## SPOD

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### A double-blind, placebo-controlled, randomised trial of extracorporeal shockwave therapy as a novel treatment for intermittent claudication

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**Aims:** Intermittent claudication (IC) is a prevalent manifestation of peripheral arterial disease. Pilot data has shown Extracorporeal ShockWave Therapy (ESWT) as a novel, non-invasive treatment for IC. We aim to compare the effects of ESWT on quality of life (QoL) and walking distances of patients with lower limb IC through a randomised trial.

**Methods:** A double-blind, placebo-controlled, randomised trial, where patients with lower limb IC were randomised at a 1:1 ratio to ESWT or placebo. Primary outcome was the physical functioning domain of the SF-36 QoL questionnaire at 12-week follow up. Secondary outcomes included claudication and maximum walking distances, and Ankle Brachial Pressure Index (ABPI).

**Results:** Full study power achieved with 138 patients randomised. The ESWT group had a significantly higher physical function score at 12 weeks (Mdn 41 vs 34, $z=-2.1$, $p=0.033$). At 12 weeks the ESWT group had significantly longer claudication and maximum walking distances (Claudication Mdn 125 vs 88, $z=-2.9$, $p=0.004$) (Maximum Mdn 179 vs 129, $z=-2.4$, $p=0.013$). The increase in claudication and maximum walking distance at 12 weeks from baseline was also significantly higher in the ESWT group (Mdn 51 vs 24, $z=-2.8$, $p<0.01$) (Mdn 63 vs 17, $z=-4$ $p<0.01$).

**Conclusion:** This study demonstrates ESWT is clinically effective in improving QoL and walking distances in patients with lower limb IC.