

# Analysis of compliance and tympanometric gradient in infants with reflux

## *Análise da compliância e gradiente timpanométrico em lactentes com refluxo*

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### ABSTRACT

**Purpose:** To analyze and compare the tympanometric gradient and the compliance obtained in probe tones of 226 and 1 kHz between groups of infants with and without gastroesophageal reflux (GER). **Methods:** Participants were 118 full-term and preterm infants, from newborns to 6-month-olds – 63 with clinical diagnosis of physiological GER performed by pediatricians or gastroenterologists, and 55 without GER –, who were submitted to tympanometry with probe tones of 226 and 1 kHz. **Results:** Higher compliance values were found with 1 kHz in both groups. Comparing the average compliance between groups, we observed that the group without reflux showed higher values. The mean value of the tympanometric gradient was higher in the group without reflux, when compared to the one with reflux. **Conclusion:** The 1 kHz probe tone has higher compliance in infants with and without GER, when compared to the 226 Hz probe tone. Infants with reflux have compliance within normal limits, although they present lower compliance than infants without reflux. Regarding the gradient, infants with GER have altered values and/or within normality limits in both ears.

**Keywords:** Acoustic impedance tests; Ear, middle; Gastroesophageal reflux; Infant; Hearing

### INTRODUCTION

Gastroesophageal reflux (GER) is a common physiological process, especially in infants<sup>(1)</sup>. It occurs in approximately 50% of children under 3 months old, in 67% of those aged between 4 and 6 months and 5% aged between 10 and 12 months. It can be classified as physiological and pathological. The only physiological causes are regurgitation and/or vomiting, not interfering with the normal development of the child. However, in the pathological reflux, in addition to vomiting and/or regurgitation, other clinical manifestations are present, such

as growth arrest, suggesting signs of inflammation of the esophagus (esophagitis), mainly irritability, persistent crying and difficulty sleeping, mostly found in infants<sup>(2-4)</sup>. The refluxed material contains hydrochloric acid, pepsin, bile acids and pancreatic enzymes, which makes it irritating to tissues which are not adapted to its presence<sup>(2)</sup>.

Constant exposure of the gastric juice causes inflammation, swelling and ulceration throughout the respiratory epithelium. The passage of gastric acid and pepsin leads to impaired functioning of the Eustachian tube after constant exposure to pH<4, which favors the onset of average otitis<sup>(5)</sup>. This type of change may be common in infants who have GER and undergo newborn hearing screening (NHS), through otoacoustic emissions. This test is sensitive to changes in middle ear, it is imperative to evaluate the same (by tympanometry) in neonates due to the high incidence of GERD aged zero to six months<sup>(6)</sup>.

Tympanometry is the most widely used method in clinical practice to assess functional condition of the middle ear, mobility of the tympanic membrane and dynamic ossicle<sup>(7)</sup>. The tympanometric findings are described qualitatively and quantitatively. Different criteria for interpretation of the results may lead to different conclusions and, therefore, to different procedures regarding the diagnosis, in other words, details may be lost if we consider the tympanograms only by their qualitative classifications<sup>(8)</sup>.

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**Conflict of interests:** None

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Tympanometric patterns observed in neonates are not in accordance with conventional standards found in children and adults, making the application of conventional classification of tympanograms as types A, B, C, D, and Ad difficult<sup>(9)</sup>. Thus, to avoid occasional errors and misinterpretation, you need a complement to the quantitative criteria, which are influenced by the transmission factors in the auditory system<sup>(8)</sup>.

The quantification of tympanometric measurements facilitates the development of appropriate standards for comparing tympanometric data among clinics and occasionally conducts sensitivity and specificity data that are not yet formalized. Quantitative measures are used in addition to qualitative measures to characterize the tympanograms more precisely. These features include: Acoustic Admittance Peak Compensated Static (Ymt) Equivalent volume of external acoustic meatus Ear (Vea), Tympanogram Gradient (GR) and Tympanogram Peak Pressure (TPP)<sup>(8,10)</sup>. In the present study the measures of compliance and gradient will be discussed.

The compliance measures the mobility of the middle ear, in which factors such as mass, stiffness and strength work, facilitating or hindering its movement, being the same, measured in terms of equivalent volume in milliliters (ml), providing information that help other measures. The greater the mobility, the greater the peak height and the lower mobility, the lower the peak height. The static compliance can be obtained by calculating the difference between two other measures: the external ear volume and total volume (the external ear volume plus the volume of the middle ear). It is used to identify middle ear alterations through the peak height or tympanometric curve that can increase or decrease. The height decreases as the static compliance is abnormally low, which occurs when there is stiffness in the middle ear and it is associated with disorders such as ossicular chain fixation, cholesteatoma, otosclerosis and fluid in the middle ear, the latter being the most common cause in children. On the other hand, the static compliance increases when admittance is abnormally high, which may result from changes that add mass to the system of the middle ear<sup>(11)</sup>.

The tympanometric gradient is an objective measure that describes the slope of tympanometric shape near the peak. The plan tympanogram plan can be quantified by means of the gradient, which describes the relationship of its height to its width. The gradient of absolute tympanograms can be measured in terms of mmhos or ml being necessary to draw a horizontal line at the point where the width of tympanogram is  $\pm 100$  daPa, then, the peak height on this line and the overall height of peak to the base is measured, locating the gradient by dividing the peak height and the total height<sup>(7)</sup>. The values range from 0.0 to 1.0 ml. Gradients smaller than 0.2 are considered to be unusually low and associated with the presence of middle ear fluid<sup>(12)</sup>.

When changes in static compliance and tympanometric gradient are detected in isolation, a second test is necessary, however, when this change occurs in both tympanometric measurements, changes in middle ear are suggested, necessitating referral for additional tests<sup>(13)</sup>.

The conventional tympanometry is performed with the 226 Hz probe tone and the results with this probe tone have considerable diagnostic value for seniors, adults and children

over 6 months of age, however, there is controversy for newborns and infants under 6 months, due to the lower resonant frequency and the low sensitivity, i.e., the high false negative rate in this population<sup>(6,7)</sup>. Neonates of up to 6 months with surgically confirmed effusion, when tested with low probe tone frequency, may have normal tympanograms of single or double peak<sup>(14)</sup>.

The literature shows that a tympanometry with high frequency tone (1 kHz) is more sensitive to middle ear disorders in infants under 6 months than the tympanometry probe tone at 226 Hz<sup>(6)</sup>, and it is useful in distinguishing the sensorineural loss caused by failure and conductive disorders. The use of tympanometry at 1 kHz tone should provide a basis for evaluating the benefits of various treatment options in this population<sup>(7)</sup>.

Based on the considerations above, it may be noted that it is extremely important that the tympanometric curve is obtained accurately. The lack of a guide for the treatment of middle ear is particularly attributed to the lack of an effective diagnostic test for babies under 6 months. Thus, studies are important to compare the analysis of tympanometric measurements in different probe tones, due to high incidence of middle ear disorders in infants under reflux, once even in normal tympanometric curves enlargement and reduction of amplitude of the compliance can be seen.

The objective of this study was to analyze and correlate the compliance probe tones at 226 Hz and 1 kHz between groups of infants with and without gastroesophageal reflux, but also analyze and compare the tympanometric gradient probe tone at 226 Hz between the groups.

## METHODS

Data collection started after approval of the Ethics Committee of the Universidade Estadual de Ciências da Saúde de Alagoas (UNCISAL), under protocol number 829. The study was conducted in the service of Otorhinolaryngology, Woman Institute, Hospital Santa Juliana de Alagoas.

The sample consisted of 118 infants ranging in age from newborns to 6-month-olds, who were divided into two groups: study group (SG) and control group (CG). The experimental group was composed of 63 infants with physiological gastroesophageal reflux, referred by pediatricians or gastropediatricians with a clinical diagnosis. The CG consisted of 55 infants without GER. The clinical diagnosis was made through a form based on the ROME II protocol<sup>(15)</sup>, which classifies the RGE when the infant has the following symptoms: regurgitation, nausea, vomiting, delayed weight gain, irritability, excessive crying, arching, hiccups, respiratory symptoms (cough, wheezing, stridor, apnea) and dystonia. In the present study, GER was classified as physiological when the infant had at least two of these symptoms.

Exclusion criteria were infants with cleft palate, external ear malformation and/or average, poor training of head and neck, and genetic syndromes associated with hearing impairment.

All infants in this study were submitted to otorhinolaryngological examinations prior to hearing, with Hinne Walchilling® otoscope to assess the external and middle ears.

Tympanometry was performed with the middle ear analyzer Impedance Audiometer - AT235h - Interacoustics®, using 226 Hz and 1 kHz probe tones. Two tympanometric measures were analyzed, the compliance and the gradient. The compliance was measured in both types of probe tones and the gradient was evaluated only with the 226 Hz probe tone, both obtained in ml.

The sample size calculation was performed for cross-sectional study, comparing the group with reflux and without reflux, giving an alpha and beta error of 5%. For comparison of the compliance between the groups in each ear, at the 226 Hz and 1 kHz probe tones, we used the Mann-Whitney test and for comparison of the compliance between the probe tones we used the Wilcoxon test.

## RESULTS

In the distribution of infants in relation to the variable gender, there was a slight predominance of females in both, the study group as well as the control group (Table 1). Although differences existed between the percentages of both groups with and without GERD, the differences were not significant.

By applying the Mann-Whitney, difference was found in the comparison of the results of the average compliance between the groups, either at 226 Hz or 1 kHz probe tones. When a 226 Hz probe tone was used, the mean values of compliance found were of 0.55 ml in both ears in groups with reflux. In the group without GER the values were: 0.66 ml in the right ear (RE) and 0.62 ml in the left ear (LE). When using the 1 kHz probe tone, the compliance average was 1.01 ml in the right ear and 0.86 ml in the left ear in the group with GERD. In the group without reflux it was observed 1.13 ml in the right ear

**Table 1.** Comparison of subjects by gender, in both groups

Gender	SG		CG		p-value
	n	%	n	%	
Female	36	57.10	30	54.50	0.777
Male	27	42.90	25	45.50	
Total	63	100.00	55	100.00	

Note: SG = study group; CG = control group

and 1.06 ml in the left ear. When comparing the results of the compliance averages between the groups, we observed higher values in the group without reflux in both ears, regardless of the type of probe tone used.

When comparing the results of static compliance between the probe tones in the same ear in each group, there was greater compliance using the 1 kHz probe tone, in all studied infants in relation to the 226 Hz probe tone, with a significant difference (Table 2).

In the comparison of results between the groups of the tympanometric gradient, difference was found between the groups regarding the value of the gradient in both ears. It was still possible to observe that infants with GER showed mean values of the gradient lower when compared to those without reflux. However, it was also observed in the group without reflux altered values in Q1 in the right ear (0.15) and left ear (0.19), however very different from the values of the group under reflux (Table 3).

## DISCUSSION

In the present study it was found a slight prevalence of GERD in females. In other studies, it was found a slight predominance in males. This may be due to a bigger sample of this population present in this study<sup>(16-18)</sup> (Table 1).

In this study infants with GER had a normal compliance standard, but lower when compared to infants without GER. It is possible that GE shows a slight change of the middle ear, not yet detected by tympanometry. According to some authors<sup>(1,2)</sup>, infants with GERD may have middle ear disorders (mild to severe), considering the low value of tympanometric height, which may be associated with less mobility of the tympanic-ossicular system<sup>(7)</sup>.

When the comparison made between the 226 Hz and 1 kHz probe tones (Table 2), the 1 kHz probe tone showed higher values of compliance than the 226 Hz probe tone, confirming the study<sup>(19)</sup> made with 110 babies of 6 to 30 days of age. This can be explained by the resonance frequency of the middle ear of the newborn, and the system dominated by mass in this age group<sup>(7)</sup>.

**Table 2.** Comparison of results of static compliance at 226 Hz and 1 kHz probe tones for each ear and between groups

Compl. – Timp.	SG				CG			
	RE		LE		RE		LE	
	226 Hz	1 kHz	226 Hz	1 kHz	226 Hz	1 kHz	226 Hz	1 kHz
Mean	0.55	1.01	0.55	0.87	0.66	1.13	0.62	1.06
Median	0.51	0.85	0.51	0.77	0.59	1.04	0.54	0.80
SD	0.32	0.90	0.35	0.74	0.31	0.66	0.29	0.77
Q1	0.34	0.19	0.29	0.17	0.43	0.57	0.40	0.49
Q3	0.70	1.67	0.77	1.45	0.85	1.55	0.77	1.50
N	63	63	63	63	55	55	55	55
CI	0.08	0.22	0.09	0.18	0.08	0.17	0.08	0.20
p-value	<0.001*		0.003*		<0.001*		<0.001*	

\* Significant values ( $p \leq 0.05$ ) – Wilcoxon test

Note: SG = study group; CG = control group; Compl. = compliance; Timp. = tympanometry; RE = right ear; LE = left ear; SD = standard deviation; CI = confidence interval

**Table 3.** Comparison of results of tympanometric gradient obtained at 226 Hz probe tone for the each ear and between groups

Timp (226 Hz)		Mean	Median	SD	Q1	Q3	n	CI	p-value
Grad. RE	With GER	0.20	0.12	0.27	0.07	0.24	63	0.07	<0.001*
	Without GER	0.28	0.23	0.26	0.15	0.30	55	0.07	
Grad. LE	With GER	0.18	0.14	0.14	0.09	0.25	63	0.03	0.001*
	Without GER	0.25	0.23	0.11	0.19	0.30	55	0.03	

\* Significant values ( $p \leq 0.05$ ) – Mann-Whitney test

**Note:** GER = gastroesophageal reflux; Grad. = gradient; RE = right ear; LE = left ear; SD = standard deviation; CI = confidence interval

These findings are in agreement with the study that analyzed and compared tympanometric 226 Hz and 1 kHz probe tones, finding average values of static compliance of 0.85 ml in 1 kHz probe tone and 0.37 ml in 226 Hz probe tone, noting significant difference<sup>(20)</sup>. In another study, we analyzed the effects of tympanometry of 226 Hz, 678 Hz and 1 kHz in a group of children with normal brainstem auditory evoked potential (BAEP) and the other with ABR suggestive of conductive hearing loss in the range of five to 25 weeks. For the frequency of 226 Hz there was no difference between the static compliance in both groups evaluated. The tympanogram carried out at 678 Hz probe tone demonstrated various peaks and various types of curves in both groups, while at 1 kHz probe tone tympanograms with single peak were found in the normal group, and in the changed group, tympanograms without peak were found. The authors concluded that the use of 1 kHz probe-tone tympanometry had more precise results in the evaluation of the function of the middle ear of children less than 25 weeks<sup>(21)</sup>.

Due to the high index of lowered results of tympanometric gradient in the group with reflux, it was observed that when the mean of these results is held, the study group presented borderline values and changed (Table 3), indicating the presence of impairment as regards the tympano-ossicular system, such as the outpouring of the middle ear. Higher values of gradient in the right ear were also observed in both groups, corroborating some authors<sup>(7)</sup> that found mean values of compliance and static tympanometric gradient significantly higher in the right ear

in relation to the left one. A fact which drew the attention, it was the changed value of Q1 in the group without reflux, and this may have occurred due to the high standard deviation of the measure. In subjects with changes of the middle ear, the gradient is less than 0.2 and tympanogram is more flattened, being classified as curve with “round peak”. Its analysis, is often difficult, especially in borderline cases, i.e. in curves that show compliance with lowered values of neighboring gradient<sup>(22,23)</sup>.

Faced with the difficulty of interpretation of some tympanograms with lowered compliance or altered gradients or borderline, it is necessary to refer this population for additional tests, such as otoacoustic emissions and auditory brainstem response by air and bone conduction, as well as a specific otorhinolaryngological assessment, in order to confirm possible changes of the middle ear and start treatment immediately.

## CONCLUSION

The compliance is greater at a 1 kHz probe tone, both in infants with GERD and without GERD, compared to the 226 Hz probe tone. Infants with reflux have compliance within the normal range for middle ear integrity, however, show lower compliances when compared to infants without reflux. With respect to the gradient, infants with GERD present values of the gradient changed and/or within the boundary of normal patterns in both ears.

## RESUMO

**Objetivo:** Analisar e comparar o gradiente timpanométrico e a compliância obtida nas sondas de 226 Hz e 1 kHz entre os grupos de lactentes com e sem refluxo gastroesofágico. **Métodos:** Cento e dezoito lactentes a termo e pré-termo, de recém-nascidos a 6 meses de idade – 63 com diagnóstico clínico de refluxo gastroesofágico fisiológico realizado por pediatras ou gastropediatras e 55 sem refluxo –, foram submetidos a timpanometria com sondas de 226 Hz e 1 kHz. **Resultados:** Foram observados maiores valores de compliância com sonda de 1 kHz em ambos os grupos. Ao se comparar a média de compliância entre os grupos, observou-se que o grupo sem refluxo apresentou maiores valores. A média dos valores do gradiente timpanométrico foi maior no grupo sem refluxo, quando comparada ao grupo com refluxo. **Conclusão:** A sonda de 1 kHz apresenta maior compliância em lactentes com e sem refluxo, em relação à sonda de 226 Hz. Lactentes com refluxo apresentam compliância dentro dos padrões de normalidade, porém apresentando menor compliância quando comparados com lactentes sem refluxo. Com relação ao gradiente, lactentes com refluxo apresentam valores alterados e/ou dentro dos padrões limítrofes da normalidade, em ambas as orelhas.

**Descritores:** Testes de impedância acústica; Orelha média; Refluxo gastroesofágico; Lactente; Audição

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