

Effects of sildenafil on maximum walking time in patients with arterial claudication: The ARTERIOFIL study

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BACKGROUND: Patients with lower extremity peripheral artery disease (PAD) frequently experience claudication, a clinical symptom indicative of reduced walking capacity. Recommended care consists of exercise rehabilitation combined with optimal medical treatment and surgery. The effects of a single oral dose of sildenafil, a phosphodiesterase type-5 inhibitor, on patients with claudication are discussed. The aim of this study was to test the efficacy of a single 100 mg dose of sildenafil compared to placebo in terms of maximal walking time (MWT) in patients with claudication.

METHODS: The ARTERIOFIL study is a crossover, double-blind, prospective, randomized, single-center study conducted at Angers University Hospital in France. MWT (primary endpoint) was assessed using a treadmill test (10% incline; 3.2 km/h). Secondary endpoints (pain-free walking time (PFWT), transcutaneous oximetry during exercise and redox cycle parameters and safety) were also studied.

RESULTS: Fourteen patients were included of whom two were ultimately excluded. In the 12 remaining patients, the MWT was significantly improved during the sildenafil period compared with the placebo period (300 s [95% CI 172 s-428 s] vs 402 s [95% CI 274 s-529 s] $p < 0.01$). Sildenafil had no significant effect on pain-free walking time or skin tissue oxygenation during exercise. According to redox cycle parameters, sildenafil significantly reduced blood glucose and pyruvate levels and the 3-hydroxybutyrate/acetoacetate ratio, while there was no significant effect on lactate, 3-hydroxybutyrate, acetoacetate and free fatty acid levels. Symptomatic transient hypotension was observed in two women.

CONCLUSIONS: The ARTERIOFIL study has shown that a single 100 mg oral dose of sildenafil had a significant effect on increase in MWT but had no significant effects on PFWT and oxygenation parameters in patients with claudication. A double-blind, prospective, randomized, multicenter study (VIRTUOSE©) is ongoing to evaluate the chronic effect of six month-long sildenafil treatment on MWT in PAD patients with claudication.

CLINICAL TRIAL REGISTRATION: This clinical trial was registered at clinicaltrials.gov, registration. number: NCT02832570, (<https://clinicaltrials.gov/ct2/show/NCT02832570> [26]).

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