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**Safety and efficacy of hyperbaric oxygen therapy for the treatment of interstitial cystitis: a randomized, sham controlled, double-blind trial.**

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**PURPOSE:** We conducted a double-blind, sham controlled study to evaluate the safety, efficacy and feasibility of hyperbaric oxygenation for interstitial cystitis. **MATERIALS AND METHODS:** A total of 21 patients with interstitial cystitis were randomized to 90 minutes treatment in a hyperbaric chamber pressurized with 100% O<sub>2</sub> to 2.4 atmosphere absolute for 30 treatments sessions or 1.3 atmosphere absolute, breathing normal air in the control group. Moderate or marked improvement in a global response assessment questionnaire was defined as treatment response (primary outcomes). Secondary measurements included changes of pain and urgency evaluated by visual analog scales, functional bladder capacity and frequency. Changes in the O'Leary-Sant Interstitial Cystitis Index and rating of overall satisfaction with the therapeutic outcome were also reported. **RESULTS:** There were 3 of 14 patients on verum and no control patients who were identified as responders ( $p < 0.05$ ). At 12-month followup 3 patients (21.4%) still reported treatment response. Hyperbaric oxygenation resulted in a decrease of baseline urgency intensity from 60.2 +/- 15.0 to 49.9 +/- 35.2 mm at 3 months and decrease of pain intensity from 43.1 +/- 20.5 to 31.2 +/- 19.8 mm, respectively ( $p < 0.05$ ). The Interstitial Cystitis Symptom Index score sum decreased from 25.7 to 19.9 points in patients on verum. Sham treatment did not result in improvement of the baseline parameters. **CONCLUSIONS:** A total of 30 treatment sessions of hyperbaric oxygenation appear to be a safe, effective and feasible therapeutic approach to interstitial cystitis. In the treatment responders application of hyperbaric oxygenation resulted in a sustained decrease of interstitial cystitis symptoms with a discordant profile regarding the peak amelioration of the various interstitial cystitis symptoms compared with a normobaric, normoxic sham treatment. PMID: 16952654 [PubMed - in process]