

A composite outcome measure for mild traumatic brain injury in a hyperbaric oxygen clinical trial

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BACKGROUND

Recovery after mild traumatic brain injury (mTBI) is often measured by patient-reported symptoms, because neuropsychological testing (NPT) and neurological function are interpreted normal. We incorporated symptoms, NPT, and functional outcome into a composite score to quantify multidimensional change in a clinical trial of hyperbaric oxygen (HBO₂) for persistent post-concussive symptoms (HOPPS).

METHODS

We assigned HOPPS assessment to equal-weight categories. Symptom scores (NSI: dizziness, headaches, concentration, forgetfulness, slow thinking, fatigue, irritability) were totaled and divided by two. For NPT (Trails B, Stroop Color/Word, verbal fluency (D-KEFS), verbal learning (CVLT-II), visual-spatial memory (BVM-T-R), procedural reaction time (ANAM)), participants received 1 point for test performance > 1 standard deviation (SD) below the mean, > 2SD below the mean (2), and > 3SD below the mean (3). For functional outcome, grooved pegboard was scored like NPT. Sharpened Romberg (best of 4 attempts) was scored ≥ 30 seconds (0), 20-29 (1), 10-19 (2), 5-9 (3), 0-4 (5). Anxiety (BAI), depression (CES-D), and sleep (PSQI) were scored normal (0), mild (1), moderate (2), and severe (3). The composite score was the sum of scores from each domain.

RESULTS

72 participants enrolled (3 female, mean age 31 years, mean 3 lifetime concussion events, most recent mTBI 23 months prior to enrollment), and 64 had complete data at 13-week follow-up. Composite scores and total symptom scores were:

		Local Care (no chamber) (n=20)	HBO ₂ (1.5 ATA) (n=23)	Sham (1.2 ATA air) (n=21)
Composite	Baseline	15±8	17±9	18±7
	Follow-up	17±8	13±8	14±9
Total NSI Score	Baseline	32±15	33±17	34±17
	Follow-up	33±19	30±16	27±17

CONCLUSIONS

The local care group did not change. Chamber groups trended towards improvement without apparent discrimination by NSI score or our exploratory, unvalidated composite. These data suggest patient-reported symptoms may adequately reflect status change after mTBI.