

# The French Registry

## The Immediate and Medium-Term Safety of 12,173 Sclerotherapy Sessions

The objective of this prospective multicenter registry was to assess the safety of liquid and foam sclerotherapy in the treatment of varicose veins.

### **Treatment method**

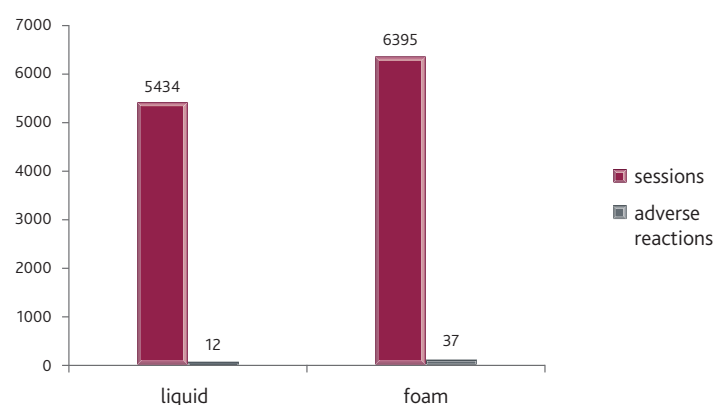
In this registry 22 phlebologists were included, 20 French, 1 Italian and 1 Spanish. To evaluate the daily practice in phlebology, no specifications were given regarding the sclerosing technique or agent. The sclerosant mostly used was polidocanol followed by sodium tetradecyl sulphate. No data on the efficacy of the treatment were collected.

All adverse reactions had to be reported consecutively during the 4-week registry period and at an additional 1 month follow-up. Pigmentation and matting were not separately assessed.

### **Results: All types of varicose veins can be safely treated with sclerotherapy**

During the observation period 12,173 sclerotherapy sessions were carried out in 22 phlebology clinics. All types of varicose veins were treated, from telangiectasias and reticular varicose veins (5,924 sessions) to saphenous varicose veins (2,395 sessions). Liquid sclerosant was used in 5,434 sessions, foam in 6,395 and both foam and liquid were used in 344 sessions. In the treatment of telangiectasias and reticular varicose veins, liquid sclerotherapy was more common (3,631 versus 2,293 foam sessions), whereas foam was applied significantly more in the treatment of great and small saphenous varicose veins (2,025 versus 370 liquid sessions). Ultrasound guidance was used in 35% of the sessions.

### **Safety: The French Registry confirms the safety of liquid and foam sclerotherapy**



Overall, adverse reactions were reported in 49 cases (0.40%) after 12,173 sessions of sclerotherapy. In the liquid group, 12 (0.22%) reactions were observed and in the foam group, 37 (0.58%).

#### **Immediate safety of sclerotherapy**

Visual disturbances were the most frequent immediate adverse reactions with 16 cases (0.25%) in the group treated with foam and 4 cases (0.07%) in the liquid group. Interestingly, 70% of the visual disturbances occurred after treatment of reticular veins and telangiectasias. Other reported cases were vasovagal fainting in 0.08%, coughing in 0.03%, paresthesia in 0.02% as well as nausea and metallic taste in 0.01% of patients. All incidents were mild and spontaneously regressed without any sequelae.

#### **Medium-term safety of sclerotherapy**

Medium-term complications were rare and solely observed after foam sclerotherapy. One femoral vein thrombosis (0.008%) was reported and one distal muscular vein thrombosis (0.008%), both of which could be treated without sequelae. In addition, 4 cases (0.03%) of benign extensions of the sclerosing process to muscular or perforating veins were observed and 3 cases of intense superficial thrombophlebitis. No other adverse reactions were observed.

#### **Conclusion**

- The risk of complications after treatment with sclerotherapy is very low (0.40%)
- All incidents observed after sclerotherapy were transitory and resolved spontaneously
- No other than the above-mentioned adverse reactions were observed in this registry

In summary, those results clearly demonstrate that sclerotherapy with liquid and foam is a very safe treatment for all types of varicose veins.