adequacy of excision was better and the implications of an incompletely excised basal cell carcinoma are usually not as serious. Nevertheless, it is clear from our results that attention to pathology reports is critical as some tumours where recurrence is expected do not appear to have had further treatment. The follow up data on malignancies adds support to the view that adequate record keeping is a valid criterion to include in assessment of premises for minor surgery; this was the single most frequent reason for failure to meet criteria for adequacy of premises in a recent study.⁹

We conclude that minor surgery in general practice has advantages but also raises concern about the increase in laboratory workload, the likelihood that some benign lesions may be excised for no reason other than diagnostic uncertainty, the inappropriateness of biopsy of rashes, and the generally poor rate of diagnosis and adequate treatment of malignant tumours. Our results highlight the relatively small number of specimens submitted by even the most prolific general practitioners, and suggest that further training and guidelines may be helpful.

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(Accepted 9 October 1991)

Appendix

(1) *Correct diagnosis*—Accurate diagnoses were recorded; "mole" was taken to mean naevus.

(2) *Incorrect diagnosis*—Cases where (a) clinical information was omitted entirely or was brief and uninformative (such as "lump"), (b) the clinical diagnosis suggested was inconceivable given the pathological diagnosis (such as diagnosis of lipoma as a wart), or (c) the diagnosis was potentially dangerous—for example, "mole" for squamous cell carcinoma.

(3) *Uncertain*—For example, the clinical information for most rashes biopsied did not enable the accuracy of diagnosis to be established.

(4) *Adequate description*—For example, keratosis was used for a wide variety of different diagnoses and as a descriptive term, so was coded as a description unless qualified by a more specific term such as actinic (solar) keratosis, etc.

(5) *Reasonable suggested diagnosis*—Almost all pathological diagnoses where the clinical diagnosis was not accurate but suggested "mole" or "wart" were classified as category 5 unless the suggestion was entirely inappropriate. For analysis of tumours, we specifically recorded whether descriptions or suggested diagnoses included the possibility of any malignant disorder.

Diagnostic value of microtympanometry in primary care

Ruut A de Melker

Abstract

Objective—To determine the reliability, validity, and feasibility of a new hand held microtympanometer.

Design—Comparison of microtympanometry by two independent observations of a general practitioner and a nurse, and against a validated reference instrument.

Setting—Primary care health centre of a school for the deaf in the United States.

Subjects—111 schoolchildren receiving a regular check up.

Main outcome measures—Tympanometry with the Grason Stadler 28, classified with a slightly modified Jerger's classification.

Results—Interobserver reliability was 0.95 (Cohen's κ). Results of microtympanometry were highly comparable with results of the reference instrument (likelihood ratio of positive results, 161.2).

Conclusions—The microtympanometer could be used in general practice: it is hand held, child friendly, easy to handle, and accurate.

Introduction

Tympanometry is a reliable and sensitive test for diagnosing otitis media with effusion in children,¹⁻³ which is difficult to diagnose in general practice^{4,5}; data collected by history is of limited value^{7,8} and otoscopy is rather unreliable.^{1,4,9,10} The cumulative incidence of

bilateral otitis media with effusion is 50-60% in open populations of children aged 2-6 years.^{6,8,11} About 5% of 5 year olds have severe otitis media with effusion and suffer developmentally as a result.¹²⁻¹⁴

The hand held microtympanometer (Welch Allyn, Skaneateles Falls, New York) seems a good instrument to diagnose otitis media with effusion in primary care, but has not been sufficiently validated.^{15,16} The aim of this study is to determine the reliability, validity, and feasibility of using the microtympanometer. I set out to determine the interobserver and intraobserver reliability of microtympanometry in a group of schoolchildren aged 1-16 years; to discover the likelihood ratio of positive and negative results of the microtympanometer with the Grason Stadler GSI 28 tympanometer as reference instrument; and to assess the feasibility of a general practitioner and a nurse trained in ear, nose, and throat practice using the microtympanometer in a primary care setting.

Subjects and methods

The population consisted of 111 schoolchildren aged 1-16 years in a school for the deaf. They came for a regular ear, nose, and throat checkup in the primary care health centre of the school during the period November 1989 to January 1990. Primary health care was delivered by two nurses, a family doctor, and an ear, nose, and throat surgeon as consultant.

The history of upper respiratory tract infections was

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BMJ 1992;304:96-8

collected from the records of the health centre of the school. Pneumatic otoscopy was carried out by a nurse trained in ear, nose, and throat practice to judge for cerumen and the direction of the ear canal. Microtympanograms were made independently by the nurse and the author, an experienced general practitioner with special interest in this field. Tympanometry with the Grason Stadler 28 was carried out by the nurse. If necessary the ear was cleaned of cerumen. In 20 children the measurements were repeated after two weeks.

Tympanometry measures changes of acoustic admittance of a test zone in a closed ear canal as a function of changing air pressure.³ After otoscopy a test probe is placed on the ear canal. In the test probe there are three small holes: one for the test tone, one for the reflected noise, and one for the air pump. In this way the impedance and compliance of the eardrum under variable pressure on the eardrum is measured. The result of the measurement is printed as a tympanogram. The position of the compliance peak indicates the pressure in the middle ear; the height of the peak indicates the compliance of the eardrum³; the gradient indicates the shape of the curve in the vicinity of the peak. The microtympanometer is an acoustic admittance meter with a test tone of 226 Hertz and a tympanometric peak pressure range of +200 to -300 dPa. The reference instrument used, the Grason Stadler 28 Auto Tymp, has a test tone of 226 Hertz and a peak pressure of +200 to -400 dPa.

A slightly modified Jerger's classification of the tympanograms was used (box).⁷ A and C1 curves were defined as "normal, no effusion" because of the low predictive value of a C1 curve for effusion; and B and C2 curves were defined as "abnormal, effusion very probable" because of their high predictive value for effusion.^{2,3} The gradient of the curves printed on the microtympanograms were classified in four groups: 0, 5-115, 120-135, and ≥ 140 . The cutoffs were based on the mean (SD) values and frequencies of values.

The tympanograms were classified by the author. A sample of 25% of all tympanograms was classified by another well trained general practitioner. The interobserver reliability of these classifications was very high (Cohen's κ 0.95).

Cohen's κ was used to determine the interobserver agreement between the microtympanograms read by the practice nurse and the general practitioner. Cohen's κ is an index of concordance characterised by correction for the chance agreement that would be expected to occur if two classifications were totally unrelated.¹⁷ It is appropriate for discrete variables.¹⁸ Sensitivity, specificity, and the likelihood ratios as an index for the diagnostic value of the microtympanometer were determined with the Grason Stadler 28 as reference instrument. The likelihood ratio contrasts the proportions of patients with and without otitis media with effusion who display the presence (or absence) of abnormal results of tympanometry.¹⁹

To determine the influence of age on the dichotomised results of tympanometry with the Grason Stadler 28 odds ratios with 95% confidence intervals were calculated. The odds ratio expresses the strength of the association of age and otitis media with effusion by comparing outcome rates in patients in different age categories. The higher the odds, the greater the association.^{17,18} Confidence intervals indicate the precision of the sample study estimates as population values.²⁰

Results

With regard to intraobserver reliability, no relevant differences were found between the two measurements of the same 20 children with the microtympanometer

Modified Jerger's classification

Type A curve	Maximum compliance same or more than middle ear pressure from -99 to +200 dPa
Type B curve	Maximum compliance <0.2 or middle ear pressure <400 dPa
Type C1 curve	Maximum compliance same or >0.2 with middle ear pressure of -199 to -100 dPa
Type C2 curve	Maximum compliance same or >0.2 with middle ear pressure of -399 to -200 dPa

by the general practitioner (table I). The interobserver reliability between the ear, nose, and throat nurse and the general practitioner was very high (table II). The interobserver agreement of the gradients printed on the two microtympanograms was low (table III).

TABLE I—Intraobserver reliability of microtympanometry by general practitioner; two week interval between measurements (20 children)

First microtympanometry	Second microtympanometry				Total
	Abnormal		Normal type A or C1 curve	Failure	
	Type B curve	Type C2 curve			
Abnormal:					
Type B curve	2			1	3
Type C2 curve		1		1	2
Normal (type A or C1 curve)			34		34
Failure					0
Total	2	1	34	2	39

TABLE II—Interobserver reliability of microtympanometry of ear, nose, and throat nurse and general practitioner (111 children)

Microtympanometry by general practitioner	Microtympanometry by nurse				Total
	Abnormal		Normal type A or C1 curve	Failure	
	Type B curve	Type C2 curve			
Abnormal:					
Type B curve	14				14
Type C2 curve	1	17	1		19
Normal (type A or C1 curve)		2	171	1	174
Failure		1		7	8
Total	15	20	172	8	215

Cohen's κ = 0.95.

TABLE III—Interobserver agreement of the gradient of microtympanograms assessed by ear, nose, and throat nurse and general practitioner (111 children)

Gradient assessed by general practitioner	Gradient assessed by nurse				Total
	Normal		Abnormal		
	0	5-115	120-135	≥140	
Normal					
0	46	8	1	2	57
5-115	8	109	18		135
Abnormal:					
120-135	1	14	6	1	22
≥140	2	3		3	8
Total	57	134	25	6	222

Cohen's κ = 0.25.

The results of microtympanometry by the general practitioner were highly comparable with the results of the reference instrument, and the likelihood ratio of abnormal results of microtympanometry was very high (table IV). There were three failures with the microtympanometer and six with the reference instrument; all except one were in different ears.

TABLE IV—Microtympanometry by general practitioner compared with tympanometry with Grason Stadler 28 (111 children)

Microtympanometry	Tympanometry				Likelihood ratio
	Abnormal	Normal	Failure	Total	
Abnormal					
Type B curve	12		4	16	161.2
Type C2 curve		1	1	19	
Normal (type A or C1 curve)		2		173	0.065
Failure (repeated)	2	171	1	3	
Total	12	19	6	211	

Sensitivity of abnormal curves = 29/31 = 0.94.
Specificity of normal curves = 171/172 = 0.99.

TABLE V—Number of abnormal and normal tympanograms, Grason Stadler 28 tympanometer by age category (105 children)

Age (years)	Abnormal		Normal	Total	Odds ratio (95% confidence interval)
	Unilateral	Bilateral			
1-5	9	6	12	27	9.6 (3.42 to 26.8)
6-9	2	4	32	38	0.51 (0.18 to 1.42)
≥10-16	1	2	37	40	0.17 (0.05 to 0.61)
Total	12	12	81	105	

Abnormal tympanograms were most common in the youngest age category, 1-5 years (odds ratio 9.6; 95% confidence interval 3.42 to 26.8; table V).

The microtympanometer was easy to handle and use with children. The general practitioner needs knowledge of and training in tympanometry and the use of the instrument. Otoscopy is necessary to look for cleanliness and the direction and width of the ear canal. If the test probe impacts on the wall of the ear canal, the microtympanometer signals failure and the test needs to be repeated. Especially for younger children it was sometimes difficult to find the right rubber tip for the test probe. It was absolutely necessary to close the ear canal appropriately. The procedure, otoscopy included, took only a few minutes.

Discussion

Tympanometry was carried out by an experienced ear, nose, and throat nurse; the measurements are valid and reliable. The Grason Stadler 28 is well validated and frequently used in the United States.^{21,22} Jerger's classification is well accepted, especially in Europe.^{7,8} Our finding that age is an important predictive factor for abnormal tympanograms is in accordance with other studies.^{4,5,10,23}

Results with the instrument are comparable to those with the Grason Stadler 28. The high agreement between the two independent microtympanograms of the nurse and general practitioner shows that the microtympanometer is reliable. The hand held microtympanometer seems suitable for use in general practice and in well children's clinics.

The gradient printed on the microtympanogram seems not to be reliable. There is, however, no

agreement regarding the usefulness of the gradient for predicting effusion.³

General practitioners need a training course with regard to the principles and procedure of tympanometry and the use of the microtympanometer, especially in the classification of tympanograms. Checks on intra-observer and interobserver reliability are necessary for appropriate classification. Microtympanometry has to be carried out in combination with otoscopy to prevent a failure due to the lumen of the test probe impacting on the wall of the auditory canal.⁵

Microtympanometry may improve the general practitioner's ability to diagnose otitis media with effusion. With early detection and follow up in primary care an adequate referral policy for ear, nose, and throat surgery can be implemented.¹² More validation studies are needed, especially in general practice and in hospital populations, using the "gold standard" of effusion or not after myringotomy.

I thank Dr Sylvan Stool, paediatric otolaryngologist, Children Hospital, Pittsburgh, and Rose Faber, ear, nose, and throat practice nurse, health centre of the School for the Deaf of Pennsylvania, Pittsburgh; Professor Francis Touw-Otten, epidemiologist, for the statistical analysis; Dr Marijke Kuyvenhoven for her critical comment; and Welch Allyn for providing the microtympanometer.

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(Accepted 8 October 1991)