Place of Hyperbaric Oxygen Therapy in the Management of Cerebral Palsy

Summary

AGENCE D'ÉVALUATION DES TECHNOLOGIES
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Québec

Place of Hyperbaric Oxygen Therapy in the Management of Cerebral Palsy

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Report prepared for AETMIS by

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Mission

The mission of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) is to help improve the Québec health-care system. To this end, it advises and supports the Minister of Health and Social Services and decision-makers in the health-care system with regard to the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for the disabled, as well as the methods of providing and organizing services. The assessments examine many different factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic issues.

Foreword

Place of Hyperbaric Oxygen Therapy in the Management of Cerebral Palsy

The use of hyperbaric oxygen therapy (HBOT) for children with cerebral palsy (CP) dates back to the 1980s. Since then, a few researchers and clinicians have published the outcomes of their studies on the contribution of HBOT to improving the functional status of these children. In 2000, the Conseil d'évaluation des technologies de la santé (CETS) published a report on the use of HBOT in Québec, identifying its recognized indications. According to that report, the lack of good-quality scientific evidence precluded any conclusions about the real effects of this technology for the treatment of CP.

Nevertheless, some of the published studies and the positive experience of parents whose children with CP had undergone HBOT sessions outside Québec raised high hopes among other parents in Québec. Their lobbying efforts led the Ministère de la Santé et des Services Sociaux to set up a randomized controlled trial in 1999 to help shed greater scientific light on the efficacy of HBOT in the treatment of CP. The outcomes of that multi-centre trial were published in *The Lancet* in 2001 and showed significant improvements that were similar in the two groups of children (experimental and control) in terms of motor function, neuropsychological functions, language and speech, and functional performance. Although the researchers concluded that hyperbaric medicine was not effective, that interpretation of the outcomes was far from unanimous and lead to considerable controversy.

Parents of children with cerebral palsy and health professionals in Québec have lobbied members of the National Assembly and the news media to have the clinical utility of HBOT recognized for the management of CP.

This was the context in which the Minister of Health and Social Services asked AETMIS to update the 2000 report by giving special consideration to cerebral palsy. The minister wanted to find out, in particular, if recent clinical research studies had yielded results on the efficacy of HBOT in the treatment of this disorder. A more complete update would also help identify the full range of medical conditions for which HBOT would be indicated.

This initial report deals only with the place of hyperbaric oxygen therapy in the management of cerebral palsy. The importance of the stakes involved in this issue justify such an approach. The other indications are the subject of parallel studies, the outcomes and conclusions of which will be published later by AETMIS in a separate report.

Dr. Juan Roberto Iglesias, President and Chief Executive Officer

Executive Summary

Cerebral palsy (CP) is an incurable disorder affecting more than 2000 children in Québec. The management of CP is multidisciplinary in nature and generally aims at improving muscle function, joint mobility and verbal skills, along with orthopedic corrections. This disorder imposes considerable responsibilities on parents, which contributes to their interest in different approaches, including hyperbaric oxygen therapy (HBOT).

Although some studies, of poor quality for the most part, have suggested improvements in motor and cognitive functions associated with HBOT, doubts have remained as to its effectiveness. A randomized controlled trial conducted in Québec in 2000 attempted to dispel this uncertainty, but the interpretation of its outcomes instead gave rise to considerable controversy. In fact, similar improvements in the subjects' functional parameters were observed both in the control group given pressurized air and in the experimental group given 100% oxygen in a hyperbaric setting. The few research studies that came out after the Québec trial have not managed to shed greater light on this issue.

After the current assessment, which consists of a rigorous and exhaustive review of the scientific literature and an in-depth examination of the contextual issues surrounding this matter, AETMIS makes the following conclusions:

- the efficacy of hyperbaric oxygen therapy for the treatment of cerebral palsy has thus far not been scientifically demonstrated, and uncertainty persists;
- given this lack of scientific demonstration, the procedure must remain experimental for the time being;
- the outcomes of the Québec study published in 2001 indicate, however, that hyperbaric oxygen therapy among children with CP is possibly associated with significant improvements in motor function, neuropsychological functions, language and speech, and functional performance;
- other well-designed controlled studies must be conducted, in addition to the U.S. studies already underway, to supply a definitive answer to the question of the efficacy of HBOT for the treatment of CP.

It is therefore recommended that:

to dispel uncertainty,

- the efficacy of hyperbaric oxygen therapy in the management of cerebral palsy should be the subject of a new research study in Québec to be funded as a joint Canadian or international project;
- granting agencies should encourage and pursue rigorous studies on the epidemiology of cerebral palsy, as well as on the needs of children with CP and on issues related to their care, in conjunction with key stakeholders and representatives of these children's parents;
- the U.S. and international studies in progress should be closely monitored, and their outcomes and implications should be rigorously assessed;

to optimize safety,

- the use of hyperbaric oxygen therapy for the medical management of cerebral palsy should be limited to formal research projects;
- physicians treating children with cerebral palsy should inform parents wishing to use HBOT of the unrecognized status of this treatment and of the means to be taken to minimize its risks.

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DISCLOSURE OF CONFLICTS OF INTEREST

None to be declared.

Summary

Introduction

Hyperbaric oxygen therapy (HBOT) is a treatment modality whereby patients breathe 100% oxygen intermittently while inside a chamber in which the pressure is greater than that at sea level. The use of HBOT for children with cerebral palsy (CP) dates back to the 1980s and has led to considerable controversy, which is still on-going. In the wake of this controversy, parents of children with CP and health professionals in Québec have lobbied members of the National Assembly, the news media and Internet users in a bid to have the clinical utility of HBOT recognized for the management of CP.

In this context, the Minister of Health and Social Services asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to review the current state of knowledge about HBOT and its potential contribution to the management of CP. In the letter of request, the Minister recalled that, in its 2000 report on HBOT in general, the Conseil d'évaluation des technologies de la santé (CETS, predecessor of AETMIS) did not classify CP as one of the recognized indications and that CETS emphasized the need to obtain a clearer understanding of available scientific evidence or to initiate new research studies.

Hyperbaric Oxygen Therapy

HBOT is recognized today for the treatment of 13 medical conditions: gas embolism; carbon monoxide poisoning; gas gangrene (clostridial myonecrosis); crush injuries, compartment syndrome and other acute traumatic ischemias; decompression sickness; problem wounds (non-healing or slow-healing, chronic or refractory); anemia resulting from exceptional blood loss; intracranial abscesses; necrotizing soft-tissue infections; refractory osteomyelitis; osteoradionecrosis and soft-tissue radionecrosis; compromised skin grafts and flaps; and thermal burns. For these conditions, 100% oxygen is generally compressed at pressures from 2 to 3 atmosphere absolute (ATA). However, the pressures used to treat neurological disorders, including cerebral palsy, do not exceed 2 ATA for durations ranging from 40 to 60 minutes, for 40 sessions, the pressure generally being around 1.5 ATA.

Some have proposed an alternate definition to that mentioned in the introduction above, whereby HBOT involves using a pressure greater than 1 ATA, but without specifying the oxygen concentration required to treat certain conditions or its mechanisms of action. This alternative definition, however, has not been the subject of in-depth studies, much less consensus.

There are two types of hyperbaric chambers: monoplace and multiplace. The choice of chamber depends on the need and the conditions to be treated. HBOT is recognized as a generally safe procedure with few contraindications. Some risks must nevertheless be taken into consideration during use. These risks are grouped into four major categories: the risks due to hyperpressure for certain organs such as the middle ear, inner ear, sinuses, lungs, and teeth; the risks of oxygen toxicity; the risks of explosion; and the risks of fire. Of these complications, barotrauma of the middle ear is the most frequent.

Cerebral Palsy

Cerebral palsy describes a group of disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, cognition, communication, perception and/or behaviour, and/or by a seizure disorder.

Four major classifications are proposed in the literature, depending on the type or physical location of the impairment. The most common classifies CP in three groups: spastic, extrapyramidal and hypotonic. According to the National Institute of Neurological Disorders and Stroke (NINDS), the spastic form is the most frequent, affecting between 70% and 80% of patients with CP.

The causes of CP are multifactorial and may occur during the prenatal (including preconceptional), perinatal or postnatal period. The three greatest risk factors appear to be low birth weight, intra-uterine infections and multiple pregnancy. The pathophysiological mechanisms cited to explain the onset of CP during the prenatal period relate especially to windows of vulnerability, one affecting the periventricular white matter of the brain between 26 and 34 weeks of gestation, and the other affecting the basal ganglia in the fetal brain between 38 and 40 weeks of gestation. The clinical manifestations resulting from the neurological deficits depend on the extent and type of brain damage, the site of irreversible damage and the ability of the central nervous system to adapt and reorganize itself after the onset of damage.

The United Cerebral Palsy (UCP) Association estimates that 500,000 people have CP in the United States. By extrapolation, this prevalence would be on the order of 55,000 in Canada, and roughly 13,700 in Québec. However, owing to the lack of reliable data, our consultation of clinicians in Québec regarding the number of people with CP did not yield a consensus, but most estimated that between 2000 and 2500 children have CP.

Since motor deficit is the central element of the definition of CP, motor function is the main variable of clinical interest. The Gross Motor Function Measure (GMFM) is the most commonly used measurement instrument to assess the motor condition of children with CP, and to monitor its progression and development in a clinical or research context. Since CP also affects children's daily living activities and cognitive functioning, two other validated tests are used to assess these dimensions: the Pediatric Evaluation of Disability Inventory (PEDI) and the Test of Variables of Attention (TOVA).

The management of children with CP aims to decrease the functional consequences of the disorder in all aspects related to brain function. As a result, it must be carried out by a team of specialists from various disciplines: pediatrician, pediatric physiatrist or pediatric neurologist, orthopedist, physiotherapist, speech therapist, dietician, social worker, educator, and so forth. Some authors believe that early and structured management allows children to gain appreciable benefits.

Efficacy of HBOT in the Management of CP

Several hypotheses have been proposed in an attempt to explain the possible effects of HBOT in children with CP. A first hypothesis is based on "idling cells" that could be activated by certain stimuli, such as higher doses of oxygen. A second hypothesis, synaptic reorganization leading to the restauration of impaired nervous pathways, leaves little room for HBOT. A third hypothesis is based on stem cells. These cells would initially be mobilized following an ischemic insult and this mobilization could be accelerated through administration of HBOT.

Since these hypotheses are not actually connected to the acute and chronic pathophysiological processes associated with CP, evidence for the efficacy of HBOT must be based not on biological plausibility but above all on the outcomes of clinical trials.

Examination of the literature on the efficacy of HBOT in the management of CP reveals that:

- the scientific literature can be divided into two categories: clinical trials measuring the effects of HBOT on patients with CP, and literature reviews (systematic or narrative);
- there are few clinical trials measuring the effects of HBOT on patients with CP and they are repeatedly cited in the literature reviews;
- among the literature reviews, that by the Agency for Healthcare Research and Quality (AHRQ) on the efficacy of HBOT for brain trauma (brain injury, CP and stroke) published in 2003 represents the most recent rigorous and thorough analysis of the question.

The use of HBOT in the management of CP is relatively recent. Five before-after observational studies, without control groups, were published between 1989 and 2002 and showed improvements in the children's condition in relation to several clinical parameters, especially motor function. These studies raised the possibility, in the scientific community, that HBOT might be effective for treating CP, but did not demonstrate it.

This was the context in which two controlled clinical trials were conducted in 2000 and 2001. The first was conducted in New York in 2000 (the Cornell Study) and was the subject of only a brief summary. The author noted no significant difference in GMFM scores between the experimental and control groups, but the parents involved observed some improvement in some functions, including motor skills.

The second randomized controlled trial was conducted in Québec with a group of 111 children. The outcomes of this trial were published by Collet et al. in 2001 and by Hardy et al. in 2002. The authors reported no significant difference between the experimental and control groups. They observed equivalent improvement in the two groups in terms of the four dimensions evaluated by the study: motor function, some neuropsychological functions, including memory and attention, language and speech, and functional performance. The improvements in motor function were substantial and at the same level as those obtained through intensive physiotherapy.

These results provoked considerable controversy, with some maintaining that the improvements were caused by a participation effect tied to the extra attention and care offered to the two groups, and others believing that these improvements were attributable to "hyperbaric oxygenation." The latter maintained that the control group was also technically exposed to a form of "hyperbaric oxygenation therapy," considering that the children in that group received air at 1.3 ATA, which would be equivalent to an oxygen concentration of roughly 28%.

All the research studies mentioned above, except one in Spanish and another led by the U.S. Army Medical Corps in 2002, were taken into account in the AHRQ systematic review published in 2003. This review, carried out in accordance with strict standards, concluded that there is no scientific evidence supporting the fact that HBOT is effective for treating children with CP. It also concluded that uncertainty persists and that further studies are required.

Since the AHRQ review, 18 narrative reviews on different topics related to CP and published as recently as 2006 have converged toward the same conclusion. Another randomized controlled trial was published in 2003 by Sethi and Mukherjee. It concluded that HBOT associated with occupational therapy and physiotherapy is effective in improving the motor skills of children with CP. However, the authors themselves pointed out the limitations of their trial, and other methodological weaknesses lead this study to be considered of poor quality.

Two U.S. studies are currently in progress: these are randomized controlled trials studying questions that have already been raised. The first is being conducted by the Children's Medical Center of Dayton and is funded by the U.S. Department of Defense. The second is being run by the UCLA/Orthopaedic Hospital Center for Cerebral Palsy and has been recruiting subjects since March 2006.

Clinical researchers in Québec are pursuing their work in this area. For example, the outcomes of a before-after observational study of 118 Québec children with CP treated with HBOT were presented at the 5th International Symposium on Hyperbaric Oxygenation held in July 2006 in Fort Lauderdale, Florida. The results suggest significant improvements in motor skills, but remain difficult to interpret, especially because of the lack of a control group.

Official Positions of Organizations and Third-Party Payers

The official positions of recognized and credible organizations on the use of hyperbaric oxygen as a therapeutic modality for CP may be summarized as follows. For the Undersea and Hyperbaric Medical Society (UHMS), according to its 2003 publications and the information available on its Web site, CP is not an indication for HBOT. The United Cerebral Palsy (UCP) Association indicates that current scientific evidence does not allow us to conclude whether or not this therapy contributes to improving patients' neurological status, and further investigations are required. In addition, the guide published on the site of the Ontario Federation for Cerebral Palsy does not deal with HBOT as a treatment for CP.

None of the Canadian provincial health insurance plans that we were able to consult (Alberta, British Columbia, Ontario, and Newfoundland and Labrador) include cerebral palsy as one of the medical conditions for which HBOT is reimbursed.

The same is true for Medicare, which does not include cerebral palsy as an indication for which HBOT is covered. Blue Cross and Blue Shield Association Health Insurance (BCBS), Aetna and CIGNA consider HBOT to be an experimental technology for cerebral palsy, and thus do not cover HBOT for this medical condition.

However, with respect to the United States, a recent court decision in Georgia ruled that a beneficiary with CP insured under Medicaid, the government-funded health insurance plan, was entitled to be reimbursed for all of his HBOT sessions. In its conclusions, the Superior Court, basing itself on the ruling of the Georgia Appeals Court in the same matter, recalled that, pursuant to the requirements of the law (U.S. Code 42, section 1396d), the beneficiary was not obliged to prove that HBOT is a generally accepted medical practice or that it corresponds to the definition of "medical necessity" used by Medicare, but that it was sufficient to prove that it improves or corrects the beneficiary's medical condition.

Legal Framework

The act of using a hyperbaric chamber for the purpose of treating a disease does not fall under the jurisdiction of Health Canada but of the Collège des médecins du Québec, in accordance with the powers vested in it by the Medical Act. Under the Professional Code, physicians are obliged to offer their patients all the treatments required by their health condition, insofar as these treatments are recognized by the medical profession. Nevertheless, patients remain free to undergo unrecognized treatments. Given that HBOT for cerebral palsy is not a recognized treatment, physicians can not prescribe it for the time being. This excludes the case of research studies, insofar as they have protocols duly approved by a research ethics committee.

Given that patients or their parents, in the case of minors, maintain their freedom regarding the therapeutic decisions that concern them, they are not forbidden to acquire and use a hyperbaric chamber. In such cases, physicians have the duty to inform their patients or their parents about unrecognized treatments, and they must also provide all the necessary care, if required. But what about third-party administration of HBOT? In accordance with the Québec Medical Act, whether a treatment is recognized or not, if there is a risk of harm for a patient, it may not be administered by a third party. In this case, the Collège des médecins may intervene to put a halt to such practice.

Conclusion and Recommendations

The literature review we have conducted leads us to the following conclusions:

- The efficacy of HBOT for the treatment of cerebral palsy has thus far not been scientifically demonstrated, and uncertainty persists.
- Given this lack of scientific demonstration, the procedure must remain experimental for the time being.
- The outcomes of the randomized controlled trial conducted in Québec indicate, however, that hyperbaric oxygen therapy among children with CP is possibly associated with significant improvements in motor function, neuropsychological functions, language and speech, and functional performance.
- Other well-designed controlled studies must be conducted, in addition to the U.S. studies already underway, to supply a definitive answer to the question of the efficacy of HBOT for the treatment of cerebral palsy.

The consideration of these conclusions in the light of contextual information leads to the following recommendations, which take into account the situation as a whole:

To dispel uncertainty,

AETMIS considers that further research is necessary for the following reasons: uncertainty persists about the efficacy of HBOT in the management of CP; the outcomes of most of the observational and controlled studies on this issue converge; medical imaging techniques are now available to better document the presence of clinical outcomes; the U.S. studies now in progress will not be able to answer all the questions raised; and finally, this technology raises high hopes among parents.

Recommendation 1: *It is recommended that the efficacy of HBOT in the management of CP should be the subject of a new funded research project. In this research study, a number of aspects should be considered:*

a) the research study should be a multi-centre randomized controlled trial, ideally conducted as a joint international or Canadian study;

b) the research should be placed under the scientific direction of a research group recognized for its objectivity, experience and expertise;

c) the research group responsible for the study should work in conjunction with experts in the fields of hyperbaric oxygen therapy, cerebral palsy and research methodology acting as an advisory group in order to agree on the conditions that are essential for the success of the experiment, including the type of study design, the dose(s) of hyperbaric oxygen, the methods to preserve blinding, requisite clinical variables, measurement instruments, and so forth. This advisory group should take part in interpreting the data;

d) the controversies surrounding the question should motivate researchers to identify the effects of the following variables in the research study: 1) hyperbaric therapy (increase in pressure) and oxygen therapy (increase in proportion of inhaled oxygen); 2) hyperbaric therapy alone; 3) oxygen therapy alone: 4) normobaric[1] conditions and ambient air; and 5) participation effect;

e) the variables and measurement instruments should be validated and should evaluate not only gross motor function (GMFM) and neurocognitive functions, but also spasticity and changes in brain tissue documented by medical imaging techniques; and

f) a sufficient budget should be granted to meet all the conditions raised.

Moreover, given that, in Québec, there are limited data on the epidemiology of CP and on the needs of pediatric patients and the implications for the care and services offered to them:

Recommendation 2: *It is recommended that granting agencies should encourage and pursue rigorous research on their epidemiology of CP, as well as on the needs of children with CP and on issues related to their care. This research should be done in conjunction with key stakeholders and representatives of the parents of children with CP.*

Finally, the research studies in progress in the United States and elsewhere should be carefully monitored to better position Québec's research initiatives in this area, but also to be able to put their applications to use in a timely manner.

Recommendation 3: *It is recommended to closely monitor the U.S. and international studies in progress and to rigorously assess their outcomes and implications.*

To optimize safety,

while waiting for research to shed greater light on this issue, some parents will continue to make use of HBOT in the hope of seeing improvements in their children's condition, and some clinicians, convinced of the effectiveness of HBOT in the management of CP, will want their patients to benefit from its expected effects. Such decisions must follow certain guidelines. The following recommendations comply with the position statement issued by the Collège des médecins du Québec with regard to unrecognized treatments:

Recommendation 4: *It is recommended that HBOT not be generally prescribed by physicians, except in the context of a formal research project; and*

Recommendation 5: *It is recommended that physicians treating children with CP inform parents wishing to use HBOT of the unrecognized status of this treatment modality and of the means to be taken to minimize its risks.*

1. Related to normal atmospheric pressure.

Agence d'évaluation des technologies et des modes d'intervention en santé

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