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Beneficial effect of HBOT on healing of chronic foot ulcers in patients without critical ischemia

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Background and aims: We have previously reported a beneficial effect of Hyperbaric Oxygen treatment (HBOT) on ulcer healing in patients with diabetes and foot ulcers with a duration of more than 3 months. The aim of this study was to compare healing rates in these patients with or without a systolic toe blood pressure above 40 mm Hg. **Patients and methods:** The HODFU study is a randomized, single-center, double-blind placebo-controlled clinical trial that evaluates the effect of HBOT on ulcer healing in patients with diabetes mellitus and chronic foot ulcers. The outcomes for the group receiving HBOT were compared with those of the group receiving treatment with hyperbaric air (2,5 ATA /90 minutes / 40 sessions). If a patient had more than 1 ulcer the largest one was considered index ulcer and followed through out the study. Fischers exact test was used for statistical analysis and $p < 0,05$ was considered as statistical significant. **Results:** All 75 patients who completed at least 35 treatment sessions are included in this analysis. Of those 48 patients with a toe blood pressure higher than 40 mm Hg healing rates at the one year follow up were 60 % in the HBOT group and 24 % in the placebo group ($p < 0,01$). No statistical differences in healing rates were seen between groups comparing patients with toe blood pressure ≤ 40 mm Hg (53 % vs. 36 %). **Conclusion:** Adjunctive treatment with hyperbaric oxygen significantly improved ulcer healing of chronic foot ulcers in diabetic patients. This outcome was more apparent in patients with a systolic toe blood pressure above 40 mm Hg.