Hyperbaric Oxygen Treatment of Chronic Refractory Radiation Proctitis: A Randomized and Controlled Double-Blind Crossover Trial With Long-Term Follow-Up


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Purpose

Cancer patients who undergo radiotherapy remain at life-long risk of radiation-induced injury to normal tissues. We conducted a randomized, controlled, double-blind crossover trial with long-term follow-up to evaluate the effectiveness of hyperbaric oxygen for refractory radiation proctitis.

Methods and Materials

Patients with refractory radiation proctitis were randomized to hyperbaric oxygen at 2.0 atmospheres absolute (Group 1) or air at 1.1 atmospheres absolute (Group 2). The sham patients were subsequently crossed to Group 1. All patients were re-evaluated by an investigator who was unaware of the treatment allocation at 3 and 6 months and Years 1–5. The primary outcome measures were the late effects normal tissue-subjective, objective, management, analytic (SOMA-LENT) score and standardized clinical assessment. The secondary outcome was the change in quality of life.

Results

Of 226 patients assessed, 150 were entered in the study and 120 were evaluable. After the initial allocation, the mean SOMA-LENT score improved in both groups. For Group 1, the mean was lower ($p = 0.0150$) and the amount of improvement nearly twice as great (5.00 vs. 2.61, $p = 0.0019$). Similarly, Group 1 had a greater portion of responders per clinical assessment than did Group 2 (88.9% vs. 62.5%, respectively; $p = 0.0009$). Significance improved when the data were analyzed from an intention to treat perspective ($p = 0.0006$). Group 1 had a better result in the quality of life bowel bother subscale. These differences were abolished after the crossover.

Conclusion

Hyperbaric oxygen therapy significantly improved the healing responses in patients with refractory radiation proctitis, generating an absolute risk reduction of 32% (number needed to treat of 3) between the groups after the initial allocation. Other medical management requirements were discontinued, and advanced interventions were largely avoided. Enhanced bowel-specific quality of life resulted.