Sclerotherapy of telangiectases and reticular veins: a double-blind, randomized, comparative clinical trial of polidocanol, sodium tetradecyl sulphate and isotonic saline (EASI study)

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Abstract
Objectives: To assess the efficacy and safety of polidocanol (POL) in comparison to sodium tetradeccyl sulphate (STS) and isotonic saline (placebo) for sclerotherapy of telangiectases or reticular veins by means of standardized digital imaging system, independent medical observers and detailed monitoring.
Methods: Of 316 randomized patients, 160 with telangiectases were randomly assigned to 0.5% POL, 1% STS or placebo, and 156 with reticular veins received 1% POL, 1% STS or placebo. Veins selected for injection were clearly visible telangiectases or reticular veins in a predefined treatment area (10 x 10 cm). Exact retrieval of the location was guaranteed by a newly established digital imaging system. Images were taken before first injection and 12 and 26 weeks after the last of three possible injection visits, and evaluated by the investigator and two blinded independent observers. The detailed safety monitoring included ultrasound screening for ‘silent’ deep vein thrombosis, electrocardiograms and clinical laboratory tests.
Results: POL demonstrated a statistically significant superiority versus placebo (P < 0.0001) for the primary criterion ‘improvement of veins’. Significantly more patients were satisfied with POL at 12 or 26 weeks (84%, 88%) compared to STS (64%, 63%; P < 0.0001) and placebo (14%, 11%; P < 0.0001). POL was safe and well tolerated apart from expected local symptoms at the injection site.
Conclusion: Sclerotherapy of telangiectases and reticular veins with detergent-like sclerosants such as polidocanol (POL) or sodium tetradeccyl sulphate (STS) is a well-established technique. However, evidence from clinical trials comparing these substances with a non-active solution is sparse and does not live up to expectations of modern clinical trial concepts necessary for authorisation purposes. The presented multicentre EASI study fulfills these requirements and clearly demonstrates that Sclerotherapy of C1 veins with POL is highly effective and deserves the adjunct ‘gold standard’.

Keywords: telangiectases; reticular veins; sclerotherapy; polidocanol; sodium tetradeccyl sulphate

Introduction
Telangiectases (spider veins) and reticular veins, summarized as C1 veins according to the clinical, aetiological, anatomical and pathological elements (CEAP) classification, are a common phenomenon. A German epidemiological study demonstrated that 35% of the participants had reticular veins and 13%