

The French Polidocanol Registry The Long-Term Safety of Sclerotherapy with Polidocanol

In the first French registry 12,173 sclerotherapy sessions performed by 22 physicians were analyzed for medium-term safety. The sclerosant mostly used was polidocanol (POL, French trade name: Aetoxisclérol®). To determine the long-term safety of POL, this follow-up registry over a period of 4 years was conducted with patients of the first registry who had been treated with POL. The FDA encouraged this registry and the results accounted for the approval of POL in the USA.

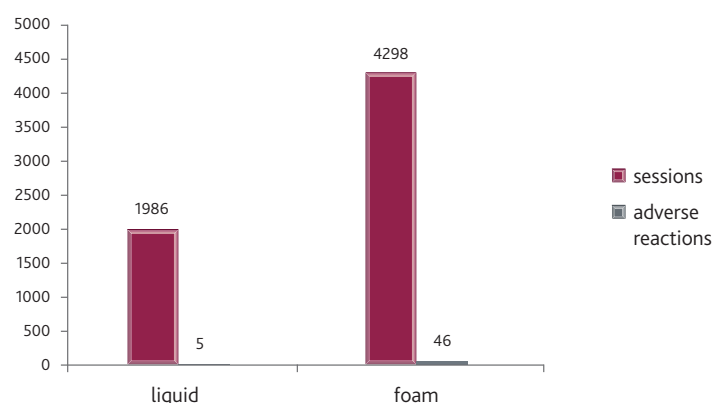
Treatment method

Twelve physicians of the first French registry participated in this long-term safety evaluation. Patients with at least one POL injection during the first registry and potential additional injections with POL during the observation period of this registry were included. Consequently, the number of adverse reactions differs slightly between the two registries. Patients were interviewed over telephone or face-to-face for immediate and delayed adverse reactions of each injection. The mean follow-up time was 27 months, 50% were followed-up for 32-44 months, thus covering a total of 3,357 patient years.

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

During the observation period 1,605 patients were treated with POL in 6,284 sessions. Most of the sessions were performed with Aetoxisclérol® foam (4,298 versus 1,986 with liquid). Telangiectasias and reticular varicose veins were the most frequently treated veins, followed by saphenous varicose veins, tributaries and recurrent varicose veins. Different vein types were treated in one session.

Safety: The French Polidocanol Registry confirms the long-term safety of polidocanol



Overall, immediate, medium-term and long-term adverse reactions were reported in 51 cases (0.81%) after 6,284 sessions of sclerotherapy. The onset of adverse reactions occurred mostly at the day of treatment or within the first 4 weeks after sclerotherapy. In the liquid group, 5 (0.25%) reactions were observed and in the foam group, 46 (1.07%).

The incidents observed after sclerotherapy with liquid POL included 2 cases of inflammation, 1 case of cramp, 1 case of pigmentation and 1 of visual disturbance.

After foam sclerotherapy were observed 13 cases of visual disturbances (0.30%), 8 muscular vein thromboses (0.19%), 7 cases of headaches or migraines (0.16%), 6 cases of vasovagal fainting (0.14%) and 3 cases of nausea and vomiting (0.07%). One deep vein thrombosis (0.02%) occurred after foam sclerotherapy in a patient with thrombophilia after anticoagulant treatment had been discontinued. Additionally, 2 cases of inflammation and 1 case of allergic reaction, 1 of shortness of breath, 1 of chest tightness, 1 of paresthesia, 1 extension of the sclerosis to a perforating vein and 1 case of superficial phlebitis were reported. No other incidents were observed.

Conclusion

- The overall risk of complications after sclerotherapy with POL is very low (0.81%)
- Liquid sclerotherapy with POL has an even lower incidence of adverse reactions (0.25%)
- Visual disturbances occurred very rarely after liquid and foam sclerotherapy altogether, but seem to be slightly more frequent with foam (0.30%); they all spontaneously regressed without any sequelae
- No other than the above-mentioned adverse reactions were observed

In summary, those results clearly demonstrate the very good safety profile of polidocanol in the short and long term for the treatment of all types of varicose veins.