

Home Oxygen Therapy for the Treatment of Cluster Headache

AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Home Oxygen Therapy for the Treatment of Cluster Headache

Technology Brief prepared for AETMIS
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MISSION

The mission of the *Agence d'évaluation des technologies et des modes d'intervention en santé* (AETMIS) is to contribute to improving the Quebec health care system and to participate in the implementation of the Quebec government's scientific policy. In order to accomplish this, the Agence advises and supports the Minister of Research, Science and Technology as well as the decision-makers in the health care system with respect to the assessment of health services and technologies. The Agence makes recommendations based on scientific reports assessing the introduction, distribution and application of health technologies, including technical aids for disabled persons, as well as the modes of providing and organizing services. The assessments take into account multiple factors, such as the efficacy, safety and efficiency, as well as the ethical, social, organizational and economic implications.

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FOREWORD

HOME OXYGEN THERAPY FOR THE TREATMENT OF CLUSTER HEADACHE

Cluster headache is a rare disorder that affects between one out of 1,400 and one out of 250 people and is more common in men than women. In its episodic form, it is accompanied by very severe unilateral pain that lasts between 45 and 90 minutes on average; the attacks occur daily for a few weeks, followed by periods of remission.

Following the experience of the use of oxygen as a treatment for cluster headache by several clinicians, a group of Quebec neurologists asked the *Ministère de la Santé et des Services sociaux* to add oxygen to the list of products covered under the public health plan. The Minister forwarded an assessment request to the *Agence d'évaluation des technologies et des modes d'intervention en santé* in order to determine whether cluster headache could be added to the indications for the home oxygen therapy program.

According to the international experts on cluster headache, oxygen therapy constitutes the treatment of choice during attacks. This use is supported by a single methodologically sound study involving a small number of patients.

Although certain pharmacotherapeutic options for the treatment of attacks exist, they are not reliable and safe enough to replace oxygen therapy completely and hence relieve the severe suffering associated with this disorder.

In this context, AETMIS believes that this disorder should be included in the indications accepted in the ministerial frame of reference for clients requiring oxygen therapy at home.

In publishing this brief notice, AETMIS hopes to provide optimal assistance to the decision-makers concerned by this issue in the Quebec health services network.

Renaldo N. Battista
President and CEO

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INTRODUCTION

Cluster headache is a rare disorder with an estimated prevalence of between 0.07% and 0.4% of the general population. It is also known as autonomic faciocephalgia or suicide headache due to its greater severity than migraine. The pain is unilateral, very severe and lasts on average from 45 to 90 minutes. In their most frequent, episodic form, the attacks occur daily for a few weeks and are followed by a period of remission that can last several months, hence the name cluster headache. The prevalence is approximately 5 times higher in men than in women [Dodick *et al.*, 2000].

This assessment arises from a request made by several neurologists of the *Clinique de la Migraine de Montréal* to the *Conseil consultatif de pharmacologie* to add oxygen for the treatment of cluster headache to the list of recognized drugs under the drug insurance program. Since oxygen is not classified as a drug, the *Ministre de la Santé et des Services sociaux* (Minister of Health and Social Services) asked the *Agence d'évaluation des technologies et des modes d'intervention en santé*: “to assess the therapeutic value of oxygen in such an indication [cluster headache]. If it resulted that this gas had therapeutic properties for this indication, the minister will have to make a decision on this issue”. A ministerial program allowing for the provision of oxygen therapy at home for clients suffering from chronic obstructive lung disease already exists.

In order to establish this therapeutic value, AETMIS relied on the search and the analysis of published scientific documentation as well as on the examination of the clinical practices and reimbursement practices of other countries.

CLUSTER HEADACHE

The first clinical description of cluster headache is found in *Tulp's Observationes Medicae* (1641) by the Dutch anatomist Nicolas Tulp, immortalized in Rembrandt's painting *The Anatomy Lesson*¹ [Mendizabal *et al.*, 1998]. In 1939, Horton contributed to an improved description of the characteristics of this form of vascular headache. Cluster headache differs from the various forms of migraine in its shorter duration and unilateral nature, the patient's agitation and the absence of an aura or gastrointestinal symptoms [Dodick *et al.*, 2000]. The classification of the International Headache Society identifies the following diagnostic criteria for the episodic form of cluster headache [Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. Headache Classification Committee of the International Headache Society, 1988]:

- intense, unilateral, orbital, supra-orbital and/or temporal pain lasting between 15 and 180 minutes without treatment;
- headache associated with at least one of the following autonomic signs on the affected side: conjunctival injection, nasal congestion, rhinorrhea, forehead and facial sweating, miosis, ptosis (abnormal drooping of eyelid), eyelid edema;
- frequency varying between one attack every two days and eight attacks per day over a period of seven days to one year, separated by asymptomatic periods of at least 14 days.

On average, the attacks occur over periods of 6 to 12 weeks, with asymptomatic periods of 12 months. The attacks often take place with clockwork regularity, mainly at night, during the rapid eye movement phases of sleep. During symptomatic periods, the attacks are often triggered by alcohol consumption or by other vasodilators. Tobacco usage is a serious risk factor for the development of cluster headache since up to 85% of patients have a history of tobacco use [Dodick *et al.*, 2000].

The chronic form differs from the episodic form in a duration of longer than one year and asymptomatic periods of less than 14 days. The chronic form appears in approximately 15% of patients [Dodick *et al.*, 2000].

From a pathophysiological perspective, cluster headache is associated on the one hand with vasodilation of the ophthalmic artery, related to an activation of the ganglion of the trigeminal nerve, and on the other hand with an activation of part of the hypothalamus [Dodick *et al.*, 2000; Goadsby, 1999; Pradalier *et al.*, 2001]. These changes explain both the typical distribution of the pain and of the autonomic symptoms as well as the periodic character of the headaches.

From an epidemiological perspective, the prevalence of cluster headache in the general population is estimated at between 0.07% (approximately 1 out of 1,400) and 0.4% (1 out of 250), although it is around 5 times higher in men. However, this ratio seems to have been diminishing in the past few decades, since a growing number of women are suffering from cluster headache [Dodick *et al.*, 2000].

1. See http://www.maitrise-orthop.com/corpusmaitri/orthopaedic/86_masquelet/masquelet.shtml

TREATMENT BY OXYGEN THERAPY

The preventive treatment of attacks may make use of various pharmacological options, including the administration of verapamil, lithium and corticoids. However the preventive approach seems to present limited efficacy [Pradalier *et al.*, 2001].

Various solutions have been suggested for the treatment of attacks. The use of analgesics represents an initial option, but given the sudden onset of the pain, its severe intensity and a duration that usually does not exceed 90 minutes, this therapy has very limited usefulness. First introduced by Horton in the mid 1950's [Horton, 1956], the use of oxygen therapy has since become the standard treatment in relieving headache attacks. This approach is based on the inhalation of oxygen using a non rebreathing face mask, at a rate of 7 to 10 litres per minute for 10 to 20 minutes [Dodick *et al.*, 2000; Ekbohm, 1995; Mendizabal *et al.*, 1998].

In the past few years, the use of injections of sumatriptan which were shown to be effective in the symptomatic treatment of cluster headache has been recommended [Dodick *et al.*, 2000; Ekbohm, 1995; Mendizabal *et al.*, 1998]. The disadvantages of this medication are its high cost and the danger of coronary angiospasm. The Canadian monograph by the manufacturer advises caution: "There is insufficient information on the efficacy and safety of sumatriptan in the treatment of cluster headache, which is present in an older, predominantly male population. The need for prolonged use and the demand for repeated medication in this condition renders the dosing information inapplicable for cluster headache." [Canadian Pharmacists Association (CPA), 2001, page 711].

The recommendations concerning the use of oxygen therapy as the standard treatment to relieve headache attacks are based on three clinical trials, only one of which was randomized. In an uncontrolled study, oxygen therapy was found to be effective in 6 out of 10 patients [Heckl, 1986]. In another uncontrolled study, this treatment had positive effects on 39 of the 52 patients [Kudrow, 1981]. In a third study, 19 men of between the ages of 20 and 50, were randomized in a double-blind crossover study, comparing oxygen and air inhalation, and the results showed a marked superiority of the oxygen [Fogan, 1985].

The use of oxygen in high concentrations for short periods of time, as is required for cluster headache, does not have any adverse effects [Salvesen, 1999]. The integration of home oxygen therapy in the organization of service delivery does however entail considerable challenges in terms of equipment, supply, reimbursement procedures, etc. [Comité de travail sur les clientèles nécessitant de l'oxygénothérapie à domicile, 2000; Garattini *et al.*, 2001].

REIMBURSEMENT IN OTHER COUNTRIES

The reimbursement status of oxygen therapy for cluster headache seems to vary greatly from one country to another. Patient discussion groups dedicated to cluster headache² often refer to the difficulties in obtaining reimbursement from insurers, especially in the United States. Patients exchange scientific reference materials in order to convince insurance companies of the merits of this therapy [Ted, 2001].

Although the Australian Medicare Benefits Scheme does not reimburse home oxygen therapy for any indication, the various Australian states subsidise the purchase of equipment and oxygen for patients with respiratory failure³. In the Netherlands, all insurance companies pay for home oxygen therapy for cluster headache⁴. In Israel, the national list of covered health care services does not include oxygen therapy for this indication⁵.

2. See the Web site: <http://www.clusterheadaches.com>

3. Personal e-mail communication with Alex Lloyd, Medical Services Advisory Committee (Australia), January 1, 2002

4. Personal e-mail communication with Stijntje Leguit-Lambers, Clusterhoofd pyn, January 7, 2002

5. Personal e-mail communication with Nina Hakak, Israeli Center for Technology Assessment in Health Care, February 21, 2002

CONCLUSION

According to the experts on cluster headache, oxygen therapy is the treatment of choice for attacks. This use is only supported by a single methodologically sound study including a small number of patients. Although pharmacotherapeutic options exist to treat attacks, they are not reliable and safe enough to replace oxygen therapy completely and to relieve the huge suffering related to this disorder.

In this context, AETMIS believes that cluster headache should be included in the indications considered in the ministerial frame of reference for clients requiring home oxygen therapy.

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