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Clinical comparison of tympanic membrane displacement with invasive intracranial pressure measurements

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Abstract

A non-invasive method of assessing intracranial pressure (ICP) would be of benefit to patients with abnormal cerebral pathology that could give rise to changes in ICP. In particular, it would assist the regular monitoring of hydrocephalus patients. This study evaluated a technique using tympanic membrane displacement (TMD) measurements, which has been reported to provide a reliable, non-invasive measure of ICP. A group of 135 hydrocephalus patients was studied, as well as 13 patients with benign intracranial hypertension and a control group of 77 volunteers. TMD measurements were carried out using the Marchbanks measurement system analyser and compared between the groups. In 36 patients, invasive measurements of ICP carried out at the same time were compared with the TMD values. A highly significant relationship was found between TMD and ICP but intersubject variability was high and the predictive value of the technique low. Taking the normal range of ICP to be 10–15 mmHg, the predictive limits of the regression are an order of magnitude wider than this and therefore Vm cannot be used as a surrogate for ICP. In conclusion, TMD measurements do not provide a reliable non-invasive measure of ICP in patients with shunted hydrocephalus.

Keywords: hydrocephalus, shunt, intracranial pressure, tympanic membrane displacement, non-invasive ICP

Introduction

Hydrocephalus is a disorder of the central nervous system where the normal production or absorption of cerebrospinal fluid (CSF) is disturbed. Control of the CSF balance is often achieved by the implantation of fluid shunts which are pressure operated devices that often drain fluid from the ventricles or lumbar spine into the peritoneal cavity. A shunt normally consists of a reservoir, valve and drainage tubing and a major difficulty is that these devices often fail to perform in an optimal manner. This can be due to malfunction of the valve, displacement or blockage and may result in either over or under drainage leading to raised or lowered intracranial pressure (ICP). The diagnosis of shunt malfunction can be difficult and whilst ICP monitoring can be helpful, as an invasive procedure it is often poorly tolerated and cannot be used repeatedly. A reliable and repeatable non-invasive estimation of ICP would be of help in the decision to introduce or replace a shunt system.

A method for measuring tympanic membrane displacement (TMD) may provide an indirect index that is related to ICP (Moss *et al* 1990, Samuel *et al* 1998). Stimulation of the acoustic reflex can induce a TMD and it has been reported that this is related to ICP. An aural stimulus above the acoustic reflex threshold (ART) will cause a contraction of the stapedius muscle, resulting in a movement of the tympanic membrane. The kinematic chain between the stapedius and the tympanic membrane involves the ossicles. One of these, the stapes, rests on the oval window of the cochlear. This is a flexible membrane and consequently the pressure of the intracochlear fluid determines the initial position of the stapes, and hence the size and direction of its movement. If there is fluid communication via the cochlear aqueduct (CA) between the intracochlear and intracranial spaces then TMD measurements may be able to provide an indirect estimation of the ICP. Cochlear aqueduct patency is a prime determinant for successful measurement, but it is known to reduce with increasing age, falling to 50% over the age of 40 and 30% over the age of 60 (Wlodyka 1978, Marchbanks 1993).

Previously reported (Marchbanks 1993) results have indicated that a normal ICP results in a bi-directional displacement whereas in cases of high ICP the resting position of the stapes on the protuberant oval window causes an inward movement of the tympanic membrane. When the ICP is low, the stapes rests into the oval window, and contraction of the stapedius muscle causes an outward movement of the tympanic membrane.

The objectives of this study were to establish the range and distribution of TMD in healthy volunteers and hydrocephalus patients and to examine the relationship between TMD and invasively measured ICP in a series of hydrocephalus patients.

Approval for this study was obtained from the local Ethics Committee and informed consent obtained prior to any measurements being made.

Methods and materials

Subjects

The main study group comprised 135 hydrocephalus patients with previously inserted CSF shunts. The median age of the patients was 35 years (range 4–92) and 53% were female. A second group of 13 patients with a diagnosis of benign intracranial hypertension (BIH) (median age 27, range 16–53 years, 92% female) was studied. Finally a control group comprising 77 healthy volunteers was examined. The median age of this group was 41 (range 21–58), 38% of whom were female. Thirty six patients (32 hydrocephalus and 4 BIH) had simultaneous invasive ICP measurements at the time of TMD testing.

TMD measurement

On each occasion TMD was measured as a response to an applied acoustic stimulus using the Marchbanks measurement system (MMS) analyser. Prior to each set of measurements,

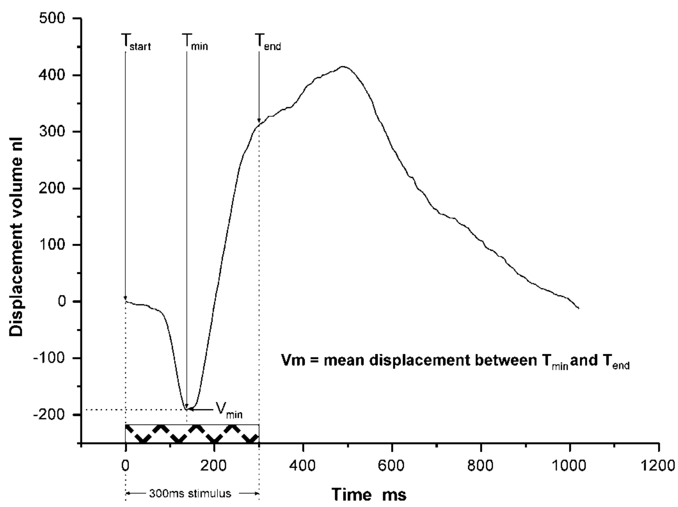

Figure 1. Calculation of Vm from TMD waveform.

tympanometry was performed to establish normal middle ear function and pressure, using a Kamplex KT20 hand-held UniTymp. The acoustic reflex threshold (ART) was determined for each ear. TMD measurements were carried out with the stimulus sound intensity set above the ART, where possible measurements were repeated using at least three different stimulus levels, subject to a safety limit of 110 dB.

The ear canal was sealed with a rubber ear tip and a stimulus tone was applied at 1 kHz for 300 ms at intervals of 1 s. The MMS analyser measured TMD over each stimulus response cycle, recording the average waveforms of ten reliable responses with a time resolution of 2 ms. Responses containing artefacts (heart beat or movement) were rejected automatically by the analyser; consistency of the responses to be averaged was confirmed by operator observation.

The mean displacement of the tympanic membrane from the point of maximum inward displacement to the end of the stimulus (Vm) was calculated (figure 1). The association between TMD and ICP relies on the patency of the cochlear aqueduct, so a comparison of the results from tests in the sitting and supine positions was made. Postural change affects ICP and concomitant changes in TMD between the two positions were used to indicate the patency of the cochlear aqueduct.

Statistical analysis

Statistical analysis was carried out using GraphPad Prism version 4.03 for Windows, GraphPad Software, San Diego, CA, USA, www.graphpad.com. The following analyses were performed.

(i) An assessment was made of the range and distribution of the measured TMD variables in the sample of healthy volunteers and hydrocephalus patients. This included investigating the symmetry of bilateral TMD measurements and the effects of age and stimulus intensity. Values obtained in the supine position were used for this comparison.

(ii) Linear regression analysis was carried out on the data from the invasively monitored patients who had successful TMD measurements, specifically regression of ICP on Vm. Where left and right TMD measurements were obtained, mean values were used to allow comparison with single ICP values.

Table 1. Summary of test success rates and reasons for failure according to group and age.

Group		Controls	Hydrocephalus	BIH
n		77	135	13
Successful test in at least one ear		54 (70%)	475 (35%)	5 (38%)
Excluded due to failed tympanometry		3 (4%)	245 (18%)	0
Successful tympanometry but unable to determine CA patency		185 (23%)	62 (46%)	8 (62%)
Excluded other reasons		2 (3%)	2 (1%)	0
Age < 40	*n*	37	50	13
	Successful test	29 (78%)	35 (70%)	5 (38%)
	Unsuccessful	8 (22%)	155 (30%)	8 (62%)
Age 40+	*n*	40	85	0
	Successful test	26 (65%)	11 (13%)	0
	Unsuccessful	14 (35%)	745 (87%)	0

(iii) The effect of stimulus intensity on the relationship between TMD and ICP was quantified repeating (ii) for Vm grouped according to the relative stimulus intensity used compared to each subject's ART, i.e. at 5, 10, 15 and 20 dB above ART.

Results

The success rate of the test, determined by a subject having a successful test in at least one ear, is shown in table 1. Subjects were excluded due to failed tympanometry, i.e. failure to establish the presence of a normal acoustic reflex and determine the threshold. Subjects were also excluded if the mean values of TMD with changing posture did not indicate a patent CA in either ear. Three subjects were excluded due to equipment failure (one control and two hydrocephalus patients) and one subject, in the control group, could not tolerate the test.

Age affected the likelihood of a successful test. There was a significant difference between subjects aged under 40 and those aged 40 or over in the likelihood of at least one ear having a successful test (Fisher's Exact, $p < 0.0001$). These data are also summarized by group in table 1.

(i) Figure 2 shows a histogram of the distribution of Vm magnitude between the study groups. The data are not normally distributed (failed D'Agostino–Pearson normality test). Kruskall–Wallis analysis showed no significant difference between the groups' medians.

There was a statistically significant difference between the median values obtained from the right and left (−15 and −88 nl, respectively, Mann–Whitney $p = 0.0028$). Analysing the groups separately, the difference was only significant in the hydrocephalus group ($p = 0.0078$) and not in the BIH or healthy volunteer groups.

Stimulus intensity did not correlate significantly with Vm. Age showed a significant correlation with Vm (Spearman $p = 0.0220$). The under 40 and over 40 age groups had significantly different median values for Vm, −89 and −17 nl, respectively (Mann–Whitney $p = 0.0040$).

(ii) Linear regression of invasively measured ICP on Vm showed a strong relationship between these quantities. Confidence intervals and prediction limits are shown with the regression in figure 3. The regression line was significantly non-zero ($p < 0.0001$).

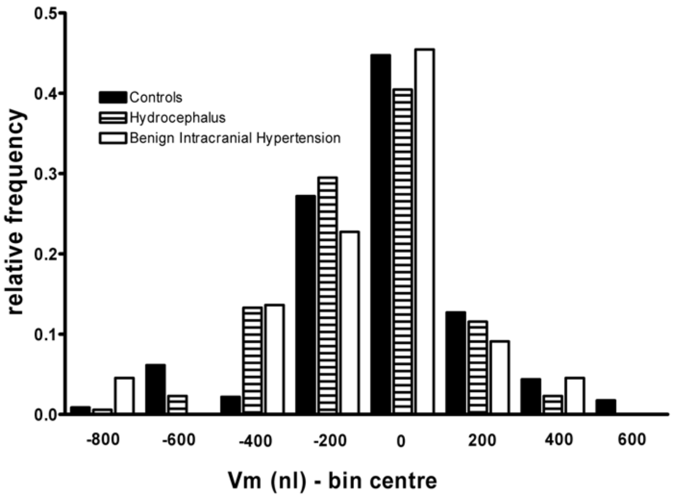

Figure 2. Histogram of Vm by study group.

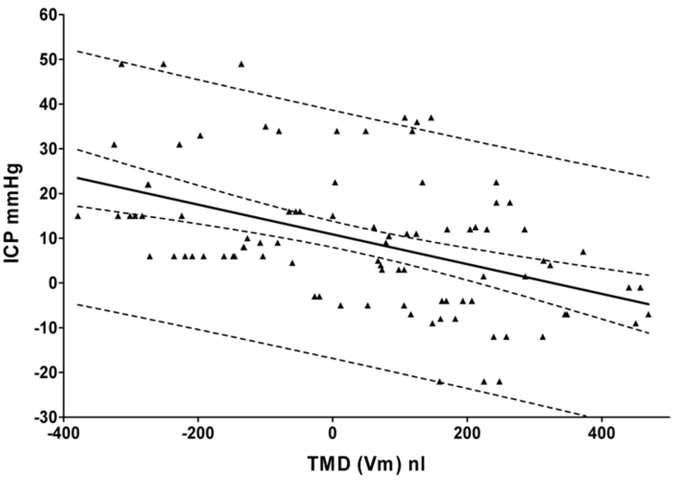

Figure 3. Regression of Vm on invasive ICP.

(iii) Regression of ICP on Vm data grouped by stimulus intensity is shown in figure 4. The regression line is significantly non-zero at three out of four stimulus levels as shown in the figure. The gradient of the regression line appeared to increase with increasing stimulus intensity, but the differences in gradient were not significant.

Discussion

This measurement technique proved to have a very low success rate. A combination of failed tympanometry and a lack of demonstrable cochlear aqueduct patency excluded approximately two thirds of the patients in the two study groups from analysis, and this would cast doubt on the clinical utility of the technique notwithstanding any considerations of accuracy.

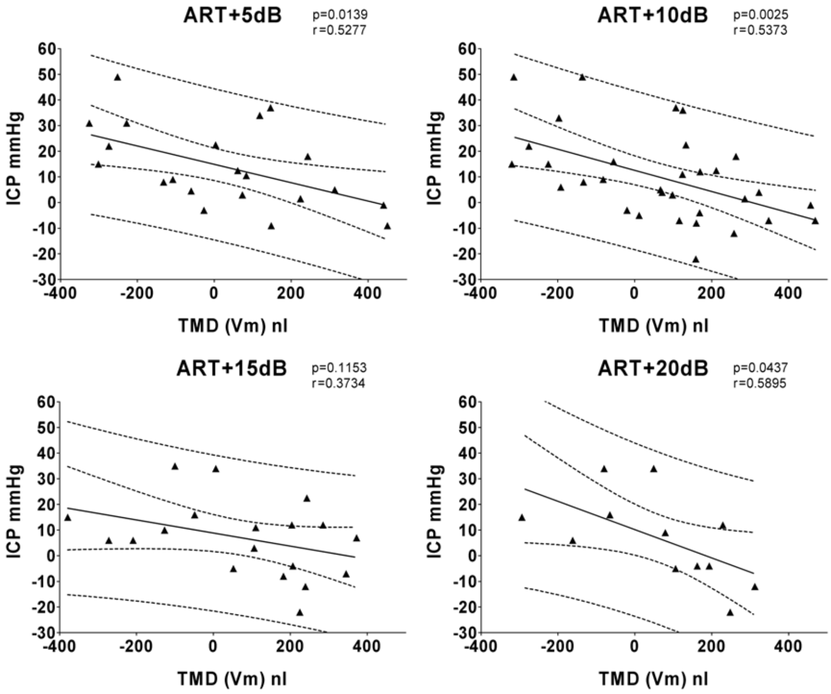

Figure 4. Regression analysis by stimulus intensity normalized to ART.

It has to be assumed that the success rate of the test is closely associated with cochlear aqueduct patency and its assessment. This study used an *a priori* hypothesis that cochlear aqueduct patency could be assumed on the basis of changes in the TMD value between the sitting and supine positions. Selecting patients in this way and then analysing the observations may have introduced a measure of bias in the results. In addition, age is an important factor as it is known that cochlear aqueduct patency reduces over the age of 40 (Wlodyka 1978). Phillips and Marchbanks (1989) reported that an increased proportion of older subjects had no change in TMD with posture and that where changes were observed they were smaller in older individuals. It is likely that the difference in success rates of the test between the groups is due partly to age differences.

Previous work has claimed that TMD measurements can provide a reliable measure of ICP (Moss *et al* 1990), and of perilymphatic pressure and CSF-perilymphatic pressure transfer (Marchbanks and Reid 1990). Samuel *et al* (1998) reported that TMD testing predicted changes in ICP with 93% sensitivity and 100% specificity, and that a value of Vm less than −200 nl indicated high ICP and greater than +200 nl indicated low ICP. We did not carry out serial measurements of ICP, so we are unable to comment on the first finding, but the second is not compatible with our data (figure 3).

Moss *et al* (1989) reported that patients with spina bifida and without ventricular shunts had higher ICP than the normal population. This finding was based entirely on the use of TMD measurements, which are treated in the paper as a direct replacement for ICP measurement. Our data suggest that, while the relationship between Vm and ICP is highly significant, intersubject variability is large, as the wide prediction limits shown in figure 3 indicate. Taking the normal range of ICP to be 10–15 mmHg, the predictive limits of the regression are an order of magnitude wider than this and therefore Vm cannot be used as a surrogate for ICP.

Negative studies can also be found. Walsted *et al* (2002) reported that an induced decrease in cerebral blood flow and resulting reduction in ICP were not detected using TMD measurements. Ayache *et al* (2000) also reported high intersubject variability in their study on TMD measurements in patients with Meniere's disease, which concluded that the technique was not useful in this group of patients.

The fact that no statistical difference could be found between the groups in this study precludes the establishment of meaningful normal ranges for these patient groups from these data. The distributions overlap to such an extent that, even if a statistical difference between the group medians could be established, this would not be clinically useful.

Inspection of figure 4 suggests that the relationship between ICP and Vm is similar at all stimulus levels between 5 and 20 dB above ART, although the gradient of the regression line increases with increasing stimulus intensity. A study by Albera *et al* (2001) supports this observation. The authors reported that TMD measurements were effective in detecting specific action on glycerol in reducing perilymph pressure in Meniere's disease, but only at stimulus levels of 20 dB and 25 dB above ART. We did not find that normalizing the Vm data to ART improved the ability of Vm to predict ICP.

The finding that age had an effect on Vm is in agreement with Phillips and Marchbanks (1989). However, regression analysis indicated that the effect is very small compared with the range of the Vm distribution, and can probably be ignored.

We have observed a significant difference between the median values of Vm measured on the right and left in patients with hydrocephalus. Experimental and clinical work has shown (Chambers *et al* 1998) that significant and lasting ICP gradients can exist in patients with non-evacuated mass lesions. Our data might suggest that such gradients may also be associated with unilateral shunting of CSF in hydrocephalus patients. However, without bilateral invasive ICP data, and in the light of our findings regarding the utility of TMD for measuring ICP, no firm conclusions can be drawn from this interesting observation.

Conclusions

The results of this study are consistent with the theory relating tympanic membrane displacement to intracranial pressure. However, low success rates combined with high intersubject variability mean that the technique is not clinically useful for establishing normal, high or low pressure in an individual patient. Using the parameter Vm as defined in the method, normal and abnormal ranges overlap to such an extent as to be meaningless. Tympanic membrane displacement measurement is not a reliable non-invasive indicator of intracranial pressure.

Acknowledgment

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