Chapter 4. Conclusions

In this review, we sought to answer the question: how strong is the overall evidence regarding hyperbaric oxygen for brain injury, cerebral palsy, and stroke, and what are the logical next steps?

1. Does HBOT improve mortality and morbidity in patients who have traumatic brain injury and anoxic ischemic encephalopathy?

Traumatic Brain Injury

Overall, the two available fair-quality trials provide fair evidence that HBOT might reduce mortality or the duration of coma in severely injured TBI patients. However, in one of these trials, HBOT also increased the chance of a poor functional outcome. Therefore, they provide conflicting evidence to determine whether the benefits of HBOT outweigh the potential harms.

Although they are cited frequently, the case series and time-series studies of HBOT for TBI patients had serious flaws. There were no high-quality studies of the use of HBOT to improve function and quality of life in patients with chronic, stable disabilities from TBI. The most important gap in the evidence is a lack of a good quality time-series study or controlled trial of the effects of HBOT on cognition, memory, and functional status in patients with deficits due to mild and moderate chronic TBI.

Studies of the effects of HBOT on ICP levels also had mixed results. HBOT may be effective in reducing elevated ICP in some acute TBI patients, but rebound elevations higher than pretreatment levels can occur. The clinical benefit of the ICP lowering and the harm attributable to the rebound elevations are unclear. Without further delineation of the patient or treatment factors that may be associated with successful lowering of ICP, the current evidence is insufficient to determine whether the overall effect of HBOT on ICP is beneficial or harmful.

Other Brain Injury

We did not identify any good or fair-quality studies of HBOT for anoxic-ischemic encephalopathy. We found one randomized controlled trial and five before-after studies of patients with various kinds of nontraumatic brain injuries. All of these studies were poor-quality. The controlled trial lacked details regarding the subjects' recruitment and baseline characteristics and the methods used to randomize subjects and measure outcomes. All five before-after studies lacked objective outcome measures and masked assessment, and timing of baseline and followup measures was not clear.

2. Does HBOT improve functional outcomes in patients who have cerebral palsy?

There is insufficient evidence to determine whether the use of HBOT improves functional outcomes in children with cerebral palsy to a greater degree than pressurized room air. In the

only controlled trial, HBOT and pressurized room air resulted in similar, clinically significant improvements in motor function. Two fair-quality observational studies (one time-series, one before-after) found improvements in functional status comparable to the degree of improvement seen in both groups in the controlled trial. The data suggest that, at least temporarily, HBOT and pressurized room air improved caregiver burden.

3. Does HBOT improve mortality and morbidity in patients who have suffered a stroke?

The best evidence from three fair-quality RCTs showed no benefit to HBOT on neurological outcomes, but external validity is limited by protocol (one treatment only) in two studies, and by low response rate and adherence to treatment in another. No controlled trial measured mortality. Results from poor-quality controlled trials and observational studies were more positive, but it is not possible to rule out bias and confounding as explanations for their results.

4. What are the adverse effects of using HBOT in these conditions?

Ear problems and pulmonary complications were relatively common in patients undergoing HBOT for brain injury. Evidence about the type, frequency, and severity of seizure and other manifestations of oxygen toxicity is inadequate. In observational studies, reporting of adverse effects was limited, and no study was designed specifically to assess adverse effects. The frequency and severity of complications in community practice has not been studied.