



Ultrasound Guided Injection Sclerotherapy Information and Consent Form

It has been determined that you are a candidate for ULTRASOUND GUIDED INJECTION SCLEROTHERAPY. Please read the following before consenting to proceed with this treatment.

What is ultrasound guided injection-compression sclerotherapy?

Injection-compression sclerotherapy is one method of eliminating varicose veins. The treatment consists of two steps:

1. A medicine called a sclerosing agent is injected into the vein guided by ultrasound. There is only 1 FDA approved sclerosant in the U.S. (Sotradecol liquid). Making it into a foam is therefore "off label." Saline is another sclerosant used but is also "off label" when used to treat spiders veins. Worldwide, polidocanol is the most popular product because in many studies has been shown to be one of the safest, most effective agents available with the least side effects. In the whole world there has been one reported death after literally millions of injections. It is in the process of FDA approval in the US. For these reasons we prefer to use it in a foam consistency.
2. Next, compression is applied to the leg, either in the form of stocking or a bandage. This compression is worn for 3 days to 2 weeks, depending on the patient's veins.

How many treatments will I need?

Generally one treatment of a very concentrated sclerosing agent is successful in closing down very large veins such as the Greater Saphenous vein or the Lesser Saphenous vein. Very concentrated solutions should only be injected with ultrasound guidance. Occasionally an additional treatment may be required.

Does injection-compression sclerotherapy work for everyone?

Most patients who have injection-compression sclerotherapy will have improvement in their venous disease. Unfortunately, neither cosmetic nor symptomatic improvement is guaranteed. Sometimes the results do not meet the patient's expectations. Rarely, a patient may actually be worse after the treatment.

What are the major risks of injection-compression sclerotherapy?

1. Some patients may develop brown discoloration of their skin consisting of spots or streaks after treatment. In most cases, this resolves 6-12 months after treatment. In rare cases, this discoloration may be permanent.
2. New spider veins may form in a treated area. Most of these will resolve within a year. Occasionally, treatment of these new veins will be required, either with sclerotherapy or laser.
3. Ulceration of the skin may occur after sclerotherapy. Usually, this consists of a small sore in the skin. This sore generally heals within a month, leaving a small scar. Very rarely, a large, painful ulceration may occur that will require several months to heal and may leave a larger scar.
4. Phlebitis, inflammation and clot within a vein, may occur after this treatment. Generally, this will resolve with anti-inflammatory medication and compression of the area. It is possible for a clot in a deep vein to develop after sclerotherapy, although this is extremely unlikely.

5. Allergic reactions to any of the sclerosing agents may occur. These allergic reactions are generally immediate and may include rashes, hives, breathing problems, or death. Giving a "test dose" prior to sclerotherapy will not prevent an allergic reaction.
6. Injection of the sclerosing agent into an artery is very uncommon. When this occurs, it may result in large areas of skin and tissue damage and even loss of the limb.

What side effects should I expect?

1. Itching and mild to moderate pain or aching in the legs are common for 1-2 days after sclerotherapy. Walking more will usually relieve this.
2. Numbness and swelling of the leg or ankle may uncommonly result from the compressing and will usually resolve within 1-6 months.
3. Bruising is common and will fade within a month.
4. Tender lumps may indicate the presence of trapped, broken-down blood within a treated vein. This blood may need to be removed at an office visit. This can be done after a local anesthetic is injected.
5. The bandage or stocking may cause a rash, blisters, or skin irritation.

Are there other treatments for varicose veins?

Surgeries, such as vein stripping, ligation, phlebectomy and laser closure are possible alternative treatments for larger varicose veins.

What are the possible complications if my varicose or spider veins are not treated?

Some patients with large varicose veins may develop phlebitis, ulcers of the skin, or hemorrhage. Symptoms will worsen over time and may become disabling. Some spider veins, especially near the ankle, may bleed profusely.

CONSENT

By signing this form, I attest that I have read and understand the procedure and its risks, and that it has been explained to my satisfaction. I understand the above details including possible complications and risks of the procedure. I also agree to the use of an off label or non-FDA approved sclerosant. I have had the opportunity to ask questions about this procedure and alternatives including no treatment and my questions have been answered to my satisfaction. I agree to proceed with the treatment today.

Photographs: I consent to the taking of photographs while I am undergoing treatment and the use of those photos for scientific, educational or research purposes. I understand that I will never be identified personally with the photos.

Signature

Date

Print Name