

Evaluation of Role of Hyperbaric Oxygen Therapy in children with Cerebral Palsy - Our experience at Armed Forces Hospital, King Abdul Aziz Naval Base, KSA

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ABSTRACT

Background: HBOT is medical treatment in which oxygen is used at an ambient pressure greater than atmospheric pressure for management of various clinical conditions in children like cerebral palsy, Bell's palsy and cerebral stroke.

Aims:: To compare the efficacy and safety of HBOT in children with cerebral palsy with controls, To make recommendation/suggestion for the staff awareness regarding HBOT and to make recommendation for establishment of HBOT facility for cerebral palsy children.

Study design: A single blinded randomized controlled Trial

Methods: All children with clinical diagnosis of cerebral palsy were included in this study. They were divided into cases and control after randomization. Those with neurobehavioral disorders / abnormal brain MRI or chromosomal or genetic syndromes were also excluded from the study. Seven (7) cases were dropped out of the studies due to other neurological disorder (ADHD/Autism) in which role of HBOT has not been clearly defined in the literature.

Settings: Deep sea medical unit of Armed Forces Hospital, KANB, Jubail, KSA.

Study period: June 2015 to June 2016

Results: This data analysis showed 66.5% of the patients (96% in Cases) and 37% in (Controls) showed improvement in neurological development (Gross motor functions measures scale) and 63% (95% in cases and 31% in control) in activity of daily livings score (self-reliance) and 46% (50% in cases and 42% in control) in parent's satisfaction index. While 64% showed improvement in hearing (37% in cases and 91% in control) but 30% showed improvement (33% in cases and 27% in control) in speech. Safety index was 93% (94% in cases and 95% in control).

Conclusion: All the children included in this study showed significant improvement in neurological outcome (Improvements were noted in Gross motor functions, activity of daily living). The improvement was less remarkable in hearing, speech and parent's satisfaction index.

Key words: Hyperbaric Oxygen Therapy, King Abdul-Aziz naval base, Central nervous system

INTRODUCTION

Cerebral palsy is the name for a group of lifelong conditions that affect movement and co-ordination, caused by a problem with the brain that occurs before, during or soon after birth. The symptoms of cerebral palsy aren't usually obvious just after a baby is born. They normally become noticeable during the first two or three years of a child's life¹⁶. Causes of cerebral palsy includes asphyxia, intracranial hemorrhage and CNS infection (Meningitis). There's currently no cure for cerebral palsy, but treatments are available to help people with the condition have a normal and independent life. Treatment includes pharmacology, physiotherapy, speech therapy to help with speech and communication, occupational therapy and surgery to treat movement or growth

problems. Selective rhizotomy is the most effective treatment to reduce spasticity in most but not all types of cerebral palsy². Hyperbaric oxygen therapy (HBOT) is medical treatment in which an ambient pressure greater than sea pressure is used. HBOT is the medical use of oxygen at an ambient pressure higher than atmospheric pressure. The equipment required for hyperbaric oxygen treatment consists of a pressure chamber, which may be of rigid or flexible construction, and a means of delivering 100% oxygen. Operation is performed to a predetermined schedule by trained personnel who monitor the patient and may adjust the schedule as required. This therapy (HBOT) has been used in various parts of the world with variable results. The application of HBO to the therapy of various human diseases developed over a period of 300 year. Like most of medicine, the basis of these applications was and continues to be pragmatic in nature, and involves uncritical and untested judgments. The possibility of risks has been

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understated and possible benefits have been overstated¹.

Deep sea medicine unit is established at Armed Forces Hospital, King Abdul Aziz Naval base, Jubail since 20 years and pediatric patients are being treated since 8 years with diagnosis of cerebral palsy, learning disability, bell's palsy and poorly healing wounds (post-traumatic and diabetics). Tentative evidence shows a possible benefit in cerebrovascular diseases³. The clinical experience and results so far published has promoted the use of HBO therapy in patients with cerebrovascular injury and focal cerebrovascular injuries. However, the power of clinical research is limited because of the shortage of randomized controlled trials⁶.

MATERIAL AND METHODS

This study was carried out at deep sea diving & medicine unit, AFH-KANB, Jubail, KSA. 200 children cases (n=96) and control (n=104) with clinical diagnosis of cerebral palsy were enrolled in this study after randomization using SPSS V20 irrespective of gender. Seven (7) cases were dropped out due to other neurological disorders like ADHD and Autism. Finally, 90 cases and 103 controls were included in this study. Cases received hyperbaric oxygen therapy (HBOT) and controls did not receive HBOT. All cases underwent 5 cycles of HBOT. Each cycle comprised of 40 sessions of HBOT over a period of 2 months, one session per day, 5 days per week for 8 weeks. Each session consists of 60 min and 100% oxygen @ 1.5 ATA in specialized HBOT chamber was delivered via a hood in the multi-place chamber. All children underwent a complete physical examination (by pediatrician, ENT and ophthalmologist) before and after the session with a special focus on the central nervous system (CNS), ears and respiratory system. During the trial, a pediatrician recorded the improvement using Modified GMFMS Score sheet, Barthel Index of activity of daily living (ADL) score sheet and hearing, speech improvement in all children of both groups. In modified GMFMS, score more than 5 was taken as improvement, higher the score higher the improvement while in ADL score less than 16 was taken as improvement while score more than 17 as no improvement, so lesser the score higher the improvement. Parents satisfaction index (PSI) using questionnaire was also recorded. All adverse health events occurring during the course of the study (Barotrauma, oxygentoxicity, confinement anxiety, ocular defect) corresponded to the adverse outcomes was recorded as a measure of safety of HBOT. These events could occur during a particular session or in between sessions. A safety score 0-2

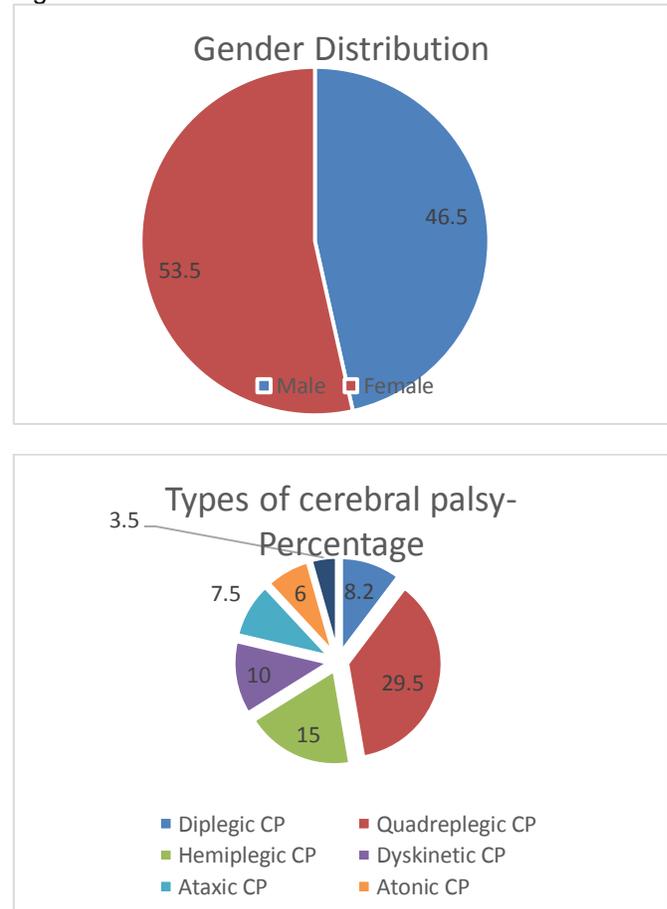
was taken as measure of safety of the intervention (HBOT), lesser the score safer is the procedure.

Data analysis: It was based on an intention-to-treat approach. All children included are reported in the results. Chi-square test was used to evaluate the result of our study. Level of statistical significance was set at 0.05 (type 1 error) and analyses were done with SPSS v 20.

RESULTS

Two hundred children were included in the study 97(48.5%) as cases and 103(51.5%) as control using randomization (Table-1). Seven children were dropped out of the study due to other neurological disorders so finally 90 cases (45%) and 103(51.5%) controls completed the study. General differences in study groups (case and control) like age, gender, clinical types of cerebral palsy and parameters used to assess efficacy and safety of HBOT are shown in table-1 and 2. Statistical analysis (by chi square test) are shown in table-3. Pie, line and bar charts are also shown to highlight frequency distribution of variables in both groups (Fig:1).

Fig. 1:



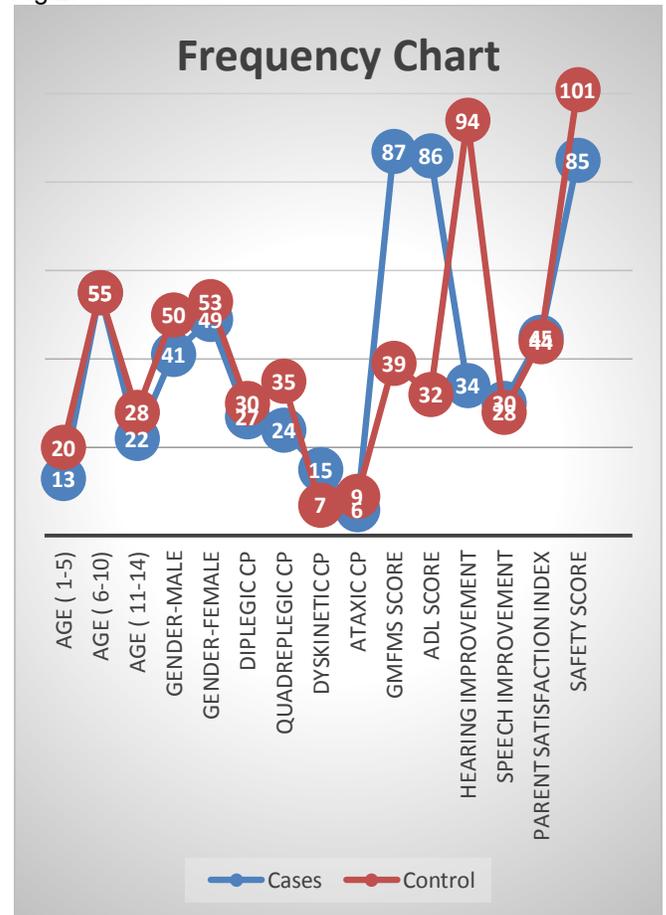
Gender distribution showed 93(46.5%) were male and 107(53.5%) female child between the case and control groups and this again was statically insignificant as P value 0.895. Age distribution was 16.5% (1-5 years, n=33), 57% (6-10 years, n=114) while 53(26.5%) were in age group 11-14 years. (Table 1)

Table 1:

Variables	Frequency	%	Valid%	Cumulative%
Age				
1-5 years	33	16.5	16.5	16.5
6-10 years	114	57	57	73.5
11-14 years	53	26.5	26.5	10
Gender				
Male	93	46.5	46.5	46.5
Female	107	53.5	53.5	53.5
Groups				
Cases	90	45	45	45
Control	103	51.5	51.5	51.5
GMFM				
No Improvement	67	33.5	33.5	33.5
Improvement	126	63	63	63
ADL				
Improvement	118	59	59	59
No improvement	75	37.5	37.5	37.5
Hearing				
Responsive	128	64	64	64
Unresponsive	65	32.5	32.5	32.5
Speech				
Intelligent	58	29	29	29
Incomprehensible	134	67	67	67
None	1	0.5	0.5	0.5
Satisfaction				
Not Satisfied	89	44.5	44.5	44.5
Satisfied	104	52	52	52
Safety index				
Safe	186	93	93	93
Unsafe	7	3.5	3.5	3.5

Chi square test results showed this difference in age and gender in both groups is statistically insignificant as P value was 0.511.

Fig:2:



As for diagnosis is concerned spastic diplegia 57(28.5%) and spastic quadriplegia 59(29.5%) were the most common type, followed by spastic hemiplegia 30(15%) and dyskinesia cerebral palsy 20(10%). Rest were ataxic cerebral palsy 15(7.5%), atonic cerebral palsy 12(6%) and others 7(3.5%) respectively (Fig-2). Statistical analysis showed this difference was insignificant as P value was 0.537 (Table 2).

As for the results are concerned, data showed improvement in GMFMS 66.5% (n=126) (96% and 37% in group 1 & 2), while 33.5% did not show any improvement (n=67) P values was 0.000, while in Activity of daily living (ADL) 63% (95% and 31% in Group 1 & 2 respectively) showed improvement while 37.5% did not showed any improvement. Statistical analysis showed p value.

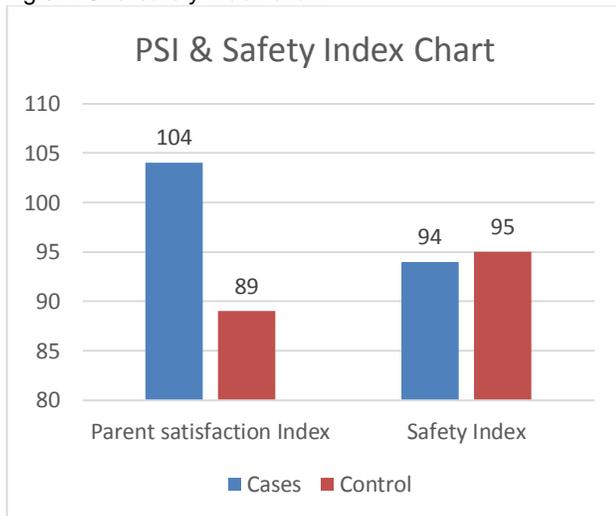
Table 2: Chi Square test

Variable	Value	Df	Asymp significances
Age	3.287	4	0.511
Gender	0.222	2	0.895
Type of CP	4.085	5	0.537
GMFMS	275.938	4	.000
ADL	287.120	4	.000
Hearing	263.744	4	.000
Speech	201.724	6	.000
Safety	201.860	4	.000
PSI	201.062	4	.000

which was statistically significant (Fig-2) As for hearing and speech are concerned, statistical analysis showed some improvement (lesser as compared with motor improvement)in 64%(37% and 91% in group 1 & 2) and 30% (33% and 27% in Group 1 & 2) of the patients respectively while 34% and 70% did not showed any improvement with a p values of 0.000, meaning by statistically significant. As for parent satisfaction index (PSI) is concerned 54% (50%& 42% in group 1 & 2)were satisfied but 46% were unsatisfied (P value (0.000) (Fig. 3).

As for safety is concerned 94.5% (94% & 95%in case and control groups) of patient did not had any significant side effect while only 3.5% showed minor side effects like earache and confinement anxiety with a P value of 0.000suggesting statistically significant results

Fig.3: PSI & safety index chart



DISCUSSION

Results of this study showed that neither the difference in age and gender nor was the difference in clinical type of cerebral palsy statistically significant as for efficacy and safety of HBOT is concerned. Our results showed significant improvement in GMFM

score, ADL score and to a lesser extent in hearing and speech. The GMFMS improvement has also been documented in other study in which score increased by 2.9% in the children on hyperbaric oxygen¹⁵. A retrospective case study including 6 patients also reported that HBOT is effective⁷. Treatment with hyperbaric oxygen has also been shown to reduces mortality and neurological sequelae in term neonates with hypoxic-ischemic encephalopathy¹⁰. There was also significant improvement in parents' satisfaction index. Two fair-quality uncontrolled 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 tria⁹. All these results were statistically significant and has positive clinical correlation in our studies. As for side effects are concerned, most of patients did not had any side effect related to HBOT.HBOT was found to be safe in our study. Few patients did develop minor side effects like earache and confinement anxiety during the study. Major side effects like pneumothorax, oxygen and CNS toxicity were not observed³. Short-term exposure to HBOT at medium level pressure (1.75 ATA) was responsible for a significant increase of middle ear barotrauma compared to children that received very low external pressure (1.3 ATA)¹². Statistical analysis showed these differences in side effects were significant.These results are the same as shown in other studies^{5,10}. Although we dropped out children with diagnosis of Autism or ADHD from our studies but there are reports which showed significant improvement in behavior but not in other cognitive areas⁶.

Pediatricians are not always aware of the potential benefit of HBO in the treatment of the diseases for which it is indicated, whereas the HBO staff is not always familiar with the specific management requirements of the pediatric patient, especially those who are critically ill. The physician inside the chamber caring for a ventilated, critically ill infant or child should be familiar with this type of treatment, ventilator settings, and eventual intubation or reintubation of the patient, as well as with medication man³. There is a fundamental need for pediatricians and institutions engaged in pediatric health care to be actively involved in the decision-making process for HBO therapy in the pediatric patient. Wise decision making, based on an understanding of the known benefits of this modality of treatment, may reduce the mortality and severe sequelae of those diseases for which HBO is indicated³. Although the results of this study are encouraging but it is hard to draw a definite conclusion about the role and effectiveness of HBOT therapy because of the low number of cases⁴ and

being a single center study. A large scale multicenter RCT should be done before final recommendation can be made¹⁴.

CONCLUSION

This study showed that hyperbaric oxygen therapy is quite safe and effective in children with cerebral palsy so its use should be encouraged wherever facility is available along with other therapies like physical therapy, medication, psychotherapy wherever needed. Only minor side effects like earache and confinement anxiety was noted in few children and were similar in both groups. Our study also shows that exposure to low hyperbaric pressure (1.5 ATA) reduces the chances of serious/significant side effects. We also suggest a large scale multicenter RCT study needs to be conducted to verify results (efficacy and safety) of hyperbaric oxygen therapy (HBOT).

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