Healogics®
The power to heal

Hyperbaric oxygen therapy (HBOT) and diabetic foot ulcer outcomes: A novel approach

Objective

This analysis presents findings from an external third-party analysis of the impact of hyperbaric oxygen therapy (HBOT) on diabetic ulcer outcomes, both healing and amputation, using a large sample of Healogics i-heal® data.

Introduction and background

Research findings on the impact of HBOT on diabetic ulcer outcomes varies considerably. Some studies note a positive effect of HBOT on outcomes, while other studies are less conclusive (de Smet et al., 2017). Studies of HBOT and outcomes often face a number of methodological limitations such as inadequate sample size or limited external validity. As a result, questions remain regarding the efficacy of therapy.

In order to address gaps in knowledge regarding HBOT and the diabetic ulcer, Healogics commissioned a third-party academic health services research group to conduct a HBOT outcomes study. The primary research question is what is the effect of HBOT on wound healing and amputation in Wagner grade 3 and 4 diabetic ulcers? All data analyses were conducted by the external research group. The findings of the full study will be developed for peer-review; however, a subset of the key findings is reported here.

Data and methods

The sample for this analysis includes all patients admitted to a Healogics outpatient Wound Care Center® with at least one diabetic ulcer from 2014-2017. Currently active and consultation admissions were excluded. The final sample size was N=309,350 diabetic ulcers.

An instrumental variable model was used to complete the statistical analysis. Instrumental variable analysis is an ideal methodology for examining HBOT, because it is uniquely designed to account for selection bias and is more appropriate than other models for studying the effectiveness of “rescue” type therapies, such as HBOT (Dowd et al., 2011).

The subsample presented here is limited to diabetic ulcers that were a Wagner grade 3 or 4 at first assessment. The model adjusts for wound and patient characteristics including size, depth, number of concurrent wounds, time in treatment, debridements and patient comorbid conditions.

Figure 1. Percentage of wounds healed by HBOT group

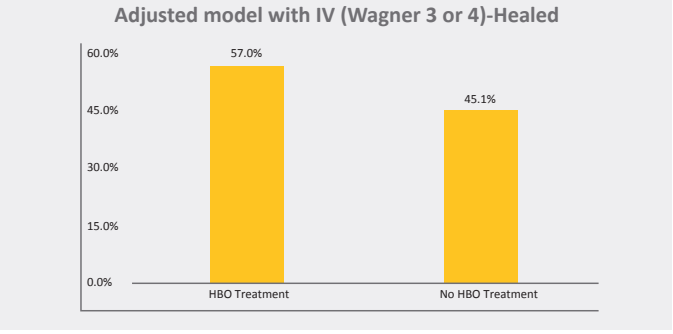
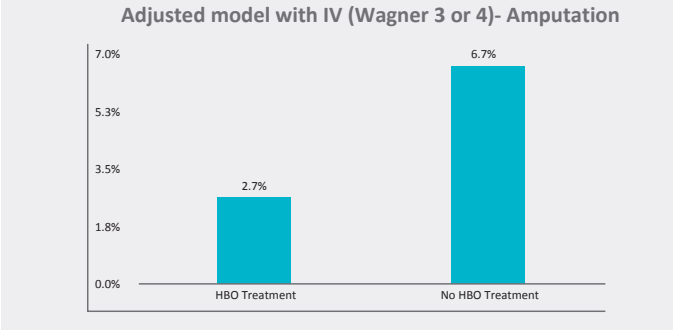


Figure 2. Percentage of wounds amputated by HBOT group



Results

Table 1 provides adjusted estimates of the impact of HBO treatment on wound outcomes using the IV approach. The IV analyses suggest that HBO treatment was effective for wounds with a Wagner score of 3 or 4 at first assessment, improving the healing rate (11.9 percentage points, p<.001) and reducing amputation rates (-4.00 percentage points, p<.001).

Table 1. Estimates for HBO treatment on wound outcomes using adjusted models with IV[a]

		Coefficient	95% CI	p-value	HBO Treatment	No HBO Treatment
					CE(SE)	CE(SE)
Healed						
	Wagner Score 3 or 4	0.119	(0.077, 0.161)	<0.001	0.570(0.013)	0.451(0.009)
Amputated						
	Wagner Score 3 or 4	-0.04	(-0.058, -0.021)	<0.001	0.027(0.006)	0.067(0.004)

[a]IV = Instrumental Variable, N=Number, CI=Confidence Interval, CE=Conditional Effect, SE=Standard Error

Conclusions

The findings of this analysis suggest that when patient and wound characteristics are controlled, Wagner grade 3 and 4 diabetic ulcers that have failed to respond to standard wound care benefit from the addition of HBOT. Adjusting for physician preference for HBOT as the instrumental variable finds an 11.9 percent difference in ulcer healing between those that received HBOT and those that did not. Furthermore, there was a four percent difference in the rate of amputation between the HBOT group and non-HBOT group. These findings underscore the added benefit of HBOT for appropriately selected diabetic ulcer patients.

Sources

Bryan E. Dowd. “Separated at Birth: Statisticians, Social Scientists, and Causality in Health Services Research.” April 2011. Health Services Research 46(2): 397-420.

Gijs H.J. de Smet, Leonard F. Kroese, Anand G. Menon, Johannes Jeekel, Antoon W.J. van Pelt, Gert-Jan Kleinrensink, and Johan F. Lange. “Oxygen therapies and their effects on wound healing.” August 2017. Wound Repair and Regeneration 25:591-608.