

The Sensitivity and Specificity of GERD Score Questionnaire in Detecting the Prevalence of GERD among Children with Recurrent Secretory Otitis Media

Reham F. Zittoon^{1,2*}, Mohamed H. Badereldin^{1,2}, Sarah A. Kamel^{1,3}

Department of Otorhinolaryngology¹, Suez Canal University Hospital², Ismailia, Suez General Hospital, Suez³, Egypt

Abstract

Background: Gastroesophageal Reflux and Otitis Media are two of the most prevalent diseases in young children. **Aim:** To describe the prevalence of Gastroesophageal reflux in infants and young children with recurrent secretory otitis media. **Patients and Methods:** This descriptive cross sectional study cross sectional included Ninety-one children of both sex aged from 3 months to 8 years were assessed with history of recurrent secretory otitis media type B Tympanometry not improved completely by medical treatment. X-ray of the nasopharynx was done. The parent or legal guardian completed the Infant Gastroesophageal Reflux Questionnaire-Revised (I-GERQ-R) symptom-based 11 points questionnaire (I-GERQ GERD). **Results:** this study include 61 male (67%) and 33 female (33%) and mean GERD score in patients with GER was (7.23 ± 3.1) compared to Non-GERD group (0.76 ± 0.83) (p<0.001). The mean GERD score in patients with GER was 5.98 +/- 4.22 compared to GERD with adenoid group (3.87 ± 2.45) and Non-GERD group (0.76 ± 0.83) (p<0.001). GERQ score ≥7 had a sensitivity of 96.2% and specificity of 98% in diagnosing GERD among our patients with overall accuracy of 97%. **Conclusion:** The I-GERQ-R is thus adequately sensitive to be used diagnostically to screen children for symptom burden.

Keywords: Gastroesophageal Reflux, Recurrent Secretory Otitis Media, Children.

Introduction

Otitis media with effusion (OME) is the most common cause of acquired hearing loss in children. It occurs in approximately 15% of children 2 to 7 years of age. The etiology of chronic OME is multifactorial, yet the main cause seems to be the dysfunction and impaired patency of the Eustachian tube. One of the factors taken into consideration is Gastroesophageal reflux

(GER)⁽¹⁾. Reflux of gastric contents beyond the esophagus into the oropharynx, larynx, tracheobronchial tree, and nasopharynx leads to extraesophageal manifestations of Gastroesophageal reflux disease GERD⁽²⁾. GERD is a common physiologic occurrence in infants and decreases in frequency during the first year of life. Pediatric middle ear disease often coexists with GERD. The size and shape of the immature Eustachian tube may contribute to

*Corresponding Author: dr.reham_zittoon@outlook.com

an increase in reflux of nasopharyngeal contents into the middle ear. The functional derangement of OME is believed to involve metaplasia of the middle ear epithelium with a proliferation of goblet cells and mucous glands, leading to hypersecretion, mucociliary dysfunction, and middle ear effusion with concomitant conductive hearing loss. An analogous process may be implicated in other disorders, such as pediatric sinusitis. In that disease, improvement with empiric antireflux therapy has been demonstrated in up to 85% of children studied, with a decrease in the number of necessary surgical procedures⁽³⁾. Because GERD and OME are 2 of the most prevalent diseases in young children, a number of investigators have taken preliminary steps to demonstrate a causative link between both diseases. Of particular interest has been the presence of gastric enzymes in the middle ear space. Studies on rats with repeated middle ear exposure to pepsin have demonstrated impaired eustachian tube function as well as impaired mucociliary clearance of middle ear contents⁽³⁾. The study aimed to describe the prevalence of Gastroesophageal reflux in infants and young children with recurrent secretory otitis media at Suez Canal University Hospital, Ismailia city.

Patients and Methods

Study design

A descriptive cross-sectional study was carried out in Otorhinolaryngology Clinic at Suez Canal University Hospital, Ismailia City from February 2019 to February 2021.

Study population

Patients under study were selected by randomization from patients attending otolaryngology clinic in Suez Canal university hospital who were diagnosed as hav-

ing otitis media with effusion by clinical criteria of OME by otoscopic examination (tympanic membrane retraction, fluid level) and by flat curve type by tympanogram that persistent more than 3 months.

Inclusion criteria: Children aged between 3 months and 8 years of Both genders who had 1) Three episodes of secretory otitis media in the past 6 months, or 4 in the past 12 months. 2) Three months of bilateral middle ear effusion tympanometry Type B not improved completely by medical treatment. 3) Patients with reflux symptoms and 4) Grade 1 or 2 adenoid hyperplasia.

Exclusion criteria

Children with previous myringotomy or ventilation tube surgery, any nasal polyps, congenital anomalies especially craniofacial abnormality or severely atelectatic tympanic membrane. Children who had been treated with antireflux medications 6 weeks before the study, those with Grade 3 or 4 adenoid hyperplasi (as it is lead to closure of eustachian tube) or have type c tympanometry.

Methods

Ninety-one children of both sexes aged from 3 months and 8 years were assessed from May 2018 to June 2019 with history of Recurrent secretory otitis media type B Tympanometry not completely improved by medical treatment at otorhinolaryngology clinic, Suez Canal University hospital. X-ray lateral view on the soft tissue of the nasopharynx was done to diagnose adenoid hyperplasia in suspected patients. The parent or legal guardian answered questions asked by the researcher according to the Infant Gastroesophageal Reflux Questionnaire-Revised (I-GERQ-R) symptom-based 11 points questionnaire (I-

GERQ GERD) with maximum score of 25 to differentiate GER from GERD and have shown that a score of >7 has 74% sensitivity and 94% specificity in diagnosing GERD in infants. This questionnaire was applied in Indian population⁽⁴⁾ and has shown to be easily adaptable and reproducible but had lower diagnostic accuracy (sensitivity of 43% and specificity of 79%) than the original study and has shown to be easily adaptable and reproducible (sensitivity of 43% and specificity of 79%), can be used to segregate those who needs empirical therapy or further investigation⁽⁵⁾.

Statistical Analysis

The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (SPSS 23). Data was presented and suitable analysis was done according to the type of data obtained for each parameter. Descriptive statistics included Mean, Standard deviation (\pm SD) and range for parametric numerical data, while Median and Interquartile range (IQR) for non-parametric numerical data. Frequency and percentage of non-numerical data. While analytical statistics included Chi-square (X^2) test of significance was used in order to compare proportions between two qualitative parameters or fisher-exact test. Independent t test was used to identify the possible association between the numerical variables. Results were considered statistically significant at a P-value less than 0.05. ROC curve analysis was done to assess the validity of GER questionnaire in diagnosing GERD in our study patients.

Results

Table 1 describes demographic characteristics of the patients with mean age of 46 months it ranged from 6 to 96 months.

Males represent 67% of the study participants and females represent 33%. Table 2 shows that 71.4% of patients had episodes of otitis media in the last six months, while the others 28.6% had episodes of otitis media in the last twelve months. All the patients had tympanometry B.

Table 1: Demographic characteristics of patients (n=91).

Characteristics	
Age (Mean \pm SD) months	(46 \pm 24)
Range	(6-96)
Gender No (%)	
Male	61 (67%)
Female	30 (33%)

Table 3 shows that 64.8% had adenoid and allergy symptoms, 44% of patients had regurgitation, 39.6% had vomiting, 30.8% had irritability, 33% had congestion, 17.6% had cough, 2.2% had hoarseness of voice, and 7.7% had arching.

Table 2: History of episodes among patients (n=91)

	No	%
Episode of OM in last 6 months	65	71.4
Episode of OM in last 12 months	26	28.6
Tympanometry B	91	100

Table 4 shows the distribution of component of I-GERQ among patients in which 33% of patients had spitting up with 1-3 times per day in 20.9% of patients and >5 times per day in 4.4% and from 1 teaspoonful to 1 tablespoonful in 24.2% of patients. 45.1% had Chocking/ Gagging, 36.3% had Irritability/ Fussiness, 39.6% had Refusal to feed up, 37.4% had trouble gaining enough weight, 33% was crying during or after feeding, 6.6% had episodes of hiccups, 7.7% had arching back and no patients had struggling to breath. The patients had a mean score of (7.25 \pm 6.4)

ranged from 0 to 25. Table 5 showed that the prevalence of GERD among Secretary OM patients is 67% and non-GERD 33%.

Table 3: Clinical data of the patients (n=91)

GERD symptoms	No	%
Regurgitation	40	44
Vomiting	36	39.6
Irritability	28	30.8
Congestion	30	33
Cough	16	17.6
Hoarseness of voice	2	2.2
Arching	7	7.7
Stridor	0	0
Adenoid hyperplasia and allergy symptoms	59	64.8

Table 6 showed that the prevalence of GERD among OM patients is 67%. GERD only group was 28.6%, GERD with adenoid hyperplasia 38.4%, while Non-GERD group was 33%. Table 7 showed that three groups had statistical insignificant age and gender difference. Table 8 showed that there was statistical insignificant difference regarding episodes of OM in the last 6 and 12 months. Table 9 showed that GERD group had significantly higher percentage of patients with regurgitation, vomiting, irritability, cough, and congestion. Table 10 showed that three groups had statistical insignificant difference in irritability, cough, congestion, and hoarseness of voice. GERD group showed higher percentage of patients with regurgitation and vomiting than other two groups with statistically significant differences. Table 11 showed that GERD group has statistically significant higher percentage of patients with spitting up and its frequency and volume than other groups. Also, GERD group has statistically significant higher percentage of patients with choking/gagging, irritability/fussiness, refusal to feed up, crying during or after feeding, episodes of hiccups and arching

back than the other group. The mean GERD score in patients with GER was (7.23±3.1) Compared to Non-GERD group (0.76±0.83) ($p<0.001$). Table 12 showed that GERD group and GERD with adenoid group had statistically significant higher percentage of patients with spitting up and its frequency and volume than other groups. Also, GERD group and GERD with adenoid group had statistically significant higher percentage of patients with choking/gagging, irritability/fussiness, refusal to feed up, crying during or after feeding, episodes of hiccups and arching back than the other group. The mean GERD score in patients with GER was 5.98 +/- 4.22 compared to GERD with adenoid group (3.87±2.45) and Non-GERD group (0.76±0.83) ($p<0.001$). GERQ score ≥ 7 had a sensitivity of 96.2% and specificity of 98% in diagnosing GERD among our patients with overall accuracy of 97% (Table 13).

Table 4: Data of I-GER questionnaire

I-GER questionnaire (n=91 patients)	No	%
Spitting up	30	33
Spitting up times		
• 1 to 3 times per day	19	20.9
• 3 to 5 times per day	7	7.7
• > 5 times/day	4	4.4
Spitting up volume		
• 1 teaspoonful to 1 table-spoonful	22	24.2
• 1 tablespoonful to 1 ounce	8	8.8
• > 1 ounce	0	0
Chocking/Gagging	41	45.1
Irritability/Fussiness	33	36.3
Refusal to feed up	36	39.6
Trouble gaining enough weight	34	37.4
Crying during or after feeding	30	33
Episodes of Hiccups	6	6.6
Arching back	7	7.7
Struggling to breath	0	0
Total score (mean ± SD) Range	7.25±6.4 (0-25)	

Table 5: Prevalence of GERD among patients (n=91)

	No	%
GERD group	61	67
Non-GERD group	30	33
Total	91	100

Table 6: Prevalence of GERD sub groups among patients (n=91)

	No	%
GERD only group	26	28.6
GERD with adenoid group	35	38.4
Non-GERD group	30	33
Total	91	100

Discussion

In the present study, children with OME were assessed for the prevalence of GERD and it was found that 67% (61 of 91 children) with OME had GERD. However, symptom descriptions of GERD are non-specific and unreliable in infants and young children and esophageal pH monitoring, is a valid and reliable measure of acid exposure in evaluating GERD in children with secretory OM. In our study diagnosis of GERD based on a 25-point infant GERD score with 11 signs and symptoms of gastroesophageal reflux (GER) as previously suggested⁽⁵⁾.

Table 7: Demographic characteristics of study groups.

Characteristics	GERD group (n=26)	GERD with adenoid group (n=35)	Non GERD group (n=30)	Test value	P-value
Age (Mean \pm SD) months	40.4 \pm 22.3	46.7 \pm 24.5	45.3 \pm 23.2	1.306	0.195
Range	12-96	6-96	6-96		
Gender				1.611	0.229
Male	20(76.9%)	21(60%)	20(66.7%)		
Female	6(23.1%)	14(40%)	10(33.3%)		

Table 8: History of episodes among study groups

	GERD group (n=26)	GERD with adenoid group (n=35)	Non GERD group (n=30)	Test value	P-value
Episode of OM in last 6 months	18(69.2%)	21(60%)	20(66.7%)	0.086	0.769
Episode of OM in last 12 months	8(30.8%)	14(40%)	10(33.3%)	0.086	0.769
Tympanometry B	26(100%)	35(100%)	30(100%)	0.00	1.00

In our study the mean GERD score with GERD was 5.98 \pm 4.22 compared Non-GERD group (0.76 \pm 0.83) ($p < 0.05$). The mean GERD score in Aggarwal et al⁽⁴⁾ study in infants with GER was 4.64 \pm 3.99 compared to 3.54 \pm 3.96 in those with no documented GER ($p < 0.05$). We found that

GERQ score ≥ 7 had a sensitivity of 96.2% and specificity of 98% in diagnosing GERD among our patients with overall accuracy of 97%. A GERD score of 5 had a sensitivity of 43% and specificity of 79%, compared to 86% and 85% observed by Orenstein et al⁽⁵⁾ in their series. The I-GERQ-R is thus ade-

quately sensitive to be used diagnostically to screen children for symptom burden, but should probably be supplemented by other, perhaps invasive, testing to assure appropriate specificity. The I-GERQ-R's validation for evaluative properties, however, supports its use for tracking symptoms within clinical trials⁽⁵⁾. The prevalence of GERD in children with OME in our study is similar to previous reports. In Velepici et al⁽⁶⁾ study reported 60%, Rozmanic et al⁽⁷⁾

55.5%, Keles et al⁽⁸⁾ 64%, Serra et al⁽⁹⁾ 54.3%. In a study by Yüksel et al⁽¹⁰⁾ reported that 54.9% of children with the symptoms of hearing loss or aural fullness and diagnosed as OME by examination and tympanometry had GERD as Children were reviewed gastroesophageal reflux disease symptoms and least one positive test of radionuclide gastroesophageal scintigraphy or 24 h pH probe in the patients with reflux.

Table 9: Clinical data of the study groups (n=91).

GERD symptoms	GERD group (n=61)	Non GERD group (n=30)	Test value	P-value
Regurgitation	40(65.6%)	0(0%)	24.33	<0.001
Vomiting	36(59%)	0(0%)	21.54	<0.001
Irritability	26(42.6%)	2(6.7%)	18.24	<0.001
Congestion	29(47.5%)	4(13.3%)	19.82	<0.001
Cough	10(16.4%)	6(20%)	4.42	0.021
Hoarseness of voice	2(3.3%)	0(0%)	1.76	0.054

Table 10: Clinical data of the study sub groups (n=91).

GERD symptoms	GERD sub groups		Non GERD group (n=30)	Test value	P-value
	GERD group (n=26)	GERD with adenoid group (n=35)			
Regurgitation	21(80.8%)	19(54.3%)	0(0%)	5.446	0.004
Vomiting	20(76.9%)	16(45.7%)	0(0%)	6.107	0.002
Irritability	6(23.1%)	20(57.1%)	2(6.7%)	1.011	0.315
Congestion	8(30.8%)	18 (51.4%)	4(13.3%)	0.08	0.778
Cough	6(23.1%)	4 (11.4%)	6(20%)	0.758	0.384
Hoarseness of voice	2(7.7%)	0(0%)	0(0%)	5.11	0.079

In a systematic review by Miura et al⁽¹¹⁾ a mean prevalence of GERD in children with Recurrent Secretary OM was reported to be 48.4%. In the other hand, Abd El-Fattah et al⁽¹²⁾ reported that only three of 17 studied children with OME had GER, this was lower than our results and reports in our studies. The differences between these results can be explained by the differ-

ences in age of studied children and difference in methodology. The difference in methodology is that they were submitted to ventilation tubes as well as adenoidectomy/tonsillectomy, and after recovery from surgery, pH monitoring was performed. As the effect of these procedures on GER are not well-established, it seems that the most appropriate time for pH

monitoring would be before surgical interventions, in the presence of chronic OM⁽¹²⁾. In Abtahi et al⁽¹³⁾ study about “Prevalence and characteristics of gastroesophageal reflux in children with otitis media in Isfahan, Iran” which found The prevalence of GER in children with Chronic Secretary OM in our study was 72.7%. and found that the most common symptoms in the studied children with OM were regurgitation, vomiting, irritability, congestion, cough and feeding complex as they asked about current symptoms that may be suggestive of GERD, using validated questionnaires. These questionnaires included the two age-stratified versions of the pediatric GERD symptoms for children

2 years old and younger, and children 3–7 years old. In our study GERD group showed higher percentage of patients with regurgitation and vomiting than non GERD group with statistical significant differences. In agreement with Abtahi et al⁽¹³⁾ study. We found in our study that there is relation between GERD and adenoid hyperplasia as 35 of 91 have adenoid hyperplasia and most common symptoms of GERD as regurgitation, vomiting, irritability, congestion and cough as found in Keles et al⁽⁸⁾ that The risk of development of adenoid hyperplasia was established 9.6 more times in children having GERD, whereas, it was 5.4 more times in children having GERD.

Table 11: Data of I-GERQ among study groups

I-GERQ	GERD group (n=61)	Non GERD group (n=30)	Test value	P-value
Spitting up	30(49.2%)	0(0%)	34.36	<0.001
Spitting up times				
• 1 to 3 times per day	19(31.1%)	0(0%)	22.07	<0.001
• 3 to 5 times per day	7(11.5%)	0(0%)		
• > 5 times/day	4(6.6%)	0(0%)		
Spitting up volume				
• 1 teaspoonful to 1 tablespoonful	22(36.1%)	0(0%)	53.17	<0.001
• 1 tablespoonful to 1 ounce	8(13.1%)	0(0%)		
• > 1 ounce	0	0(0%)		
Chocking/Gagging	41(67.2%)	0(0%)	67.76	<0.001
Irritability/Fussiness	30(49.2%)	3(10%)	32.21	<0.001
Refusal to feed up	30(49.2%)	6(20%)	29.74	<0.001
Trouble gaining enough weight	28(45.9%)	6(20%)	23.23	<0.001
Crying during or after feeding	30(49.2%)	0(0%)	34.36	<0.001
Episodes of Hiccups	6(14.6%)	0(0%)	10.49	0.006
Arching back	7(11.5%)	0(0%)	27.44	<0.001
Struggling to breath	0(0%)	0(0%)	0.00	1.00
Total score	7.23 ± 3.1	0.76 ± 0.83	42.43	<0.001

Conclusion

The I-GERQ-R is thus adequately sensitive to be used diagnostically to screen child-

ren for symptom burden, but should probably be supplemented by other, perhaps invasive, testing to assure appropriate specificity. The I-GERQ-R's validation for evaluative properties, however, sup-

ports its use for tracking symptoms within clinical trials. The IGER Questionnaire is easily adaptable and reproducible in the settings of developing countries. These

results supported that pharyngeal reflux may play an important role in the etiology of adenoid hyperplasia

Table 12: Data of I-GERQ among study sub groups.

I-GERQ	GERD group (n=26)	GERD with adenoid group (n=35)	Non GERD group (n=30)	Test value	P-value
Spitting up	18(69.2%)	12(34.3%)	0(0%)	55.48	<0.001
Spitting up times					
• 1 to 3 times per day	11(42.3%)	8(22.9%)	0(0%)	52.07	<0.001
• 3 to 5 times per day	4(15.4%)	3(8.6%)	0(0%)		
• > 5 times/day	3(11.5%)	1(2.8%)	0(0%)		
Spitting up volume					
• 1 teaspoonful to 1 tablespoonful	14(53.8%)	8(22.9%)	0(0%)	53.17	<0.001
• 1 tablespoonful to 1 ounce	4(15.4%)	4(11.4%)	0(0%)		
• > 1 ounce	0	0(0%)	0(0%)		
Chocking/Gagging	20(76.9%)	21(60%)	0(0%)	67.76	<0.001
Irritability/Fussiness	16(61.5%)	14(40%)	3(10%)	49.98	<0.001
Refusal to feed up	16(61.5%)	14(40%)	6(20%)	49.98	<0.001
Trouble gaining enough weight	14(53.8%)	14(40%)	6(20%)	3.107	0.078
Crying during or after feeding	16(61.5%)	14(40%)	0(0%)	49.98	<0.001
Episodes of Hiccups	4(15.4%)	2(5.7%)	0(0%)	10.49	0.006
Arching back	5(19.2%)	2(5.7%)	0(0%)	27.44	<0.001
Struggling to breath	0(0%)	0(0%)	0(0%)	0.00	1.00
Total score	5.98 ± 4.22	3.87 ± 2.45	0.76 ± 0.83	28.93	<0.001

Table 13: validity of I-GERQ diagnosing GERD

Variable	Cut-off	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
GERQ score	≥7	96.2	98	97.9	96.3	97

References

1. American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics Subcommittee on Otitis Media with Effusion. Otitis media with effusion. Pediatrics 2004;113:1412-1429.
2. Lieu JEC, Muthappan PG, Uppaluri R. Association of reflux with otitis media in children. Otolaryngol Head Neck Surg. 2005;133(3):357-361.
3. He Z, O'Reilly RC, Bolling L, et al. Detection of gastric pepsin in middle ear fluid of children with otitis media. Otolaryngol Head Neck Surg. 2007; 137(1):59-64
4. Aggarwal, S., Mittal, K., Kalra, K., et al. "Infant gastroesophageal reflux dis-

ease score: reproducibility and validity in a developing country." *Tropical gastroenterology: official journal of the Digestive Diseases Foundation* 25.2 2004: 96-98.

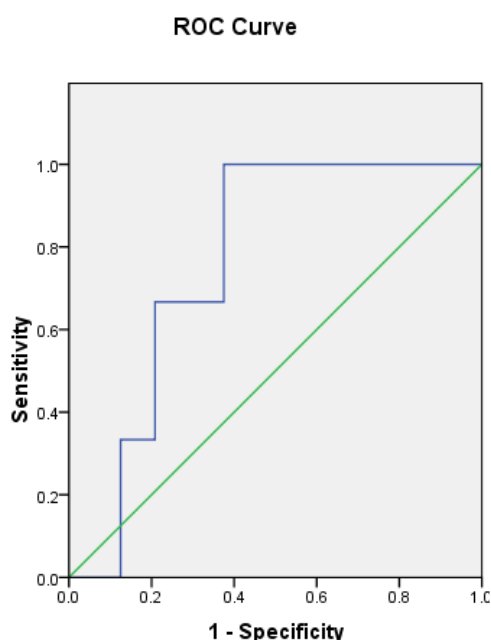


Figure 1: ROC curve for GERQ score in diagnosing GERD

5. Orenstein SR. Symptoms and reflux in infants: Infant Gastroesophageal Reflux Questionnaire Revised (I-GERQ-R)—utility for symptom tracking and diagnosis. *Current gastroenterology reports*. 2010 Dec;12(6):431-6.
6. Velepich MM, Velepich MS, Starcevic R, et al. Gastroesophageal reflux and sequelae of chronic tubotympanic disorders in children. *Acta Otolaryngol*. 2004; 124:914-7
7. Rozmanic V, Velepich M, Ahel V, et al. Prolonged esophageal pH monitoring in the evaluation of gastroesophageal reflux in children with chronic tubotympanic disorders. *J Pediatr Gastroenterol Nutr*. 2002; 34:278-80.
8. Keles B, Ozturk K, Arbag H, Gunel E, Ozer B. Frequency of pharyngeal reflux in children with adenoid hyperplasia. *Int J Pediatr Otorhinolaryngol*. 2005; 69:1103-7
9. Serra A, Cocuzza S, Poli G, La Mantia I, Messina A, Pavone P. Otologic findings in children with gastroesophageal reflux. *Int J Pediatr Otorhinolaryngol*. 2007;71:1693-97.
10. Yüksel F, Dogan M, Karatas D, Yüce S, Sentürk M, Külahlı I. Gastroesophageal reflux disease in children with chronic otitis media with effusion. *J Craniofac Surg*. 2013;24:380-3.
11. Miura MS, Mascaro M, Rosenfeld RM. Association between otitis media and gastroesophageal reflux: A systematic review. *Otolaryngol Head Neck Surg*. 2012;146:345-52
12. Abd El-Fattah AM, Abdul Maksoud GA, Ramadan AS, Abdalla AF, Abdel Aziz MM. Pepsin assay: A marker for reflux in pediatric glue ear. *Otolaryngol Head Neck Surg*. 2007; 136:464-70
13. Abtahi SH, Kazerooni A, Brejis N, Abdeyazdan Z, Saneian H. Prevalence and characteristics of gastroesophageal reflux in children with otitis media in Isfahan, Iran. *Advanced biomedical research*. 2016;5.

Email address: dr.reham_zittoon@outlook.com