FIFTEEN YEARS OF INTRATYMPANIC PRESSURE TREATMENT FOR DISABLING MÉNIÈRE'S DISEASE

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1. Introduction

Pressure treatment is regarded to be one of the therapeutical options to offer for disabling Ménière's disease (MD) when the patients are not responding to any medical treatment. As a matter of fact, after the first experimental investigations of the 1970s,[1] preliminary clinical studies were emphasizing the positive role played for MD by a pressure treatment performed inside a chamber pressure[2-4] as well as by means of a portable device.[5,6] Further experimental support was given, during the same period, from the studies by Sakikawa and Kimura[7] and Kimura and Hutta[8] that could demonstrate a positive effect of the simple middle ear ventilation on limiting the degree of endolymphatic hydrops experimentally-induced on Guinea pigs.

The Meniett® is a portable device that allows a patient to self-administer the treatment at home, whenever it is required. Although the mechanism at the basis of its functioning still remains to be elucidated, an increased oxygenation of the inner ear, a direct stimulation of baroreceptors at the round window level or an impulse to the longitudinal flow of endolymph towards the endolymphatic sac have been taken into consideration.

Since 1999, Meniett® has become at our Center the pivotal treatment for MD recalcitrant to any medical treatment. Due to our policy to select conservative procedures without risking additional damage to the inner ear, such as when applying intra-tympanic gentamicin, this pressure therapy started to be always proposed to those Ménière's subjects already selected for our gold standard surgical

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procedure, *i.e.*, vestibular neurectomy. After more than 15 years, Meniett® still plays the same role in our practice so that the purpose of the present report is:

- to present long-term data on a consistent series of subjects;
- to comment on the role of this local pressure treatment in the staircase of the therapeutical options offered for this disease;
- to comment on the possible mechanism of action, as derived by the recently applied electrophysiological investigations.

2. Material and methods

Ninety-three subjects diagnosed as having a definite MD according to the 1995 AAO-HNS guidelines[9] received a local pressure treatment with Meniett® device (Medtronic, St. Paul, USA) from 1999. This treatment has been reserved to the most severe cases of MD, classified as Class D/E and with a Functional Level Scale (FLS) equal to 5/6,[9] due to relapsing, invalidating vertiginous spells occurring during the previous three months. Our protocol was arbitrarily chosen for allowing the patients to receive the device free of charge, and consisted in one-month treatment that started the same day of insertion of a short-term, trans-tympanic ventilation tube. Each patient was instructed to use the device five times per day, considering that each session – started by pressing a button displayed on the front of the device – was running automatically for three minutes. During the treatment period, *i.e.*, one month, each patient was asked to fill a diary for annotating any symptom related to MD, mostly vertigo episodes, as well as eventual changes of hearing, fullness or tinnitus. At the end of the treatment, the evaluation regarded the rate of vertigo control that allowed framing each patient in the same or a new Class or FLS,[9] the hearing threshold assessment and the Dizziness Handicap Inventory.

A last series of subjects underwent an electrophysiological assessment with electrocochleography (ECochG) before starting the pressure treatment, in order to get evidence of the presence of a hydropic pattern,[10] and one, three and six months after the treatment, in order to shed some light on the possible correlation between the outcome of the treatment and the ECochG-related hydropic pattern. The present report takes into consideration 41 patients who, at the present time, have at least two years from the end of the treatment, while the remaining 50 treated patients were excluded for different reasons (less than two-years follow-up, decease, change of address, etc.).

3. Results

The majority of the subjects performed only one pressure session, and only few cases required additional cycles for a delayed recrudescence of the disease, with the patient still wishing not to undergo a surgical procedure.

The 6 Class E (FLS 5) subjects reported a symptomatological improvement at the end of treatment, with a DHI score that diminished from 59 to 49.7, whilst only 16% of them reached a Class A or B. At the time of the present examination, the DHI score was 39.8 and all these subjects became Class A or B.

Out of the 35 Class D (FLS 4) subjects, 42% reached Class A or B soon after the treatment, while 63% were reaching Class A or B at the present evaluation. Overall, the success rate – that in this study signified avoiding vestibular neurectomy surgery – was equal to 68.3%.

The ECochG findings of the last series of Menière's subjects showed that all of them presented with a hydropic electrocochleographic pattern, *i.e.*, an SP/AP ratio equal or greater than 0.48.[10] At the end of one cycle of Meniett® treatment, the hydropic ECochG pattern was still present in the majority of the subjects, while all of them but two referred a remarkable improvement of their symptoms. Three months later, however, the ECochG pattern was found to be normalized in nearly all the subjects but in two of them, who were also referring an unsatisfying relief from vertigo and were addressed to vestibular neurectomy. A similar ECochG finding was also confirmed six months after the end of Meniett® treatment.

4. Discussion

In Ménière's patients recalcitrant to any type of medical treatment, several but not univocal solutions are advised by the different Otologic Centers. Among them, the intratympanic gentamicin treatment represents the most applied, enabling to achieve a favorable outcome in a great percentage of patients. It is also known that gentamicin's effect is related to its toxic action on the vestibular end organs. In our clinical practice, contrarily, this form of therapy has always been considered paradoxical, as it would appear so any treatment that, in order to cure a disease, will provoke an additional toxic effect to the diseased organ. If this is the auspice for the action on the vestibular structures, it is certainly not for the auditory ones, already threatened by the disease itself and its natural course. This is the actual motivation for selecting, instead, a conservative approach, such as with the pressure treatment, in the wait of validation of similar conservative therapies, such as with intratympanic steroids, for example.

The Meniett® device has been clinically experienced by several centers worldwide, with results in agreement with our positive outcomes.[11-13] Nevertheless, this form of treatment has not achieved a validation also on the light of the last 'negative' Cochrane review.[14] Among the possible reasons, costs and, mostly, the lack of knowledge of its mechanism of action are surely playing a preeminent role in this regard.

When looking at the electrophysiological findings recorded in the last series of treated subjects, however, it would seem that the effect of Meniett® on endolymphatic hydrops is mostly relevant, not immediately after the treatment, but

only at a later stage, as evidenced three and six months after the treatment. This finding would appear of outmost importance if one consider that endolymphatic hydrops was present in all the treated subjects before the pressure treatment, as a confirmation that the selection of the patients was very accurate not only on the ground of the symptomatological aspects.

The pressure treatment with Meniett® has been shown to be efficient for avoiding to a selected, and severely impaired cohort of Ménière's subjects, recalcitrant to medical treatment, to undergo a surgical procedure. Furthermore, Meniett® has shown not to induce any side effect, although not acting on the auditory symptoms (hearing, fullness and tinnitus). It can therefore be proposed as conservative, first option treatment when the medical treatment fails.

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