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Hyperbaric-Oxygen Therapy: Better Survival at 6 Years

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STOCKHOLM — Six-year follow-up data on the use of hyperbaric-oxygen therapy in patients with chronic diabetic foot ulcer shows a significant improvement in long-term survival compared with placebo.

Results were presented at the European Association for the Study of Diabetes (EASD) 2015 Meeting, by lead investigator Magnus Löndahl, MD, of Lund University, Sweden.

The 6-year results represent a secondary end point in the randomized, double-blind, single-center, placebo-controlled Hyperbaric Oxygen Therapy as Adjunctive Treatment of Chronic Diabetic Foot Ulcers (HODFU) study, which at 12 months showed a significant difference in ulcer healing rate between placebo and hyperbaric-oxygen therapy.

Now at 6 years, 63.2% of patients who received at least 37 treatments (of 40 total) of hyperbaric oxygen survived compared with 40.5% of those who got placebo, which was hyperbaric air ($P < .05$).

Dr Giel Nijpels, from the Free University of Amsterdam, the Netherlands, the session moderator, commented on the potential clinical use of hyperbaric oxygen.

"It seems to work, but we can speculate about the disadvantages, including the high cost. Also, I have some doubts about the way the data were analyzed — I'm unsure if this is fully accurate. The problem is that they attempted to blind the patients, and there was a huge dropout rate. "Also, let's remember you find this type of treatment only in large academic centers — it isn't that easy to administer this form of therapy," he added.

Hyperbaric Oxygen Improves Survival at 6 Years

At baseline, hyperbaric oxygen and air patients had had type 2 diabetes for 23 and 21 years, respectively, had a median age of 67 and 71 years, and had foot-ulcer duration of 11.4 and 10.3 months.

The need or possibility for vascular surgery was ruled out at patient inclusion.

Comorbidities at baseline were similar between groups, as were prescription patterns of antidiabetic and cardiovascular-protective drugs. Patients who completed at least 37 treatments were included in the per-protocol analysis.

Those in the active-treatment group received 90 minutes of 100% hyperbaric-oxygen therapy per day, 5 days a week, for 8 weeks. The placebo group was on a similar schedule but with hyperbaric air at 2.5 ATA.

A total of 38 patients completed hyperbaric-oxygen treatment, 37 completed placebo treatment, and 19 did not complete treatment (both groups combined).

"There was a statistically significant difference between patients who received hyperbaric oxygen vs those on placebo. In patients given hyperbaric oxygen, mortality was around 40%, and in those receiving placebo, mortality was around 60%," Dr Löndahl reported.
There was no difference in survival between those patients on placebo and those who did not complete treatment over the 6 years of follow-up.
The incidence of foot-related death (infection or critical ischemia) was the same in both active-treatment and placebo groups, at 14%.
"Nor were there differences in cause of death, with one-third of patients in both groups experiencing sudden death without explanation. Around 20% had death caused by infection, 20% from cancer, and 15% from verified acute myocardial infarction," continued Dr Löndahl.
After adjustment for baseline differences in age among those who died, the difference in 6-year survival persisted at 63.2% in the hyperbaric-oxygen group compared with 40.5% in placebo ($P < .05$).

How Does Hyperbaric Oxygen Help?
Turning his attention to the possible reasons for the positive effect on chronic diabetic foot ulcer, Dr Löndahl said: "I have no definite explanation today. It might be a coincidence or associated with ulcer healing. It is unlikely to be due to improved macrovascular function, but we do have data that improved microvascular function might be associated with survival, not least due to improved autonomic neuropathy."
Despite the positive results, Dr Löndahl concluded that "we need more information and to further explore and verify findings before [this therapy is]…applied in clinical management of diabetic foot ulcer."
This echoes thoughts he expressed during a debate at the American Diabetes Association (ADA) 2015 Scientific Sessions earlier this year.
Dr Löndahl spoke in favor of hyperbaric-oxygen therapy at this debate, while Ludwik Fedorko, MD, associate professor of anesthesiology and pain management at the University of Toronto, Ontario, argued against it.
Dr Fedorko stressed that hyperbaric-oxygen treatment is both time-consuming and costly. "Why do we bother with a $9,000/patient treatment, if I can buy for this $9,000 all the advanced dressings…and doctor visits, etc?" he told *Medscape Medical News* at the time.
A trial investigating the cost-effectiveness of hyperbaric-oxygen therapy in ischemic diabetic foot, known as DAMOCLES, is due to begin soon. To be conducted in the Netherlands, it is considered to be the largest trial of its kind.