

The therapeutic value of hyperbaric oxygen (HBO) on children with cerebral palsy

English summary

Une production de l'Institut national
d'excellence en santé
et en services sociaux (INESSS)

Direction des services de santé et de
l'évaluation des technologies

SUMMARY

Mandate

The *Institut national d'excellence en santé et en services sociaux* (INESSS) was mandated by the *Ministère de la Santé et des Services sociaux* (MSSS) to assess the therapeutic value of hyperbaric oxygen (HBO) on children with cerebral palsy for the purpose of supporting a decision with respect to possibly adding this form of therapy to the range of public services.

Assessment process

A systematic literature review was conducted to identify evidence-based findings relevant to the evaluation of the efficacy and innocuity of HBO and its impact on the quality of life of children with cerebral palsy and their parents. Meta-analyses were performed on outcomes of interest when the scientific data so permitted.

Contextual and experiential data gathered through consultations with experts (clinicians and scientists) and stakeholders (representatives of a group of parents, an association supporting people with cerebral palsy and their relatives, hyperbaric centers and clinics, physical rehabilitation centers) were presented. Information was gathered from parents of children and young adults with cerebral palsy through the conduct of questionnaires and individual interviews with the aim of understanding their perspective and views.

Cerebral palsy and health needs

Cerebral palsy is the most common cause of physical disability and developmental delay in children. While the global prevalence is estimated at 2.11 per 1,000 live births, that of the Canadian population has not yet been defined. Cerebral palsy is a group of developmental disorders affecting movement and posture and responsible for activity limitation. These disorders are caused by non-progressive neurological dysfunctions, which occurred during the baby's brain development during pregnancy, at birth or in the newborn's first weeks of life. Various disorders are associated with cerebral palsy: cognitive, speech, perception or behavioral impairment; sensorial dysfunctions; epilepsy; and secondary musculoskeletal and oral-motor function problems.

There exists no curative treatment for cerebral palsy. Clinical profiles and disorder severity levels differ from one person with cerebral palsy to another, thus making diagnostic assessments more complex. Care management of children with clinical palsy is provided by interdisciplinary clinical teams (medical and physical rehabilitation) in partnership with the parents. It aims at improving the child's muscular function, articular mobility and oral expression capacity and at making orthopedic corrections (correction of malformation and malalignment).

Cerebral palsy has profound effects on the quality of life of the children and their parents as highlighted through interviews with parents. The parents interviewed clearly indicated their full involvement in the care and services to be given to their child. While they are generally satisfied with the care and services provided, they voiced concerns on the

issue of variability of rehabilitation services. Some parents expressed a wish to see support, respite, information and financial aid services enhanced. Most of them still remain hopeful that a treatment will contribute even more to the positive evolution of their child's condition and quality of life.

Hyperbaric oxygen therapy

Hyperbaric oxygen (HBO) therapy is a technology in which pure oxygen or a mixture of gas with greater oxygen is administered to one or many persons inside a pressurized chamber (the pressure is greater than standard atmospheric pressure - one (1) atmosphere absolute [ATA]). Health Canada now recognizes the effectiveness of HBO in the treatment of 14 types of disorders, but cerebral palsy is not one of them. Under the Quebec health system, as for the vast majority of comparable health systems, HBO treatment for cerebral palsy is not recognized and, therefore, cannot be prescribed. The two health centers in Quebec equipped with hard-shell hyperbaric chambers can only use them to treat patients who meet indications approved in Canada.

Context of use in Quebec

In Quebec, the use of hyperbaric oxygen therapy on children with cerebral palsy goes back to the 1990s. Over the years, many parents have turned to HBO treatment. A few private clinics offer this type of treatment for children with cerebral palsy, and private enterprises rent or sell portable soft-shell chambers. In general, soft-shell chambers are used at home without an additional source of oxygen; the ambient air pressure is slightly superior to atmospheric pressure (generally 1.3 ATA). The acronym used for this type of treatment is HBA, for hyperbaric air, rather than HBO. While health professionals are divided in their opinions regarding the use of HBO or HBA treatments for cerebral palsy, the parents interviewed who use either treatment expressed satisfaction with perceived effects on their children.

While hard-shell hyperbaric chambers recognized by Health Canada are considered safe to use provided that all necessary safety precautions are well respected, this is not the case for soft-shell hyperbaric chambers, which are not recognized by Health Canada.

Results

The systematic review of the literature on this topic identified ten studies, which helped assess the therapeutic value of HBO treatment on children with cerebral palsy: two (2) randomized clinical trials (RCT), the methodology of which was found to be of adequate quality (average to high); and eight (8) studies, the methodology of which was found to be of poor quality due to their many limitations: two (2) RCTs, one (1) pre-post comparative study (PPCS), and five (5) pre-post non-comparative studies (PPNCS).

Three (3) health technology assessments on HBO treatment on children with cerebral palsy were published, but none of them has reported on its effectiveness. None of the clinical practice guidelines identified recognized cerebral palsy as an indication to the use of HBO treatment.

Efficacy

Of all seven (7) outcomes of interest identified in the studies, gross motor skills were measured the most. The other outcomes of interest identified are the child's autonomy to perform tasks of daily living, ability to communicate and the child's cognitive processes, social skills, quality of sleep, fine motor skills and spasticity (muscle tone).

The scientific data available show no difference between HBO and HBA therapy in terms of efficacy in improving gross motor skills and autonomy, and no impact from an increase in the fraction of inspired oxygen (FiO₂) on these outcomes of interest. Furthermore, given the limitations of the very few scientific data available, it is not possible to recognize the efficacy of the treatment with regard to the other five outcomes of interest under review.

Innocuity

Earaches or eardrum injuries (middle ear barotrauma) are the most common adverse events reported in four (4) studies; these studies have limitations related to how their authors assessed the innocuity and reported the results. Based on the data available, it is therefore not possible to rule on the innocuity of HBO and HBA treatment on children with cerebral palsy.

Quality of life

None of the studies conducted reported data relating to the aspect of quality of life. Consequently, only data collected from consultations with some parents of a child with cerebral palsy and a few rehabilitation professionals brought to light the importance given by parents to perceived improvement, however minimal, in their child's condition. For many user parents, HBO treatment – especially when used at home (HBA) – is simple to perform and easily integrates into a family life that is complex and intense and requires managing multiple appointments for medical consultation and rehabilitation and providing almost constant support to their child.

Therapeutic value appreciation

After the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) published a report in 2007 on HBO treatment of cerebral palsy, six (6) studies were published. In the light of the assessment by the INESSS and experts consulted, the new data are limited in scope and fail to shed further light on HBO effectiveness and innocuity.

The scientific data were compiled from studies that, in most cases, have many limitations. The profiles of the subjects under study and the HBO (or HBA) protocols used are very diverse, thus making studies difficult to compare. There are multiple questions and concerns with regard to the studies published: pertinence of control groups or of simulated (sham) treatment used in RCTs; limits of study plans; and limited adjustment for main confounding variables.

For their part, the parents consulted find the treatment to have positive effects on their child, in particular on the cognitive level; these effects were assessed to a lesser degree in the studies published, which focused more on gross motor skills.

While only a few undesirable effects associated with HBO and HBA treatment are reported in the studies or by the stakeholders and user parents consulted, concerns persist among the regulatory agencies and health professionals consulted (including hyperbaric physicians).

Not a single study reported data on the quality of life of children despite the importance of this factor in the assessment of HBO treatment on children with cerebral palsy.

Consequently, demonstration of the therapeutic value has failed to be established on the basis of the data available.

Main observations

- The complexity of cerebral palsy requires the following:
 - Access to information and support adapted to the needs of the children and their family;
 - Depending on the severity of the disorders, a variety of care and services for the treatment of the children, including medical treatment, medication, surgery and rehabilitation;
 - Coordinated action between various health professionals, services and institutions (hospital centers, local community service centers (CLSC), rehabilitation centers) to ensure medical follow-up of children with cerebral palsy; and
 - Appropriate services at every stage of life of the child.
- In the hope of improving their child's condition, some parents keep looking for a therapeutic option to replace or complement standard treatments.
- There is as yet no regulatory agency or learned hyperbaric medicine society that recognizes the efficacy of HBO in the treatment of cerebral palsy, and not a single public insurance plan in Canada, in the U.S.A. or any other comparable health system reimburses HBO treatment used to treat cerebral palsy.
- With the scientific data currently available (10 published studies), it is not possible to recognize that HBO treatment is effective in improving various aspects of the health condition of a child with cerebral palsy.
- There presently is no robust scientific data to support the efficacy of HBO (or HBA) treatment on children with cerebral palsy. However, the outcomes of interest revealing effects perceived and reported by some stakeholders and user parents are not necessarily the same as those assessed in scientific literature.
- Based on data currently available, it is not possible to rule on the innocuity of HBO to treat children with cerebral palsy.
- Although cerebral palsy can have serious repercussions on the quality of life of children concerned and their family, no study assessing the effects of HBO treatment in this regard could be found.
- In Quebec, HBA is often used at home to treat children with cerebral palsy. Such equipment consists of a portable soft-shell chamber in which air is lightly pressured, with

Main observations

no additional source of pure oxygen. More data are needed to assess the efficacy and innocuity of this type of intervention (HBA) and its effects on the quality of life of children with cerebral palsy. Regarding soft-shell hyperbaric chambers, Health Canada issued a warning in the fall of 2019 stating that these chambers are not recognized and may pose health risks.

Deliberations of the Comité d'excellence clinique en services de santé

The members of the Comité d'excellence clinique (CEC) in health services deliberated on the scientific, contextual and experiential data at hand in order to decide on the therapeutic value of HBO treatment on children with cerebral palsy.

The committee members raised concerns regarding the following:

- The limitations and quality of the studies selected;
- The magnitude of the effects reported;
- The manner in which the results analyzed were measured, in particular because of the tools used, the validity of which in many cases remains to be demonstrated;
- The conditions under which the children were observed, which are not detailed and may have some impact on findings;
- The child's natural evolution, which is not taken into consideration; and
- The ongoing use, on children, of a technology that is not necessarily risk-free.

Furthermore, the committee members are puzzled by the fact that there is no solid scientific evidence on the efficacy of HBO and its potential mechanisms of action although the technology has been used on children with cerebral palsy for many years.

Based on the above data, the committee members have a common understanding that the available information does not allow them to recognize the therapeutic value of HBO. They also share the opinion that the data available do not allow to recognize a therapeutic value to HBA.

Recommendation of the INESSS

In the light of the scientific, contextual and experiential data gathered and given the lack of evidence of any therapeutic value, the INESSS considers that adding HBO or HBA to the range of public services to treat children with cerebral palsy is not a fair and reasonable option.

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