

Effects of Shock Waves on the Microcirculation in Critical Limb Ischemia (CLI) (8-Week Study)

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ABSTRACT

Shock waves (SWs) are used to control and decrease pain in several clinical conditions (eg, painful elbow and shoulder, etc). This clinical effect may be due to cellular stunning of the tissues (particularly nervous components) in the area treated with SW. It may also be the consequence of unknown metabolic actions on tissues, which may include changes in cellular permeability and the liberation of proteins and mediators locally acting on pain and nerve endings. The aim of this study was to evaluate the reduction in pain and the microcirculation improvement induced by SWs treatment in an 8-week study in patients with chronic limb ischemia (CLI). Patients with CLI (15 with rest pain only and 15 with rest pain and limited distal necrosis) were included. The treatment was based on a 30-minute SWs session, three times weekly for 2 weeks. Clinical and microcirculatory evaluation were performed with laser Doppler PO₂ and PCO₂ measurements. Pain was

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measured with an analogue scale line. A Minilith SL1 (Storz Medical, Switzerland) litotripter was used. The parabolic reflector is coupled to the skin with a silicon water cushion. Focal pressure was adjusted between 6 and 70 Mpa in eight steps. The energy flux density was variable from 0.03 to 0.5 mJ/mm². Focal diameter and distance were defined (depth of target within the patient's foot of about 70 mm). The coded intensity used in this study was between 6 and 8 and the application time was 20 min (at four impulses per second). Twenty-eight of the 30 patients with CLI (15 with rest pain only and 13 with necrosis) completed the study. The treatment was well tolerated. Blood pressure was unchanged after 8 weeks while the increase in laser Doppler flux was significant ($p < 0.05$) (at all measurements after treatment). The ORACLE score at 1 and 8 weeks was decreased ($p < 0.05$). The same trend was observed with the analogue scale line for pain ($p < 0.05$). PO₂ increased ($p < 0.05$) and PCO₂ decreased ($p < 0.05$). Tibial pressure did not change. All patients observed an increase in their subjective pain-free walking distance. The improvement was still present after 8 weeks. In a separate subset of 37 patients (mean age 60 ± 9 years; males) with CLI, a SWs dose-finding evaluation was performed. Flux changes were measured at the dorsum of the foot. Three treatment plans were used: (a) 20-minute SW treatment only once; (b) 20-minute SWs treatment every 2 days for 1 week; (c) 20 minutes every day for 1 week. Treatments were well tolerated. A different increase in flux was observed on the basis of different treatments. Flux variations generally indicated that increased SWs dosage was associated with proportional flux increase. Flux improvement was still present after 4 weeks. SWs treatment in CLI produced changes both in the microcirculation and on pain. These preliminary results are comforting and open new research options to be explored in the near future.
