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### **Adjunctive Systemic Hyperbaric Oxygen Therapy in Treatment of Severe Prevalently Ischemic Diabetic Foot Ulcer. A Randomized Study.**

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**OBJECTIVE:** To evaluate the effectiveness of systemic hyperbaric oxygen therapy (sHBOT) in addition to a comprehensive protocol in decreasing major amputation rate in diabetic patients hospitalized for severe foot ulcer. **RESEARCH DESIGN AND METHODS:** From August 1993 to August 1995, 70 diabetic subjects were consecutively admitted into our diabetologic unit for foot ulcers. All the subjects underwent our diagnostic-therapeutic protocol and were randomized to undergo s-HBOT. Two subjects, one in the arm of the treated group and one in the arm of nontreated group, did not complete the protocol and were therefore excluded from the analysis of the results. Finally, 35 subjects received s-HBOT and another 33 did not. **RESULTS:** Of the treated group (mean session = 38.8 +/- 8), three subjects (8.6%) underwent major amputation: two below the knee and one above the knee. In the nontreated group, 11 subjects (33.3%) underwent major amputation: 7 below the knee and 4 above the knee. The difference is statistically significant ( $P = 0.016$ ). The relative risk for the treated group was 0.26 (95% CI 0.08-0.84). The transcutaneous oxygen tension measured on the dorsum of the foot significantly increased in subjects treated with hyperbaric oxygen therapy: 14.0 +/- 11.8 mmHg in treated group, 5.0 +/- 5.4 mmHg in nontreated group ( $P = 0.0002$ ). Multivariate analysis of major amputation on all the considered variables confirmed the protective role of s-HBOT (odds ratio 0.084,  $P = 0.033$ , 95% CI 0.008-0.821) and indicated as negative prognostic determinants low ankle-brachial index values (odds ratio 1.715,  $P = 0.013$ , 95% CI 1.121-2.626) and high Wagner grade (odds ratio 11.199,  $P = 0.022$ , 95% CI 1.406-89.146).

**CONCLUSIONS:** s-HBOT, in conjunction with an aggressive multidisciplinary therapeutic protocol, is effective in decreasing major amputations in diabetic patients with severe prevalently ischemic foot ulcers.

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