A Prospective Single-Arm Study of Endovascular Polidocanol Foam for Venous Leak Erectile Dysfunction

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Introduction. Patients with venous leak erectile dysfunction are often refractory to approved medical treatments of ED and restorative therapies continue to be investigated in patients unwilling to undergo surgical treatment of their condition. Polidocanol foam injection is a novel treatment for venous leak ED by its unique mechanism to produce nitrous-oxide mediated endothelial cell death and local tissue remodeling over very short areas, allowing for more distal application of product closer to venous sinusoid-emissary vein junction without excessive damage to unintended structures. Although polidocanol foam is well established in the management of varicose veins and other venous insufficiencies its application to penile venous leak represents a novel, minimally invasive therapeutic strategy.

Objective. To evaluate the safety and efficacy of US guided distal endovenous polidocanol foam injection for treatment of venous leak ED.

Methods. This prospective, single-arm study enrolled adult men (>18 years old) with organic ED >6mo and documented failure or intolerance of conventional guideline pharmacotherapy/vacuum erection devices and unwilling to escalate to surgery. Patients were screened with PDUS using trimix #8, 10-50 units, for diagnosis of venous leak ED. Participants underwent at least 1 session of ultrasound-guided polidocanol foam injection targeting the deep dorsal, superficial dorsal, and/or circumflex penile veins via in office US and 25-32G hypodermic needle. Patients were permitted to continue use of erectile aides throughout study and best possible erectile function was captured as outcomes are assessed using IIEF and EHS scores.

Results. From 2023-11-14 to 2026-06-02, 40 patients have undergone at least 1 office-based session of ultrasound-guided 1% polidocanol foam sclerotherapy for venous leak ED by a single MD. A total of 141 injections were performed. Average number of injections per patient was 3.5 ± 2.4; median 3.0 (IQR 2.0-4.0; range 1.0-12.0). Volume of injected polidocanol foam per session was 1.89 ± 1.76 mL; median 1.50 mL (IQR 0.60-2.50 mL; range 0.05-10.00 mL) and total polidocanol foam volume per patient was 6.67 ± 3.86 mL; median 6.10 mL (IQR 3.88-8.38 mL; range 0.50-15.95 mL). Only minor complications were infrequently reported and temporary including decrease in sensation in 1 patient after single injection, penile pain and injection site bruising. No Clavien-Dindo complications ≥2 were observed. Preliminary analysis of 35/40 patients who have followed up at least once for re-assessment have had their baseline mean IIEF improve from 11.1 to 17 (5.9, 95% CI 3.2-8.6. $P < 0.001$) and EHS from baseline of 1.9 to 2.6 at last available follow up (median follow up 105 days after first treatment). Improvement in mean IIEF was 5.4 (n = 23, 95% CI 1.6-9.2) at 30-days, 4.0 (n = 17, 95% CI 0.6-7.4) at 90 days and 5.2 (N = 9, 95% CI -0.9-11.3) at 180-days from baseline.

Conclusions. Low volume distal/antegrade injection of 1% polidocanol foam under US guidance by an expert in sclerotherapy may be safe and well tolerated with no significant long lasting complications reported. Well conducted placebo-controlled trials with long term follow up is required to determine suitability as option for men with venous leak ED.