Tympanic membrane displacement testing in regular assessment of intracranial pressure in eight children with shunted hydrocephalus

**MADAN SAMUEL, M.B.B.S., M.S., DAVID M. BURGE, F.R.C.P., F.R.C.S., AND ROBERT J. MARCHBANKS, PH.D.**

Wessex Regional Centre for Paediatric Surgery and Child Health, Southampton General Hospital, Southampton, United Kingdom

Object. The authors assessed the accuracy and repeatability of the tympanic membrane displacement (TMD) test, an audiometric technique that is used to evaluate changes in intracranial pressure (ICP) in children with shunted hydrocephalus.

Methods. A prospective comparative evaluation of 31 clinical episodes of shunt malfunction was made by using the serial TMD test and direct ICP measurement in eight children with shunted hydrocephalus between January 1995 and February 1996.

The volume displacement of the tympanic membrane (Vm) on stapedial contraction was inward for raised ICP in 11 instances and ranged from $-120$ to $-539$ nl (mean $-263.5$ nl). This was confirmed by direct ICP monitoring, which showed values ranging from 20 to 30 mm Hg (mean 26 mm Hg). The TMD test measurement (Vm) in 18 instances of low ICP ranged from 263 to 717 nl (mean 431.3 nl); this was corroborated by direct ICP measurement, which ranged from 3 to 7 mm Hg (mean 4.2 mm Hg). The normal baseline Vm values obtained when patients were asymptomatic ranged from $-98$ to 197 nl (mean 110 nl). As a noninvasive diagnostic tool used in predicting changes in ICP, the TMD test had a sensitivity of 83% and specificity of 100%. The positive predictive value of the test was 100% and the negative predictive value was 29%.

Conclusions. The TMD test can be used on a regular basis as a reproducible investigative tool in the assessment of ICP in children with shunted hydrocephalus, thereby reducing the need for invasive ICP monitoring. The equipment necessary to perform this testing is mobile. It will provide a useful serial guide to ICP abnormalities in children with shunted hydrocephalus.

**KEY WORDS** • tympanic membrane displacement test • shunted hydrocephalus • intracranial pressure

The tympanic membrane displacement (TMD) test is an indirect assessment of cochlear fluid pressure, which is determined by observing TMD during acoustic reflex stapedial contraction. The three essential requirements of the TMD test for assessment of intracranial pressure (ICP) are: 1) a patent cochlear aqueduct; 2) normal middle ear pressure; and 3) an intact stapedial reflex.

The cochlear aqueduct communicates and drains fluids from the scala tympana to the subarachnoid space. The perilymphatic pressure directly reflects the cerebrospinal fluid (CSF) pressure through a patent cochlear aqueduct, which is the main fluid communication route between the intracranial and perilymphatic fluids. Animal (cat) experiments have shown that the labyrinthine pressure correlates to CSF pressure and that intralabyrinthine pressure can be measured only if the cochlear and vestibular aqueducts are patent. Communication within the normal ear via perivascular and perineural routes is hypothetical and, if it exists, is secondary to that of the cochlear and vestibular aqueduct. Histological studies have demonstrated that the patency of the cochlear aqueduct is age dependent and that the cochlear aqueduct has been shown to be open in children and adolescents who have hydrocephalus.

The patency of the cochlear aqueduct can be determined noninvasively by using the TMD test. The TMD test measures labyrinthine fluid pressure changes that occur with shifts in posture. Intracranial pressure is higher when the patient is supine than when the patient is sitting. The disparity in ICP with respect to the posture of an individual is reflected in the TMD test because changes in ICP are directly reflected by intralabyrinthine pressure, provided the cochlear aqueduct is patent. There will be no difference between the sitting and supine TMD if the cochlear aqueduct is not patent. A patent cochlear aqueduct is the main communication route between the CSF...
and the labyrinth; by measuring the labyrinthine fluid pressure, an indirect assessment of the CSF pressure is obtained. Pressure changes in the perilymphatic fluid produce changes in the resting position of the stapes footplate at the oval window and, hence, a change in the kinematics of the ossicular chain and TM. The measurement used to describe the TMD waveform is the mean TM volume displacement (Vm), measured from the time of maximum inward displacement to stimulus switchoff. The volume displacement of the TM is measured while the patient is sitting and later supine. To quantify the difference in the TMD function, the Vm value obtained when the patient is sitting (\(V_m\)) is divided by the value obtained when the patient is supine (\(V_m\)). If this fraction is greater than 0.1 (range 1–0.1), it determines the patency of the cochlear aqueduct.9,11 The results of the TMD test have corroborated histological studies, suggesting that the cochlear aqueduct is patent in 90% of the general population at ages younger than 40 years.2,8,9,10,11,13 Hence the pediatric population is a good cohort for assessment of ICP by the TMD test.

Perilymphatic pressure is assessed indirectly by recording displacement of the TM during reflex stapedial contractions elicited by a suprareflex threshold tone of 1 kHz. A raised perilymphatic pressure displaces the resting position of the stapes footplate laterally, causing a higher degree of motion in the medial direction. This results in an inward displacement of the TM on stapedial contraction. Low perilymphatic pressure results in an outward displacement of the TM (Fig. 1). Computer-based instrumentation that resolves volume displacements as small as 1 nl is used to measure the movements of the TM on stapedial contraction.

The aim of the current prospective study is to compare the clinical features at presentation, sequential TMD test results, and direct ICP measurements to assess the accuracy and repeatability of the TMD test in evaluating children with a corresponding shunt malfunction.
Tympanic membrane displacement test

### Patient Population

In our unit the TMD test is used as a regular investigative modality for assessment of ICP in patients with shunted hydrocephalus. The children in this cohort had an unusually high incidence of shunt malfunction. These patients required frequent assessment of their shunt function because of overt neurological symptoms of acute onset or persistent incapacitating clinical features suggestive of shunt dysfunction. This cohort of patients, therefore, provided the basis for assessing the reproducibility of the test within each individual and for evaluating high and low ICP.

Eight children (mean age 14 years, range 10–17 years) with 30 consecutive symptomatic episodes and one asymptomatic episode were assessed prospectively by serial TMD tests and direct ICP measurements between January 1995 and February 1996.

Normative data were obtained during two episodes in two patients. In Case 1 (Table 1), the patient presented with headache, nausea, irritability, and hyperactivity. Neurological examination yielded normal results and the TMD test and direct ICP measurement showed normal ICP. Normal ICP was again found in another child who was monitored when asymptomatic during an elective admission for a shunt-lengthening procedure. The TMD test and direct ICP measurement confirmed these two episodes of normal ICP. The aforementioned procedures assessed and classified the other 29 symptomatic episodes as either raised or low ICP.

Table 1 provides a summary of the primary causes of the hydrocephalus and the age and gender of the eight patients. Tables 2 and 3 display the clinical features at presentation of the eight children with 29 episodes of shunt malfunction that were designated as either raised or low ICP after having been confirmed by the TMD test and direct ICP measurement.

Figure 2 upper demonstrates the sequence of clinical presentation, TMD values, and ICP measurements and management in all eight patients; Fig. 2 lower shows similar data in the three patients who required a valve upgrade to manage their episodes of low-pressure symptoms.

Figure 3 displays the TMD values (Vm) obtained for all eight patients during a normal screening procedure. “Episodes 1” represent the normal ICP values obtained by TMD testing following shunt revision, when the patients were asymptomatic and well. “Episodes 2” represent the values obtained at the time of regular clinical outpatient follow up, when the patients were asymptomatic. These normal TMD values provided an additional valuable baseline reference for subsequent TMD assessments during periods of possible shunt malfunction. These readings also provided qualitative assessment of normal ICP by using the TMD test.

### General Study Methods

The principal author performed the tests to obtain the TMD and direct ICP measurements. The TMD tests were performed in the test room and the ICP measurements were obtained under controlled conditions in the operating room after general anesthesia had been induced in the patient.

### TABLE 1

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age (yrs), Sex</th>
<th>PHH</th>
<th>Spina Bifida</th>
<th>CH</th>
<th>VP Shunt</th>
<th>VA Shunt</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10, M</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>2</td>
<td>13, F</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>13, F</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>4</td>
<td>14, F</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>5</td>
<td>14, M</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>6</td>
<td>15, M</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>+</td>
</tr>
<tr>
<td>7</td>
<td>16, F</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>8</td>
<td>17, F</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

* CH = congenital hydrocephalus; PHH = posthemorrhage hydrocephalus; VA = ventriculoatrial; VP = ventriculoperitoneal; + = present; – absent.

### TABLE 2

<table>
<thead>
<tr>
<th>No. of Episodes</th>
<th>No. of Episodes of Raised/Low ICP in Which Symptoms Occurred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case No.</td>
<td>ICP</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>0</td>
</tr>
</tbody>
</table>

* A = ataxia; BC = behavioral change (irritability and hyperactivity); D = dizziness; H = headache; Hy = hyperacusis; LC = lapses in concentration; S = seizure; T = tinnitus; V = vomiting.

### TABLE 3

<table>
<thead>
<tr>
<th>No. of Episodes</th>
<th>No. of Episodes of Raised/Low ICP in Which Signs Appeared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case No.</td>
<td>ICP Low ICP B PC BCS RVA EBS P</td>
</tr>
<tr>
<td>1</td>
<td>0     4     0/1 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0</td>
</tr>
<tr>
<td>2</td>
<td>2     0     0/0 0/0 1/0 0/0 0/0 0/0 0/0 0/0 0/0</td>
</tr>
<tr>
<td>3</td>
<td>2     1     0/2 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0</td>
</tr>
<tr>
<td>4</td>
<td>1     2     0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0</td>
</tr>
<tr>
<td>5</td>
<td>4     1     0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0</td>
</tr>
<tr>
<td>6</td>
<td>1     3     0/0 1/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0</td>
</tr>
<tr>
<td>7</td>
<td>1     3     0/0 0/0 0/0 0/1 0/1 0/1 1/0 0/0 0/0</td>
</tr>
<tr>
<td>8</td>
<td>0     4     0/0 0/0 0/0 0/1 0/1 0/1 0/0 0/0 0/0</td>
</tr>
</tbody>
</table>

* B = bradycardia; BCS = bilateral central scotomas; EBS = enlarged blind spots; P = papilledema; PC = peritoneal cyst; RVA = reduced visual acuity (circumferentially constricted fields).
Both ears were tested. The ICP on the side of the shunt was assessed first; subsequently, the other ear was tested.

Tympanic Membrane Displacement Testing

The steps involved in the evaluation of ICP in a patient by TMD testing follow: 1) Analysis of middle ear function is performed by tympanometry in which a middle ear analyzer (Fig. 4 upper) and acoustic impedance measurements are used to determine the acoustic reflex threshold (ART) (Fig. 4 lower). 2) A tympanic displacement analyzer is used to establish the patency of the cochlear aqueduct, the main pathway of pressure transmission from the ventricles to the labyrinth. 3) The tympanic displacement analyzer is then used to assess ICP.

The first step is performed using the GSI-33 MiddleEar Analyser (Grayson Stadler, Inc., Milford, NH). The second and third steps are performed using a computer-based instrument, the MMS-11 Tympanic Displacement Analyser (Marchbanks Measurement Systems, Ltd., Lymington, Hampshire, United Kingdom), which is available commercially (Fig. 4 upper).
Preparation of Pediatric Patients for the TMD Test

The test room should appear friendly to children and contain toys, books, and posters. The parents and a play nurse should accompany the child. Prior to testing the person performing the test must establish an amicable relationship with the child, which is especially important when testing children younger than 12 years of age. This helps gain the confidence of the child and ensures a warm and friendly atmosphere. The procedure and purpose of the test are described to the patient and to the parents. The child should be at ease and alert but relaxed. The requirement that the child must remain still should be emphasized. The patient is familiarized with the headset and the ear seal set on the probe (Fig. 4 upper). The type of sound the child will hear should be explained as well. (The child may experience the feeling of being within an aircraft. It will be loud, but not uncomfortable and will occur for a few seconds.)

In children with spina bifida, a comfortable reclining and later supine posture is achieved by using soft pillows (Fig. 4 upper).

The child is encouraged to stay as still as possible and refrain from speaking. The act of swallowing does not preclude TMD testing because the background noise produced is eliminated by the TMD artifact rejection feature. In difficult situations the parent may read a book to the child. It is preferable that the children avoid reading to themselves because the constant head motion that occurs while scanning pages introduces too much “body-movement” noise, resulting in artifacts and rejections of the TMD measurements.

The test room should be quiet, with a preferred ambient noise level lower than 50 dB. The ear is examined by means of an otoscope. The purposes of the examination are to: 1) ascertain the direction of the external auditory canal to insert a probe and obtain a seal; 2) discover whether the ear has a discharge or otitis media, which are contraindications for tympanometry and TMD analysis; and 3) look for excessive wax, which is another contraindication because obstruction of the probe causes spurious readings and results, and probe insertion may risk wax impaction onto the TM.

Measurement of ICP by TMD Testing

The battery of tests required by tympanometry prior to TMD analysis of ICP includes assessment of middle ear pressure and aural acoustic compliance and determination of an intact acoustic stapedial reflex and ART intensity.

A measure of middle ear pressure and the ipsilateral and contralateral reflex threshold at 1 kHz is determined by tympanometry (GSI-33 Middle-Ear Analyser) (Fig. 4). We used the GSI-33 Middle-Ear Analyser with a nominal probe frequency of 226 Hz to obtain an aural acoustic impedance/admittance measurement (Fig. 4 upper).

The acoustic reflex is a middle ear reflex elicited by acoustic stimulation of the stapedius muscle. The TMD test is performed relative to the acoustic stapedial reflex threshold. A minimum ipsilateral reflex threshold at 1 kHz is determined to the nearest 5 dB. The contralateral reflex threshold at 1 kHz may also be required if the ipsilateral threshold is elevated above a 100-dB sound pressure level (SPL). The ipsilateral stimulus was used during each episode in this cohort of patients (Fig. 4 lower).

The acoustic reflex consists of a response by the stapedius muscle to suprathreshold acoustic stimulation of the auditory pathway. To elicit an acoustic reflex, an acoustic stimulus, such as a pure-tone noise or click, is presented to the ear canal by a probe earphone (Fig. 4 upper). The osseous chain carries a portion of this stimulus to the cochlea. The stimulus is conveyed from the cochlea to the brainstem via the eighth cranial nerve. The response elicits contraction of the stapedial muscle, resulting in displacement of the TM.

Equipment and Performance of the TMD Test

Equipment consists of a patented ultrasonic airflow sensor to measure displacement of the tympanic membrane by airflow into or out of the external auditory meatus (Fig. 4 upper). This transducer is connected to the ear by a flexible tube and a probe that is hermetically sealed into the entrance of the external auditory meatus (Figs. 4 and 5). A servomechanism ensures a constant external auditory meatal pressure during the movement of the volume displacement of the TM, by a pressure microphone concealed in the headset (Fig. 4 upper). Because the pressure is maintained at a constant level, the volume displacement of the TM is exactly matched by the displacement at a servodriven reference diaphragm (Fig. 5).

The test involves a transducer probe attached to a head-set, which is hermetically sealed in the patient’s external auditory meatus (Fig. 4 upper). A clean ear seal tip of suitable size and shape is fitted to the probe (ear seals of different shapes and sizes varying from 7 to 14 mm are widely available commercially). The probe is inserted with a rotary movement in the direction of the external auditory canal, corresponding to the shunted side first in all cases. The probe is pointed in the direction of the TM to avoid the risk of sealing the tip against the wall of the canal. The canal can be straightened to an extent by either gently pulling the pinna downward and backward or downward
and inward. In children the latter achieves ease of introduction. The headset should not touch any external surfaces such as the bed or linen and it must be securely in place (Fig. 4 upper). An airtight seal is achieved and the computer checks the integrity of the seal before commencement of TMD analysis.

A 1-kHz ipsilateral stimulus induced controlled stapedial muscle contraction and ossicular and TM movement.
The duration of the stimulus was 500 msec and the recording window was 1500 msec. The acoustic stimulus was switched on at 0 msec and switched off at 500 msec.

The TMD was measured and analyzed using computer-based instrumentation, a TMD cerebral and cochlear fluid pressure analyzer (MMS-11 Tympanic Displacement Analyser) that is available commercially (Fig. 4 upper). The records were ensemble averaged, up to a maximum of 10 records, to improve the signal-to-noise ratio and to obtain an average recording of ICP. The ICP was then indirectly quantified in terms of the mean TMD (Vm) measured from the time of maximum inward displacement achieved while the acoustic stimulus was present to the time the stimulus was switched off (Fig. 6). The Vm is the reproducible and reliable measurement and, hence, is used in the interpretation of the TMD test.

The patency of the cochlear aqueduct was determined by measuring the perilymphatic fluid pressure by means of TMD while the patient is sitting (ΔVm) (reclined at 45° to the horizontal) (Fig. 4 upper) and later while supine (Vm). The physiological increase in the ICP with posture change is reflected in the perilymphatic pressure via the patent cochlear aqueduct, which is measured by TMD testing (Fig. 7). The TMD variations were significant (mean ΔVm/Vm = 0.6; range 0.4–0.8) with changes in posture from sitting to supine, confirming the patency of the pathways essential for the transmission of the ICP to the perilymph (Fig. 7).

The time needed initially to test both ears and the patency of the cochlear aqueduct by postural variation (comparative analysis of TMD in sitting and supine posture) was 45 to 60 minutes; subsequent repeated tests were performed in 15 to 30 minutes.
An experienced audiologist or scientist is required to interpret certain results of TMD testing.

Direct ICP Measurement

In 31 instances direct ICP monitoring was performed. The opening and the maximum sustained ICP were recorded percutaneously through a Rickham ventriculos-tomy reservoir with the patient recumbent after general endotracheal isoflurane anesthesia and a normocarbic condition had been induced. The ventricular pressure was measured by connecting the ventricular portion of the shunt through rigid saline-filled tubing to a strain-gauge transducer. The ventricular pressures were referenced to the external auditory meatus and extracted from the diastolic component of the cardiac and respiratory cycles.

Figure 8 demonstrates the correlation between the results of the TMD test and the maximum sustained ICP measurements at each instance for individual patients.
Tympanic membrane displacement test

Figure 8. Scattergram demonstrating Vm values and direct ICP measurements. Correlation coefficient is 0.94, \( r = 9242 \), \( \rho = 0.96627 \), \( \kappa = 0.72 \), and \( p < 0.001 \) (CI 0.9–0.94).

Results

At the time of each evaluation all patients had normal middle ear pressure, ranging from −20 to 5 daPa (normal range −50 to 50 daPa) and compliance ranging from 0.3 to 1.1 ml (normal range 0.3–1.5 ml). The normal ipsilateral acoustic reflex threshold at 1 kHz ranged from 80 to 90 dB SPL (Fig. 4 lower). The intensity of the stimulus was 20 to 25 dB above reflex threshold for 1 kHz.

During each episode, all patients had a patent cochlear aqueduct (mean \( \Delta Vm/Vm = 0.6 \); range 0.4–0.8).

In nine (29%) of 31 episodes, an airtight seal was achieved after several attempts and by trials with several seal tips of various sizes and shapes. Achieving an airtight seal can be challenging at times; however, it is virtually always possible with practice.

Intolerance to the impedance audiometry probe was not seen in this cohort of patients. Assessment of ICP by TMD testing is not possible if the patient shows intolerance to the audiometric probe.

The ICP measurements obtained by TMD testing with respect to the shunted and nonshunted side were statistically significantly different in this cohort of patients (\( p > 0.05 \)). Direct ICP measurements were obtained on the shunted side via a Rickham ventriculostomy reservoir; hence, the TMD measurements of ICP on the shunted side were used for determination of correlation of ICP by TMD and direct ICP measurement.

In the eight patients, 31 TMD test measurements were used to assess 11 raised (35%), 18 low (58%), and two normal (6%) episodes of ICP (Table 4).

The TMD test measurement (\( Vm \)) ranged from −120 to −539 nl (mean \( Vm = 263.5 \) nl) for raised ICP and 263 to 717 nl (mean \( Vm = 64 \) nl) for low ICP at a suprareflex threshold stimulus of 20 to 25 dB (Fig. 2 upper). The normal TMD test measurements ranged from −98 to 197 nl (Vm 64 nl) and correlated with the previous normal baseline values for that particular individual obtained when asymptomatic (Fig. 3). The maximum sustained ICP measurement corroborated the TMD test results. The measurements ranged from 20 to 30 mm Hg (mean 26 mm Hg) for raised ICP and 3 to 7 mm Hg (mean 4.2 mm Hg) for low ICP (Fig. 2).

Clinical Features

All patients had headache as the common presenting symptom (Table 2). In instances of raised ICP, persistent generalized headache was associated with vomiting. Headaches were worse during the morning, especially following a restful night, and remained relatively constant throughout the day. Headaches were not associated with an aggravating or relieving factor. In episodes of low ICP, 88% of the patients exhibited a gradual worsening of the severity of their headache as the day progressed and in 63% the pain was more intense on the side of the shunt and was exacerbated on forward flexion of the neck. Headaches were less pronounced in the morning in comparison with their severity in the evening. Low-ICP headache was associated with ataxia in 71% and vomiting in 43%.

A constellation of symptoms, such as behavioral changes (irritability and hyperactivity), lapses in concentration, vertigo, tinnitus, and hyperacusis, were nonspecific and occurred both in instances of raised and low ICP. Neurological assessment, pulse, blood pressure, and vision were generally normal during most episodes of shunt malfunction. Severe low-pressure headache was associated with bradycardia and seizure in one patient (Tables 2 and 3).

Normal Baseline TMD Measurements

A normal baseline TMD test measurement obtained when the individual was asymptomatic was available in all patients (Fig. 3). The TMD tests were performed as a regular follow-up screening procedure when patients were asymptomatic. The \( Vm \) ranged from −98 to 197 nl (mean Vm 64 nl) and from −46 to 143 nl (mean Vm 64 nl). The normal \( Vm \) values shown in Fig. 3 demonstrate the range of normal recording in each individual patient.

Statistical Analysis

Sensitivity and Specificity. In cases of raised ICP, the TMD is expected to be inward and in cases of low ICP it is outward, of a magnitude that will tend to be larger than normal. As such the sensitivity and specificity of the TMD test as a detector of raised and low ICP will vary depending on the chosen inward and outward TMD limit between what is considered to be a TMD magnitude that is repre-
sentative of normal, raised, or low ICP. The sensitivity was 55% and the specificity 100% for a normal-raised TMD limit set to $-200$ nl (Fig. 8). The optimum sensitivity and specificity were 100% for a normal-low TMD limit set to 200 nl (Fig. 8). The TMD test as a noninvasive diagnostic tool used in predicting changes in ICP had a sensitivity of 83% and a specificity of 100%. The positive predictive value of the test was 100%, and the negative predictive value was 29% (Table 5). The pressure measurements made on an individual patient basis were reliable (Fig. 2). The objective measurement of ICP by using the TMD test with a Vm value of $-200$ nl and less should be indicative of raised CSF pressure and a Vm value of 200 nl and greater should be indicative of low ICP (Fig. 8).

**Interrater Agreement.** Figure 8 demonstrates data for TMD test values (Vm) and direct ICP measurements of patients with shunted hydrocephalus. These data demonstrate a clear dissociation between normal, raised, and low ICP. Kappa statistical analysis was used to measure the agreement between the categorical assessments. The strength of the agreement was very good ($\kappa = 0.7$) and the probability value was less than 0.001 (Fig. 8). The standard error (SE) for kappa was 0.09 and a 95% confidence interval (CI) for kappa was narrow (0.6264–0.817) (Table 6).

**Repeated Observations.** The reproducibility of the TMD test in the assessment of ICP in children with shunted hydrocephalus was examined by taking repeated measures of instances of raised ICP and low ICP (Table 7). Two or more repeated measurements were obtained in each patient. The total number of measurements was 24 in the eight patients. Table 8 displays the results of one-way analysis of variance (ANOVA) and Fig. 9 shows the average of the several measurements for that patient against their differences, and the standard deviation (SD) against their mean. The probability value was less than 0.001. The replicated measurements obtained in the same patient by the same observer have an error of variance of only $87$ nl, indicating the measurement error is small and the TMD test can be reproduced with an relative accuracy (Table 7 and Fig. 9). The CIs for each episode of low and raised ICP within an individual are narrow and, hence, the test is repeatable.

**Case Management**

Episodes of raised ICP resulted in revision of a blocked shunt (Fig. 2 upper). Instances of low ICP were managed conservatively with bed rest and minimal ambulation. Slow, progressive mobilization over a few days improved the patient’s symptoms and a course of acetaminophen, diclofenac sodium, and codeine phosphate was used empirically. In three patients with persistent incapacitating symptoms and repeated TMD test measurements indicating low ICP, the CSF shunt was changed to one with a different flow and pressure character in an attempt to minimize the excessive reduction of intraventricular pressure and volume due to CSF overdrainage (Fig. 2 lower). The symptoms of low ICP gradually disappeared with the return of the TMD test measurement to normal baseline values. At present these patients’ headaches are intermittent, less severe in intensity, and not incapacitating.

**Discussion**

**Clinical Features**

In patients who have shunt-dependent hydrocephalus, the overt neurological symptoms of relative rapid onset are usually attributed to raised ICP. Common symptoms include headache, nausea, vomiting, and drowsiness, as seen in our study group. These may progress to obtundation and brainstem dysfunction if normal shunt function is not restored. It has been shown that the CSF buffering capacity and brain elasticity in these patients are normal. The rise in ICP caused by shunt occlusion causes the ICP to rise along the steep portion of the normal-pressure intracranial volume curve, resulting in sustained high ICP waves. These plateau waves, in turn, cause the acute symptoms. The rise in ICP caused by shunt occlusion may also result in intracranial venous obstruction, leading to increased choroid plexus capillary pressure and increased CSF production. The headache associated with raised ICP occurs when the patient awakens from a phase of rapid eye movement.
Tympanic membrane displacement test

TABLE 7

<table>
<thead>
<tr>
<th>Episode No.</th>
<th>Case 1 Vm (nl)</th>
<th>Case 1 ICP (mm Hg)</th>
<th>Case 2 Vm (nl)</th>
<th>Case 2 ICP (mm Hg)</th>
<th>Case 3 Vm (nl)</th>
<th>Case 3 ICP (mm Hg)</th>
<th>Case 4 Vm (nl)</th>
<th>Case 4 ICP (mm Hg)</th>
<th>Case 5 Vm (nl)</th>
<th>Case 5 ICP (mm Hg)</th>
<th>Case 6 Vm (nl)</th>
<th>Case 6 ICP (mm Hg)</th>
<th>Case 7 Vm (nl)</th>
<th>Case 7 ICP (mm Hg)</th>
<th>Case 8 Vm (nl)</th>
<th>Case 8 ICP (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>454.75</td>
<td>4</td>
<td>−186.5</td>
<td>28</td>
<td>−169</td>
<td>22.5</td>
<td>379.5</td>
<td>4</td>
<td>−381</td>
<td>25.5</td>
<td>449.3</td>
<td>4</td>
<td>363.3</td>
<td>4</td>
<td>399.25</td>
<td>4.5</td>
</tr>
<tr>
<td>2</td>
<td>279.75</td>
<td>6</td>
<td>−193</td>
<td>27</td>
<td>−184</td>
<td>23</td>
<td>441.5</td>
<td>5</td>
<td>−315</td>
<td>23</td>
<td>525</td>
<td>3</td>
<td>348</td>
<td>4</td>
<td>429</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>500.75</td>
<td>3</td>
<td>−193</td>
<td>27</td>
<td>−184</td>
<td>23</td>
<td>441.5</td>
<td>5</td>
<td>−315</td>
<td>23</td>
<td>525</td>
<td>3</td>
<td>348</td>
<td>4</td>
<td>429</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>579.25</td>
<td>6</td>
<td>−193</td>
<td>27</td>
<td>−184</td>
<td>23</td>
<td>441.5</td>
<td>5</td>
<td>−315</td>
<td>23</td>
<td>525</td>
<td>3</td>
<td>348</td>
<td>4</td>
<td>429</td>
<td>3</td>
</tr>
<tr>
<td>mean</td>
<td>497.25</td>
<td>7.4</td>
<td>−186.5</td>
<td>28</td>
<td>−169</td>
<td>22.5</td>
<td>379.5</td>
<td>4</td>
<td>−381</td>
<td>25.5</td>
<td>449.3</td>
<td>4</td>
<td>363.3</td>
<td>4</td>
<td>399.25</td>
<td>4.5</td>
</tr>
</tbody>
</table>

TABLE 8

Results of one-way ANOVA of ICP according to the TMD test and repeatability of the TMD test*

<table>
<thead>
<tr>
<th>Group (case no.)</th>
<th>Count (no. of measurements)</th>
<th>Mean</th>
<th>SD</th>
<th>SEM</th>
<th>95% CI for Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>497.25</td>
<td>6.05</td>
<td>1.54</td>
<td>459.7 to 534.8</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>−128.5</td>
<td>6.05</td>
<td>1.54</td>
<td>−123.9 to 133.1</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>−193</td>
<td>27</td>
<td>18</td>
<td>−250 to −136</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>237</td>
<td>50</td>
<td>13</td>
<td>204 to 270</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>−381</td>
<td>25.5</td>
<td>6.5</td>
<td>−264 to −506</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>449</td>
<td>73</td>
<td>18</td>
<td>392 to 506</td>
</tr>
<tr>
<td>7</td>
<td>3</td>
<td>363</td>
<td>87</td>
<td>20</td>
<td>292 to 433</td>
</tr>
<tr>
<td>8</td>
<td>4</td>
<td>399</td>
<td>44</td>
<td>11</td>
<td>348 to 450</td>
</tr>
<tr>
<td>total</td>
<td>24</td>
<td>389.25</td>
<td>56.02</td>
<td>13.8</td>
<td>324 to 453</td>
</tr>
</tbody>
</table>

* When the source of the variation was between groups, the degrees of freedom were 7; the sum of the squares 2,761.892,17; the mean squares 394.556,02; the ratio of two variances 51.55; and the probability value 0.0000; when the source of the variation was within groups, the degrees of freedom were 16, the sum of the squares 122,459.83, and the mean squares 7.653.74; for both, the degrees of freedom were 23 and the sum of the squares 2,884.352. Abbreviation: SEM = standard error of the mean.

Sleep, when there is increased cerebral blood flow and a nocturnal rise in ICP.

At the other end of the spectrum of shunt malfunction is overdrainage resulting in low ICP. Low-pressure headache is characterized by exacerbation when the patient is in the upright posture and relief when the patient lies down, with progressive worsening of symptoms occurring toward evening. These characteristics of the headache were seen in 88% of our patients presenting with low ICP. Other symptoms were nonspecific, except for ataxia, which was seen in 71% of the patients. In most patients the symptoms were subtle and minimal. In three patients, incapacitating low-pressure headache was a frequent problem associated with overshunting. The problem of shunt overdrainage remains unsolved and in-shunt CSF flow studies have shown increased flow in response to a change of posture or respiratory changes and in rapid eye movement sleep, irrespective of the shunt system.1,6

Chronic shunting is known to affect the compliance of the brain, which may be increased or decreased; however, in most patients the change is of little consequence. The variability of the clinical features within an individual makes it difficult to diagnose raised or low ICP caused by shunt dysfunction. This study substantiates that symptoms are not reliable predictors of changes in CSF pressure. Radiological imaging is a static investigation and does not invariably indicate the presence of raised or reduced ICP. Direct measurement of ICP remains the standard to establish changes in ICP; however, because it is invasive, it introduces the risk of infection. There exists a need for an alternative noninvasive, ambulatory, and repeatable diagnostic tool for regular assessment of patients with shunted hydrocephalus. The TMD test as a diagnostic modality may be useful in the regular assessment of shunt function in these patients.

The TMD Test

Intracranial pressure is transmitted to the perilymph of the cochlea through the major route of pressure transfer, the cochlear aqueduct, provided this aqueduct is patent. The cochlear aqueduct was patent in all patients as determined by postural variation. Other factors (middle ear pressure and an intact acoustic stapedial reflex) essential for interpretation of the TMD test were normal in this study cohort.

The sensitivity and specificity of the test were defined with the aim of deriving an objective measurement. This would allow the prediction of CSF pressure changes in a patient without having to rely on previous baseline test results for that particular individual. Our study has shown that the sensitivity and specificity of the TMD test as a diagnostic modality are 83% and 100%, respectively. The high sensitivity and specificity demonstrated that the TMD test was viable despite intersubject variation. Although highly significant, the Pearson and Spearman correlation coefficient, with a probability value of less than 0.001, does not judge agreement. The kappa statistic, which is interpreted as the chance-corrected proportional agreement, was used to judge agreement among the three categories of raised ICP, normal ICP, and low ICP. The kappa statistic was 0.7217 and the 95% CI for kappa was narrow, 0.6264 to 0.817, which demonstrates a very strong agreement between ICP measurements by using the TMD test and direct ICP measurements.7 Pressure measurements obtained on an individual patient basis were reliable (Figs. 2 and 8). The objective measure of ICP obtained by using the TMD test with a Vm value of −200 nl or less should be indicative of raised CSF pressure and a Vm value of 200 nl or greater should be indicative of low ICP (Fig. 8).

Reproducibility of the TMD Test

The reproducibility of the TMD test within the same patient was assessed. There were two or more observa-
TMD test was used to estimate the reproducibility of the measurements by TMD. Figure 9 and Table 6 demonstrate the statistical analysis. The replicated measurements in the same patient by the same observer have an error of variance of only 87 nl, with a narrow CI, indicating the measurement error is small and the TMD test can be reproduced with relative accuracy within an individual with raised or low ICP.

The TMD test could be repeated without loss of accuracy in evaluating ICP; furthermore, there is no risk of radiation or infection and no need for induction of general anesthesia in young children, which occur in direct ICP monitoring. Our results highlight the benefit of serial TMD testing of ICP in children with shunted hydrocephalus.

In three patients the TMD test detected gradual reduction in ICP related to the deterioration of those patients’ clinical features, which subsequently required a revision of the shunt system with an upgrade of the valve to prevent siphoning (Fig. 2 lower). We also found that in instances of low ICP, following shunt revision, the test was helpful in assessing a gradual rise in the ICP and normalization of values to previous baseline results, with amelioration of symptoms (Fig. 2). This study shows that patients can be studied safely and accurately several times by using the TMD test to assess normalization of ICP following shunt revision. When performed sequentially at regular intervals, the test would be useful in evaluating CSF pressure in patients who require long-term shunts. The TMD test is relatively accurate in predicting changes in CSF pressure in patients with shunted hydrocephalus when they are monitored sequentially at regular intervals.

Advantages and Disadvantages of TMD Testing

The TMD test is noninvasive, simple, quick, painless, repeatable, and the equipment necessary to perform it is mobile. Hence, it is easily applicable to monitoring children with shunted hydrocephalus.

The existence of intracranial–cochlear pressure transfer, which is assumed to be via a patent cochlear aqueduct, can be assessed simultaneously during the analysis of ICP by using the TMD test.

Care must be taken not to overexpose the patients to acoustic stimulation because it can result in a temporary auditory threshold shift.

There are some disadvantages of the test. 1) The procedure cannot be used in children with an absent stapedial reflex as a result of brainstem or middle ear dysfunction. 2) Patients who are connected to ventilators or in a state of general anesthesia have an absent acoustic reflex due to the use of muscle relaxants and sedation. The TMD test cannot assess ICP under these circumstances. 3) The technique is currently not in a form that makes it suitable for continuous ICP monitoring or for detecting waves of pressure. 4) The technique does not measure absolute ICP, although semiquantitative measurements may be obtained. 5) Restlessness in young children would make assessment by TMD testing difficult.

Case Management

In instances of raised ICP, shunt revision for a blocked shunt was curative. Active treatment is normally instituted if ICP exceeds 25 mm Hg. This was the treatment policy in this cohort of patients, although a threshold of 15 to 20 mm Hg has been suggested to improve outcome. In most instances of low ICP, bed rest, progressive slow ambulation, and empirical use of acetaminophen, diclofenac sodium, and codeine phosphate were effective. It may be necessary to revise the shunt system by including an antisiphon device or adding a flow-regulated device to prevent episodes of low ICP. In three of our patients, revision of the shunt with a valve upgrade to prevent siphoning (Delta valve performance level 2) was effective in treating low ICP. It was possible to confirm that ICP returned to normal values in these patients.

Conclusions

Since its introduction in 1951, invasive monitoring remains the standard for detecting changes in ICP. However, its use is restricted to a few days at a time and carries the risk of infection, hemorrhage, or seizures. Our results highlight the benefit of serial TMD testing of ICP in children with shunted hydrocephalus.

The pressure measurements made on the basis of individual patients were reliable. The objective measurement of ICP made by using the TMD test with a Vm value of −200 nl and less should be indicative of raised CSF pressure and a Vm value of 200 nl and greater should be indicative of low ICP.

As a noninvasive investigative tool, the TMD test is reproducible in detecting changes in ICP in patients with...
Tympanic membrane displacement test

shunted hydrocephalus and the equipment necessary to perform the testing is mobile. It can be used for regular assessment to enable correlation of ICP with symptoms in individual patients. The test will provide a useful serial guide to ICP abnormalities.

Tympanic membrane displacement testing at the onset of minor symptoms may allow detection of an ICP change at an earlier stage without the risks of direct monitoring. This, in turn, may allow earlier treatment and prevention of morbid states such as those caused by chronic high or low ICP. It may also be used to monitor changes in ICP with different forms of treatment and shunt modification.

It is important to note that an experienced audiologist or scientist is required to interpret certain results of the TMD test.

Future Work

These preliminary findings in our cohort of patients should be confirmed by a larger independent trial. The independent trial should ideally include both pediatric and adult populations.

Disclosure

Dr. Marchbanks’ company, Marchbanks Measurement Systems, Ltd. (Lymington, Hampshire, United Kingdom), manufactures a limited supply of the MMS-11 Tympanic Displacement Analyser for clinical trials. This equipment is available in the United States for research purposes only. Drs. Samuel and Burge have no financial interest in any equipment used in this study.

Acknowledgment

We thank Mr. Mervyn D. Griffiths for allowing us to study his patients.

References


This work was presented in part at the 40th Annual Meeting of the Society for Research into Hydrocephalus and Spina Bifida, Utrecht, The Netherlands, July 12, 1996. An abstract of this work was published in Eur J Pediatr Surg 6 (Suppl 1):47, 1996.

Address reprint requests to: Madan Samuel, M.B.B.S., M.S., Department of Paediatric Surgery, Southampton General Hospital, Southampton SO16 6YD, United Kingdom.