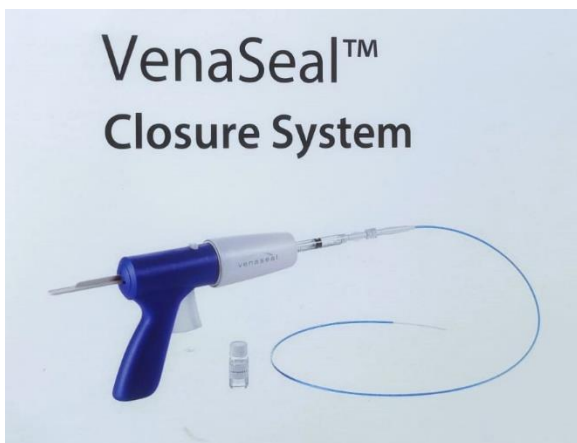


Figure 5: VenaSeal glue dispenser with the cyanoacrylate glue primed catheter.

Two injections of approximately 0.10 ml cyanoacrylate glue were given 1 cm apart at this location followed by a local compression of the junction by right hand for 3 minutes. The catheter was again pulled back 3 cm and 0.10 ml of cyanoacrylate glue was administered followed by manual compression for 30 seconds. Repeat this procedure every 3 cm, injecting cyanoacrylate glue and then treating the full length of the target vein segment with a 30-second ultrasonic probe or manual compression sequences in between. After removing the sheath and catheter, pressure the access site until hemostasis is achieved. Adhesive bandage was applied at the access site and venous occlusion was confirmed by duplex ultrasound. After completion of VenaSeal closure procedure, the ulcerated wound was treated with four-layer dressing and changed the dressing of the wound in every week for 3 wks After 3 weeks four-layer dressing was stopped and dressing the wound once daily only with 10% povidone Iodine solution for a week [Figure 6].



Figure 6: Healing of leg ulcer after VenaSeal closure procedure at 1st wk (A), 3rd wk (B), 5th wk (C) and 6th WK (D).

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Follow Up

After starting treatment, the wound took six weeks to heal. With a healed ulcer and no longer having varicose veins, the patient was free of symptoms at the time of follow-up visit. No other serious complication or adverse effects such as allergic reaction, phlebitis, infection, glue-induced thrombosis, pulmonary thromboembolism (PTE), paresthesia occurred after the procedure up to the follow-up period [Figure 7].



Figure 7: Disappearance of varicose vein after VenaSeal closure procedure.

Discussion

Varicose vein and Venous ulcer are the stages of Chronic venous insufficiency (CVI) is a form of Venous disease. CVI is caused by damage to the veins in the legs, which causes blood to pool in the veins and raises blood pressure in them. Venous ulcers are the wounds that mostly result from dysfunctional venous valves, which are brought on by trauma. It mainly associated with the varicose veins a collection of small dark enlarged superficial veins [11]. Chronic venous disease or insufficiency is a prevalent condition that tends to worsen with age. As the disease increases in severity (such as varicose veins, skin changes and venous ulcer), the quality of life diminishes and the demand of treatment increases [12]. The treatment of varicose vein associated with varicose ulcer vary from stripping and ligation of saphenous vein at saphenofemoral junction (SFJ) to thermal and non-thermal invasive procedure like endovascular radiofrequency & laser ablation. Recently, a non-thermal invasive technique 'The VenaSeal Closure System' (Medtronic, Minneapolis, Minnesota, USA) has been approved for the treatment of chronic superficial venous incompetence of lower limb. Endovenous closure of this method decreases the healing time and recurrence associated with venous ulcer.

The VenaSeal Closure System obliterates the vein by causing fibrosis and quickly polymerizing upon contact with blood, permanently closing the insufficient or incompetent vein and preventing the adhesive glue from embolizing into the deep venous system.

Thermal closure procedures restrict treatment of the entire refluxing vein since they may cause thermal nerve injury. This also limits vein access from the ankle. As a result, the majority of thermal closure procedures require postprocedural compression therapy, require perivenous tumescent anesthesia, and treat the vein from the upper/midcalf. The VenaSeal closure system eliminates the risk of thermal nerve injury and provides instantaneous closure of the entire vein without the requirement for tumescent anesthesia, all without the need for thermal energy. This permits lower venous access to treat the entire length of the diseased vein.

Endovenous cyanoacrylate ablation technique has been shown in numerous studies to be both safe and effective in treating superficial venous insufficiency. In a randomized controlled trial comparing endovenous cyanoacrylate ablation to surgical stripping, 100% of target vein closure was observed at three months in both groups. Quality-of-life gains were equal, although the cyanoacrylate group experienced much less pain and bruising of the leg [13].

A meta-analysis by Kolluri et al. showed that when compared to radiofrequency ablation, endovenous laser ablation, ligation and stripping, sclerotherapy, and mechanochemical ablation, the VenaSeal closure system was superior for anatomic success and had the highest probability of anatomic success of complete closure within 6 months after intervention. The VenaSeal closure system ranked highest in reduction of postoperative pain from baseline and had the least reported and lowest probability of incidence for adverse events [14].

In a small study, 37 patients with 43 discrete ulcers underwent treatment with the VenaSeal closure system for CVI and demonstrated healing of all wounds within the mean time of 73.6 ± 21.9 days. The primary closure rate was 100% at 1 week and 3 months, and no serious adverse events were reported [15].

The Kolluri et al meta-analysis found that the VenaSeal closure system had the lowest likelihood of causing adverse events, such as bruising, pruritus, skin irritation, rash, phlebitis, paresthesia, wound infection, thrombophlebitis, DVT, groin infection, and pulmonary embolism, out of all the CVI therapies evaluated.

When compared to alternative endovenous closure techniques, perioperative discomfort is significantly lower using the VenaSeal closure system, most likely because of the absence of tumescent [16] [17].

VenaSeal closure technique is a preferred option in young and active patients who do not wish to wear postprocedural compression stockings and patients who fear needle sticks injury. VenaSeal closure technique is also indicated for chronic venous disease such as varicose vein with varicose or venous ulcer in elderly patients where surgical procedure is contraindicated.

However, certain proceduralists may find the VenaSeal process to be limited because it is typically a more ultrasonography skill-dependent treatment. While the learning curve for visualization of the catheter and adhesive is steeper than for traditional thermal- and sclerosant-based closure procedures, once mastered, it is easily repeatable.

Conclusion

The VenaSeal closure system is a useful therapeutic alternative for CVI or Chronic venous disease. Key distinctions between the VenaSeal closure system and other therapies are supported by the literature. These distinctions include a lower likelihood of anatomic success, a lower probability of periprocedural discomfort (in comparison to thermal ablation), and a lower chance of adverse events (in comparison to radiofrequency ablation, endovenous laser ablation, ligation and stripping, sclerotherapy, and mechanochemical ablation) [18].

Thus, Cyanoacrylate glue ablation can be the treatment of choice for chronic venous insufficiency (Varicose vein and Venous ulcer) because of its benefits, which include avoiding TA, having fewer side effects, a low pain score, and allowing patients to resume their regular activities without the need for compression stockings.

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