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P-100 in the Treatment of Ménière's Disease: A Clinical Study

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Abstract: Patients suffering from Ménière's disease are particularly sensitive to negative pressure in the middle ear. For example, attacks of vertigo can be triggered by a descent in an aircraft when ventilation of the middle ear can become critical. Positive-pressure pulse treatment has been shown to have a beneficial effect on the symptomatology and is now a true alternative in the treatment of Ménière's disease. In this study, we compared two devices that produced positive-pressure pulses delivered to the inner ear via the external ear canal and after the insertion of a middle-ear ventilation tube. Both devices (Meniett and P-100) were equally successful and confirmed that positive-pressure pulse treatment is a true alternative to current treatment modalities. However, the P-100 is the preferred device, particularly for its convenience of use and its cost, which is considerably lower.

Key Words: Ménière's disease; positive-pressure pulse therapy; P-100

Ménière's disease is a disorder of the inner ear characterized by attacks of vertigo associated with hearing loss and tinnitus. Morphologically, we find an endolymphatic hydrops in the inner ear, but it remains unclear as to whether this is causally linked to the symptomatology. In animal experiments, we can create an endolymphatic hydrops, but typical symptoms are missing.

Clinical experience shows that those afflicted with Ménière's disease frequently show sensitivity to negative pressure. For example, attacks can be triggered by a descent while flying in an aircraft. As a consequence of this observation, exposure to positive pressure, as demonstrated in pressure chambers, was found to have a beneficial effect on the symptomatology [1]. Positive-pressure pulses as treatment for Ménière's disease is now a well-established form of management [2,3].

METHOD

In conjunction with the Ear Institute, Queenswood, Pretoria, South Africa, we have conducted a clinical trial to investigate the effectiveness of positive-pressure pulses delivered by a handheld, manually operated bellow device called the *P-100* (Enttex, Port Melbourne, Australia). A total of 25 patients took part in this study. All patients participating in this trial had a confirmed diagnosis of Ménière's disease and had frequent attacks. Of these, 19 were seeking further treatment options for relief of their symptoms, as the insertion of a ventilation tube alone did not give enough relief. The flowchart (Fig. 1) shows the protocol of the trial. The diagnosis of Ménière's disease was made following the criteria of the American Academy of Otolaryngology [4].

A ventilation tube was inserted either in the office setting or, alternatively, in the operating theater. Five days after the insertion of the ventilation tube, a decision was made regarding whether to proceed with the trial. Although some patients experienced an improvement of their symptoms, 19 were keen to proceed with the positive-pressure pulse treatment. Positive-pressure treatment was conducted either with the Meniett device (Metronic Xomed Inc., Minneapolis, MN, USA) or the P-100 (Enttex). Nine patients opted for the Meniett, and 10 opted for the P-100.

The Meniett device consisted of an electronic pulse generator that produced a quick succession of pulses for 1 minute. Pulses were applied via an ear plug. Pulse treatment was repeated twice after a pause of 40 seconds. Pressures did not exceed 200 mm H_2O, and patients were asked to use it three times daily.

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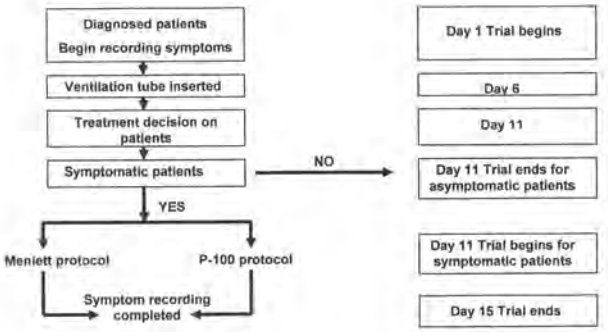

Figure 1. Flowchart of the clinical trial protocol.

In contrast, the P-100 consisted of a handheld, manually operated device that could also produce only positive pressures not exceeding 250 mm H_2O (Fig. 2). After obtaining a seal in the ear canal with the ear plug, we asked patients to compress the bellow some 10 times in succession. Patients were allowed to use it according to their needs but not more than eight times daily. The P-100 is small (smaller than the size of a mobile phone) and very light and stores easily in a pocket or handbag.

We recorded symptoms before and after treatment with positive-pressure pulses following the protocol pictured in Figure 3. Numbers from 1 to 5 indicated the severity of symptoms and corresponded in ascending order to *never*, *seldom*, *sometimes*, *often*, or *always*. We performed statistical testing using a nonparametric, Kruskal-Wallis single-factor analysis of variance by rank [5]. We considered each symptom separately, comparing the mean rank before and after treatment with either the P-100 or the Meniett device. If we detected a significant difference between means, we used post hoc, nonparametric multiple comparisons for unequal sample sizes to determine which mean ranks differed [5]. In all cases, $\alpha = 0.05$.

Figure 2. The P-100, a handheld, manually operated device, is smaller than a mobile phone and easily stored in a pocket or handbag.

	NEVER 1	SELDOM 2	S'TIMES 3	OFTEN 4	ALWAYS 5
FULLNESS					
VERTIGO					
HEARING					
TINNITUS					
NAUSEA					

Figure 3. Symptoms recorded before and after treatment with positive-pressure pulses.

RESULTS

Among the symptoms that improved significantly were vertigo, fullness in the ear, and nausea (Fig. 4). A slight difference was evident between the two devices, with the Meniett not performing quite as well as the P-100. The difference, however, was not significant. The discrepancy might have been due to the convenience of the P-100, which was immediately available when needed and did not require a cumbersome setup of the device. We saw a slight difference also between the severities of symptoms in both groups, which finding could have accounted for the discrepancy, but this difference was not significant.

We found no change in the symptoms of tinnitus, and the hearing remained stable (Fig. 5). Three patients thought that hearing improved a little, and one patient thought that hearing was slightly worse. The latter was not a concern, as other more important symptoms, such as vertigo and nausea and fullness in the ear, had improved. Three patients refused to return the P-100 after the clinical trial: The device had improved their life so much that they did not want to part with it. No side effect was observed from use of either device.

DISCUSSION

The effect of positive-pressure pulses and how they work is still unclear. It is explained by a reduction in the endolymphatic fluid volume by redistribution through

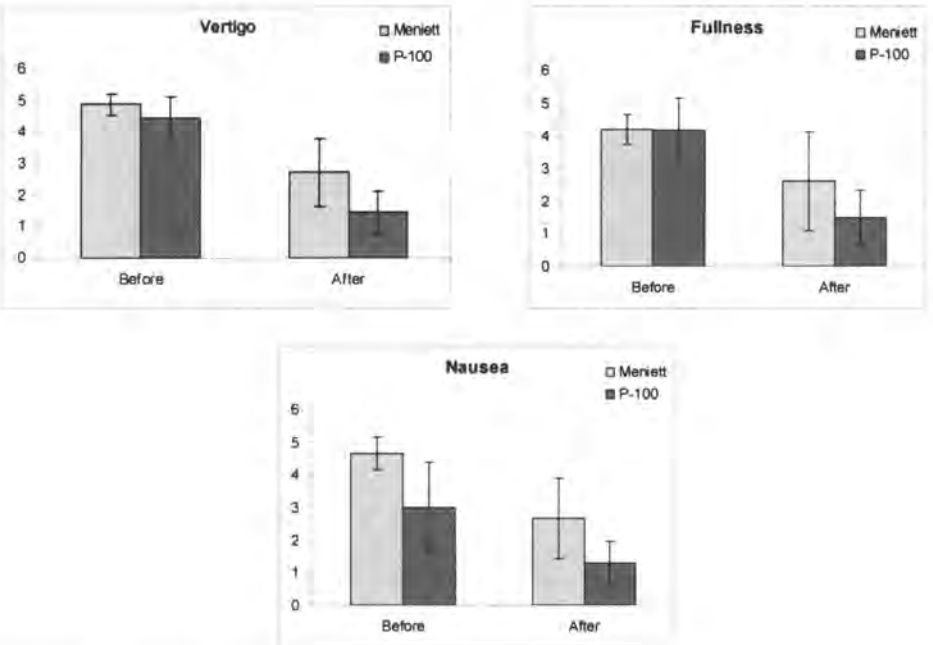

Figure 4. Improvement of vertigo, fullness in the ear, and nausea were statistically significant. No statistical difference was seen between the Meniett and P-100 devices.

the inner-ear pressure communication routes [6]. An alternative explanation has been offered by oxygenation and hormones. Down-regulation of fluid production has been suggested as well [7].

We believe that positive-pressure pulses on the round-window membrane could have the effect of an ion shift, particularly potassium, which has, as Horner [8] pointed out, an increased concentration within the scala tympani in patients with Ménière's disease. Potassium is toxic to neurons. Positive-pressure pulses on the round window could reverse the toxic effect of potassium.

This hypothesis is supported by electrophysiological observations in patients with Ménière's disease. In early stages of Ménière's disease, we can observe that the improvement of symptoms after the insertion of a ventilation tube parallels an improvement of the summating potential–action potential ratio in the electrocochleogram and that this improvement is linked to an action potential effect. This improved action potential is most likely due to potassium detoxification.

The diagram in Figure 6 shows the effect in the electrocochleogram after the insertion of a ventilation tube, with a clear improvement of the action potential. The effect of the ventilation tube suggests a disturbed middle ear–inner ear relationship. Although patients with Ménière's disease in general show type A tympanograms, to assume that Eustachian tube function is normal is misleading. Since the introduction of the modified

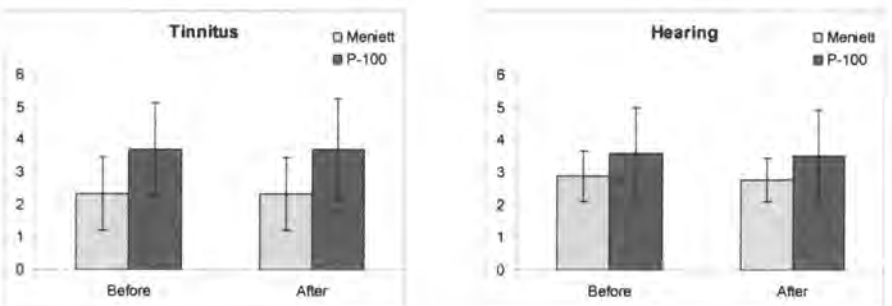

Figure 5. Tinnitus and hearing remained practically unchanged after treatment with positive-pressure pulses.

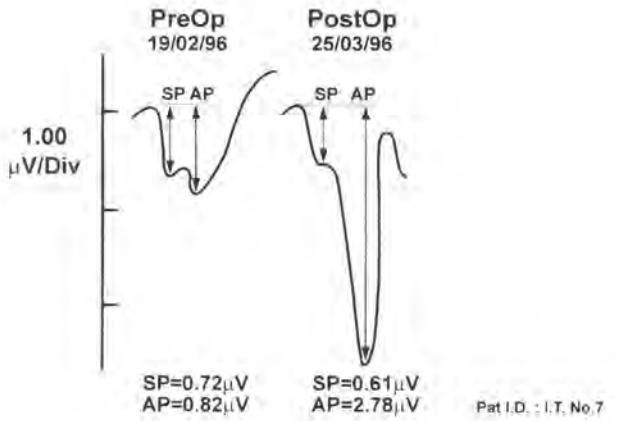

Figure 6. Electrocochleogram after insertion of a ventilation tube in a patient with early-stage Ménière's disease. Electrophysiological improvement is due to an action potential effect.

Holmquist test, one can regularly observe that patients with Ménière's disease invariably are unable to equalize negative pressure in the middle ear [9]. As all such patients had type A tympanograms, we concluded that the Eustachian tube dysfunction must be very mild.

CONCLUSION

Both the insertion of a middle-ear ventilation tube and positive-pressure pulse treatment address a disturbed relationship between the middle ear and the inner ear. Our clinical trial confirms that positive-pressure pulse treatment in Ménière's disease is a true alternative to current treatment modalities. The P-100 is the preferred device (as compared to the Meniett) for its convenience of use and its considerably lower cost.

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