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Hyperbaric oxygen as a therapy of Bell's palsy

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Racic G, Denoble PJ, Sprem N, Bojic L, Bota B. Hyperbaric oxygen as a therapy of Bell's palsy. Undersea Hyperbaric Med 1997; 24(1):35–38.—The purpose of this study was to compare the therapeutic effects of hyperbaric oxygen (HBO_2) to the effects of prednisone treatment in 79 subjects with Bell's palsy. Patients were randomly assigned either to the HBO_2-treated group ($n = 42$) or to the prednisone-treated group ($n = 37$). The HBO_2 group was exposed to 2.8 atm abs of 100% oxygen for 60 min, twice a day, 5 days a week and was given a placebo orally. The prednisone group was exposed to 2.8 atm abs of 7% O_2 (equivalent to 21% O_2 in air at normal pressure) following the same schedule as the HBO_2 group; prednisone was given orally (total of 450 mg in 8 days). Subjects from both groups were treated in the hyperbaric chamber for up to 30 sessions or to complete recovery, and were followed up for 9 mo. At the end of the follow-up period, 95.2% of subjects treated with HBO_2, and 75.7% of subjects treated with prednisone recovered completely. The average time to complete the recovery in the HBO_2 group was 22 days as opposed to 34.4 days in the control group ($P < 0.001$). In the HBO_2- treated group, at the beginning, the altered nerve excitability test (NET) was abnormal in five subjects; three of them had normal NET by the end of the follow-up period. In the prednisone group the NET was abnormal in nine subjects at the beginning and they had not recovered by the end of the follow-up ($P < 0.05$). Our results suggest that HBO_2 is more effective than prednisone in treatment of Bell's palsy.

Bells' palsy, prednisone, hyperbaric oxygen

The typical appearance of unilateral facial drooping has been known since ancient times. It can be seen in primitive tribal masks and ancient statues (1). In 30% of cases, palsy represents the symptom of an organic disease or disorder. In other cases, palsy is of unknown origin, and it is called Bell's palsy (BP). The pathologic basis of BP is presumed to be edema and hypoxia of the facial nerve in the fallopian canal.

Although BP is known to have a high rate of spontaneous recovery, an active approach in treatment is required to prevent permanent residual disability and to reduce the period of functional and esthetic handicaps, as well as absenteeism. The main goal of the treatment is to reduce edema and prevent hypoxic damage of the facial nerve. Various methods of conservative and surgical approaches have been suggested. However, despite the treatment, significant residual dysfunction may still remain in more than 50% of cases with total palsy and in about 25% of cases with severe palsy (2,3).

One of the methods that recently has been applied successfully in various hypoxic conditions is hyperbaric oxygenation (HBO_2). The oxygen is administered to patients in a hyperbaric chamber under a pressure greater than 1 atm abs. In healthy subjects, HBO_2 can cause cerebral vasoconstriction (4). In spite of that, the quantity of available O_2 in tissue is increased due to an increased quantity of O_2 dissolved in plasma. Physically dissolved O_2 diffuses in tissue better, particularly in sites where diffusion has been hindered. Beneficial effects of HBO_2 have been reported in various cranial and spinal nerve hypoxic conditions (5,6), and no harmful effects have been recorded with correctly applied HBO_2 (7).Treatment of BP with HBO_2 has not been investigated so far, with the exception of our previous study limited to 24 subjects with BP, all of whom achieved rapid and complete recovery (8).

This study was designed as a prospective, double-blind clinical experiment aimed at comparing the effect of HBO_2 treatment to the effect of prednisone given orally in BP. We chose prednisone because it recently has been the most frequently used treatment for BP. Another question of interest in this study was whether and to what extent the severity of the clinical findings affects the outcome of BP.

MATERIAL AND METHODS

The subjects in the study were volunteers selected from among the patients referred to our hospital for facial palsy. The diagnosis of Bell's palsy was established after a carefully taken history, physical examination, and the results of topognostic, electrophysiologic, radiographic, serologic, and blood tests. The severity of facial paralysis was graded as mild, moderate, severe, or total, according to the modified reference system of House (9) and Pietersen (10). All of the eligible patients were acquainted with the aim of the study and the potential risks and benefits. Entry

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criteria were: established diagnosis of Bell's palsy, presence of paralysis for less than 1 wk, severity grade moderate and above, no contraindications to increased pressure exposure, and signed informed consent to participate in the study. A total of 79 patients qualified. They were randomly assigned to either the HBO_2-treatment group or the prednisone-treated group. In the HBO_2 group, 18 female and 24 male patients participated, with an average age of 32.7 yr (range 13 to 68). The prednisone group comprised 13 females and 24 males with an average age of 38.7 yr (range 13 to 77). The first columns of Tables 1 and 2 show the distribution of patients by severity grade and treatment group.

The subjects of both groups were treated in the hyperbaric chamber at 2.8 atm abs for 60 min, twice a day, 5 days a week. According to current practice, this is rather high pressure. However, during the preliminary study this pressure was considered acceptable, and since the results of the preliminary study were excellent, without any adverse effect, we chose to continue to use the same pressure in this study.

The subjects in the HBO_2 group were breathing 100% O_2, delivered from a built-in-breathing-system type SAA-1, with external dumping of exhaled gas. In addition, subjects were given 45 placebo tablets divided the same way as tablets in the prednisone group.

Patients in the prednisone group were breathing gas administered by the same system. However, air diluted with nitrogen (7% O_2 in N_2) was substituted for O_2. It resulted in the same partial pressure of oxygen in breathing gas during the hyperbaric session as in air at normal atmospheric pressure. In addition, these patients were treated with 450 mg of prednisone administered in 10-mg tablets as follows: a) Days 1–4, four tablets twice a day; b) Day 5, three tablets twice a day; c) Day 6, two tablets twice a day; d) Day 7, one tablet twice a day; and e) Day 8,: one tablet.

Both groups were decompressed at 3 m/min with a stop at 3 m for 21 min. The number of sessions in the chamber for each subject in both groups varied depending on the recovery of facial function, with a maximum of 30 sessions. All patients were treated at the walk-in hyperbaric chamber of the Naval Medical Institute in Split, Croatia.

The development of degenerative changes and recovery were assessed daily in all subjects by the nerve excitability test (NET), before and after treatment. The NET test was considered abnormal if the current required to stimulate the nerve on the paralyzed side was 3 mA or more greater than the current required to stimulate nerve on the normal side. All patients were followed up for 9 mo. after treatment. The overall outcome was measured as the length of time to complete recovery, percent of the patients with complete recovery, and the severity of palsy if any residuals were present at the 9-mo. follow-up.

Statistical analysis used arithmetic mean, standard deviation, and sampling distribution. Sampling distribution was done with Student's t test and χ_2 test. Findings with an error probability value of <0.05 were considered to be statistically significant.

RESULTS

The severity of palsy in the HBO_2 and prednisone groups at the beginning and at the 9-mo. follow-up are shown in Table 1.

The subjects treated with HBO_2 were exposed in the chamber an average of 17.8 ± 6.1 sessions, whereas the subjects treated with prednisone were exposed in the chamber an average of 25.6 ± 3.7 sessions. In the HBO_2 group, 40 (95.2%) patients completely recovered, whereas in the prednisone group only 28 (75.7%) patients recovered completely. The recovery for various grades of palsy is shown in Table 2.

The average duration of symptoms from onset to complete recovery was significantly shorter ($P < 0.001$) for patients in the HBO_2 group (22 days) than for patients in the prednisone group (34.4 days). Positive NET was present at the beginning, or developed during the treatment, in five patients of the HBO_2 group and in nine patients of the prednisone group. However, at 9 months follow up, only two patients from the HBO_2 group still had a positive NET whereas the number of such subjects in the prednisone group remained unchanged ($P > 0.05$) (Table 3). Residual symptoms in two HBO_2 patients were mild as opposed to more severe residual or total palsy in prednisone-treated subjects.

DISCUSSION

Complete recovery in 95.2% cases treated with HBO_2 is, to our knowledge, the highest rate reported so far. It was higher than in any reported series of patients treated with prednisone. Adour (11) reported 89% recovery, Wolf et al. (12) 88%, Devries (13) 66%, Hyden et al. (2) 65%, and in this study we found 75.7% recovery in patients treated with prednisone. Only the studies of Wolf et al. (12) and Hyden et al. (2) were prospective and randomized. Laskawi et al. (14) reported 97% recovery rate in 33 patients treated with an infusion therapy of hydroxyethyl starch; this study was conducted without a control group.

The average recovery period of 22 days for the HBO_2-treated group was significantly shorter than in the prednisone group (34.4 days, $P < 0.001$). Other authors reported significantly longer recovery periods; Wolf et al. (12)

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Table 1: Final Recovery of the Patients Undergoing Treatment with HBO_2 in Relation to the Degree of Palsy After 9 mo.

	Degrees of Palsy at the Beginning	Degree of Palsy at the end of Treatment				
		Total	Severe	Moderate	Mild	Without Palsy
Total	17				2	15 (88.2%)[a]
Severe	22					22 (100%)[a]
Moderate	3					3 (100%)[a]
Mild						
Total number of patients	42					

[a]Percent of the initial number of patients at the beginning of the study.

Table 2: Final Recovery of the Patients Undergoing Treatment with Presnisone in Relation to the Degree of Palsy After 9 mo.

	Degree of Palsy at the Beginning	Degree of Palsy at the End of the Treatment				
		Total	Severe	Moderate	Mild	Without Palsy
Total	15	2	1	1	2	9 (60%)[a]
Severe	22					
Moderate			1		2	19 (86%)[a]
Mild						
Total number of patients	37					

[a]Percent of the initial number of patients at the beginning of the study.

Table 3: Number of Patients with Altered NET in the HBO_2 and Prednisone Group at the Beginning and End of the Follow Up

	Altered Nerve Excitability Test Performed:	
	at the beginning and in the course of treatment	9 mo. after the beginning of treatment
HBO_2 group, $n = 42$	5 (11.9%)	2 (4.7%) NS[a]
Prednisone group, $n = 37$	9 (24.3%)	9 (24.3%) NS[a]

[a]NS = not significant; $P > 0.05$.

reported 56 days and Hyden et al. (2), 84 days.

As expected, the final outcome of the disease was influenced by the severity of the clinical findings. Patients with moderate or severe palsy in the HBO_2 group recovered in 100% of the cases, and in the prednisone group, 86% of the cases. In subjects with total palsy, the rate of complete recovery after HBO_2 treatment was 88.2% and after prednisone, 60%. Rates comparable to our prednisone group were reported in other prednisone-treated series of patients. Devries (13) found complete recovery in 69% patients with severe palsy and in 42% with total palsy. Hyden et al. (2) reported 78% recovery in prednisone-treated cases with severe palsy and 48% recovery in cases with total palsy.

A positive NET at the beginning of the disease was found in 11.9% of patients of the HBO_2 group and in 24.3% of patients in the prednisone group. Yanagihara (15) found altered NETs in 33% of the patients whose BP was in an early stage of the disease. However, we tested our patients from Day 7 of the disease to avoid possible false negative results that may occur in 25% of the cases during the first 4–6 days (16). Kobayashi et al. (3) consider NETs to be reliable indicators of the prognosis in 90% of the cases, whereas Devries (13) regards a normal NET as a positive sign of recovery. In our study, an abnormal NET proved to be a negative prognostic sign in the group treated with prednisone, since there was no complete recovery among nine subjects with an abnormal NET. However, with HBO_2 treatment, complete recovery was achieved in three cases despite an abnormal NET.

The beneficial effects of HBO_2 on BP are probably achieved by an increase in the distribution of O_2 dissolved per volume unit of blood circulating through the regions suffering from hypo-oxygenation. The effects of HBO_2 are

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more pronounced in hypoxic tissue, and vasoconstriction does not occur in hypoxic tissue. Other possible contributing mechanisms may have been improved elasticity of the red blood cells and reduced platelet aggregation (17).

This study has shown that HBO_2, started within 7 days of symptom onset, significantly increases the chances of complete recovery in BP. Although 100% of patients with moderate and severe palsy may expect complete and fast recovery, in patients with total palsy the chances of a complete recovery increase up to 88.2%.

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