HBOT for diabetic foot: Hint of benefit for wound closure

July 6 2016

If people with a diabetic foot syndrome (DFS) receive hyperbaric oxygen therapy (HBOT) in addition to conventional treatment, this can promote wound healing. However, the certainty of conclusions of the available study results is restricted. Furthermore, the results for other aspects of treatment that are relevant to patients show neither hints of a benefit nor of harm. This is the finding of a final report published on June 2, 2016 by the German Institute for Quality and Efficiency in Health Care (IQWiG).

Diabetic foot can require amputation

If blood sugar levels are too high over many years in people with diabetes, this can damage the blood vessels. This leads to an insufficient circulation of blood in the extremities (i.e. the arms and legs) and to a reduction in the perception of pain (polyneuropathy). Smaller wounds, which heal poorly in people with diabetes anyway, are often therefore only noticed at a late stage. This is particularly the case if they are poorly visible, as on the feet.

If in addition an infection occurs or tissue dies (necrosis), DFS may in the worst case require partial or complete amputation of the foot.

Additional oxygen is supposed to improve blood circulation in the tissue

HBOT is recommended in addition to conventional wound care if all options to revascularize the tissue, that is, to supply a sufficient amount of blood again, have failed and there is a threat of amputation.

In HBOT, the patients sit in a special chamber and inhale (mostly) pure oxygen under increased ambient pressure. This is supposed to enrich the blood with oxygen and promote a better oxygen supply, also in the area of the wound.

Certainty of results is low in most studies

Overall the IQWiG researchers included 9 randomized controlled trials in their assessment. However, only 2 of these studies have a low risk of bias; their results can therefore be interpreted with greater certainty. In the remaining studies detailed information on the allocation of study participants to the respective groups was often lacking in the study publications. Moreover, most studies were not blinded.

Studies include different patients

Furthermore, the studies included very different patients; this applied, among other things, to disease severity. In part, great deviations between studies were also shown for the time of analysis. These could be the main reasons why, for single aspects of treatment, the results of the studies were very heterogeneous. However, other causes cannot be excluded.

Important studies yield discrepant results

The results for the outcome of wound closure are interpretable with sufficient certainty. Here, the pooling of data shows an advantage of HBOT over the control group. This is because the chance of wound

closure was nearly twice as high in the HBOT arm as in the control arm. For this outcome, IQWiG therefore sees a hint of a benefit of HBOT.

In the preliminary report, the IQWiG researchers had still assumed proof of a benefit. However, in the final report they were able to include a further study that was only published in full in January 2016. Now not only one, but 2 studies with a low risk of bias are available. However, these 2 studies yield discrepant results for wound closure. In the final report *IQWiG* therefore downgraded the certainty of conclusions from "proof" to "a hint" of a benefit.

Either no data or no relevant group differences

No hint of a benefit was shown for any of the other patient-relevant outcomes. There are 2 reasons for this: Either the studies contained no data - this applies to the outcomes of pain, occurrence of cardiovascular diseases, as well as dependency on outside help or need for long-term care; or the included studies contained evaluable data, but these data do not show relevant differences between conventional treatment without HBOT and conventional treatment with additional HBOT. This does not just apply to the outcomes of mortality, health-related quality of life, and duration of hospital stay, but also to the necessity for amputation.

No hint of harm

At the same time there is no hint of harm from additional HBOT in the form of adverse effects. Overall, the rate of complications is comparable between both study groups, which is why HBOT is regarded to be safe.

More information: www.iqwig.de/en/projects-resul … t-syndrome.6597.html

Provided by Institute for Quality and Efficiency in Health Care